STATE OF NEW YORK
PUBLIC HEALTH AND HEALTH PLANNING COUNCIL

ANNUAL MEETING

AGENDA

June 24, 2026
Immediately following the Committee on Codes, Regulations and Legislation Meeting
(Codes scheduled to begin at 10:15 a.m.)

Empire State Plaza, Concourse Level, Meeting Room 6, Albany

I. INTRODUCTION OF OBSERVERS

Jeffrey Kraut, Chair

II. ELECTION OF OFFICERS

A. Election of Vice Chairperson

B. Announce Committee Chairpersons and Vice Chairpersons

- Committee on Codes, Regulations and Legislation
- Committee on Establishment and Project Review
- Committee on Health Planning
- Committee on Public Health
- Ad Hoc Committee to Lead the State Health Improvement Plan

III. APPROVAL OF MINUTES

May 7, 2026 PHHPC Meeting Minutes

IV. REPORT OF DEPARTMENT OF HEALTH ACTIVITIES

A. Report of the Department of Health

James V. McDonald, M.D., M.P.H., Commissioner of Health

B. Report of the Office of Health Insurance Programs

Amir Bassiri, Deputy Commissioner and Medicaid Director, Office of Health Insurance Programs

Michael Ogborn, Deputy Medicaid Director, Office of Health Insurance Programs

- Indigent Care Pool and Bad Debt/Charity Care
- 1115 Waiver Update

C. Report of the Office of Public Health

Elizabeth Whalen, M.D., M.P.H., DipABLM, Medical Director, Office of Public Health

V. PUBLIC HEALTH SERVICES

Report on the Activities of the Public Health Committee

Jo Ivey Boufford, M.D., Chair of Public Health Committee

VI. REGULATION

Report of the Committee on Codes, Regulations and Legislation

Thomas Holt, Chair of the Committee on Codes, Regulations and Legislation

For Adoption

24-15 Repeal of Part 19 and Addition of Subpart 58-6 to Title 10 NYCRR (Certificates of Qualification for Clinical Laboratory Directors)

23-01 Repeal and Replace Part 16 of 10 NYCRR (Ionizing Radiation)

For Information

26-14 Amendment of Part 2 of Title 10 NYCRR (Communicable Disease Reporting, Definitions and Specimen Collection)

25-19 Amendment of Section 415.26 of Title 10 NYCRR (Nurse Aide Training Program)

VII. PROJECT REVIEW RECOMMENDATIONS AND ESTABLISHMENT ACTIONS

Report of the Committee on Establishment and Project Review

Peter Robinson, Chair of Establishment and Project Review Committee

APPLICATIONS FOR CONSTRUCTION OF HEALTH CARE FACILITIES

CATEGORY 1: Applications Recommended for Approval – No Issues or Recusals, Abstentions/Interests

NO APPLICATIONS

CATEGORY 2: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Without Dissent by HSA
- ❖ Without Dissent by Establishment and Project Review Committee

CON Application

Ambulatory Surgery Center – Construction

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	252166 C	Hillside Polymedic Diagnostic and Treatment Center (Queens County) Dr. Yang - Recusal Mr. Kraut - Interest	Contingent Approval

CATEGORY 3: Applications Recommended for Approval with the Following:

- ❖ No PHHPC Member Recusals
- ❖ Establishment and Project Review Committee Dissent, or
- ❖ Contrary Recommendations by HSA

NO APPLICATIONS

CATEGORY 4: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Establishment and Project Review Committee Dissent, or
- ❖ Contrary Recommendation by HAS

NO APPLICATIONS

CATEGORY 5: Applications Recommended for Disapproval by OHSM or Establishment and Project Review Committee - with or without Recusals

NO APPLICATIONS

CATEGORY 6: Applications for Individual Consideration/Discussion

NO APPLICATIONS

APPLICATIONS FOR ESTABLISHMENT AND CONSTRUCTION OF HEALTH CARE FACILITIES

CATEGORY 1: Applications Recommended for Approval – No Issues or Recusals, Abstentions/Interests

CON Applications

Ambulatory Surgery Center - Establish/Construct

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	261138 E	Saratoga-Schenectady Endoscopy Center, LLC (Saratoga County)	Approval

Diagnostic and Treatment Center – Establish/Construct

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	252183 B	St. Mary's Center, Inc. (New York County)	Contingent Approval

Residential Healthcare Facility – Establish/Construct

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	252210 E	Amsterdam SNF LLC d/b/a Wilkinson Rehabilitation and Nursing Center (Montgomery County)	Contingent Approval

Home Care Service Agency Licensures

Licensed Home Care Services Agencies - Changes of Ownership

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	222245 E	Family Respite Homecare Agency, Inc. (Please see exhibit for list of Geographical Service Area)	Approval
2.	231025 E	Family Home Care Agency Inc. (Please see exhibit for list of Geographical Service Area)	Approval
3.	242060 E	High Standard Home Care Inc. (Please see exhibit for list of Geographical Service Area)	Approval

Certificates

Certificate of Assumed Name

Applicant	**E.P.R.C. Recommendation**
Cayuga Ridge, LLC	Approval

CATEGORY 2: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Without Dissent by HSA
- ❖ Without Dissent by Establishment and Project Review Committee

CON Application

Ambulatory Surgery Center – Establish/Contruct

	Number	**Applicant/Facility**	**E.P.R.C. Recommendation**
1.	261080 B	Hawkins ASC, LLC d/b/a Vanguard Specialty Surgery Center (Suffolk County) Dr. Eisenstein – Interest	Contingent Approval

CATEGORY 3: Applications Recommended for Approval with the Following:

- ❖ No PHHPC Member Recusals
- ❖ Establishment and Project Review Committee Dissent, or
- ❖ Contrary Recommendations by HSA

NO APPLICATIONS

CATEGORY 4: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Establishment and Project Review Committee Dissent, or
- ❖ Contrary Recommendation by HSA

NO APPLICATIONS

CATEGORY 5: Applications Recommended for Disapproval by OHSM or Establishment and Project Review Committee - with or without Recusals

NO APPLICATIONS

CATEGORY 6: Applications for Individual Consideration/Discussion

CON Application

Diagnostic and Treatment Center - Construction

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	242277 B	Hyp+Care (New York County) Dr. Kalkut – Interest	Contingent Approval

VIII. NEXT MEETINGS

August 26, 2026 (Albany)
September 17, 2026 (Albany)

IX. ADJOURNMENT

******Agenda items may be called in an order that differs from above******

State of New York
Public Health and Health Planning Council

Minutes
May 7, 2026

The meeting of the Public Health and Health Planning Council was held on Thursday, May 7, 2026, at the Empire State Plaza, Concourse Level, Meeting Rooms 2-4, Albany, New York. Dr. Jo Ivey Boufford, Vice Chair presided.

COUNCIL MEMBERS PRESENT

Dr. Howard Berliner	Mr. Peter Robinson
Dr. Jo Ivey Boufford	Dr. John Rugge
Dr. Lawrence Eisenstein	Dr. Denise Soffel
Ms. Lindsay Farrell	Ms. Nilda Soto
Dr. Marcus Friedrich	Mr. Hugh Thomas
Mr. Scott LaRue	Dr. Anderson Torres
Dr. Sabina Lim	Dr. Kevin Watkins
Ms. Ann Monroe	Dr. Wendy Wilcox
Dr. Mario Ortiz	Dr. Patsy Yang
Mr. Stanfort J. Perry	Commissioner McDonald –Ex-Officio

DEPARTMENT OF HEALTH STAFF PRESENT

Mr. Jacob Bintz
Ms. Lynn Baniak
Mr. Darren Cohen
Ms. Val Deetz
Mr. Kenneth Evans
Dr. Douglas Fish
Ms. Kayleigh Gekakis
Ms. Shelly Glock
Ms. Sarah Gold
Mr. Mark Hennessey
Mr. Andrew Lebwohl
Ms. Colleen Leonard
Mr. George Macko
Ms. Kathy Marks
Ms. Marthe Ngwashi
Mr. Jason Riegert
Mr. Michael Stelluti
Mr. Christopher Squillacioti
Mr. Mark Waldenmaier
Dr. Elizabeth Whalen
Ms. Patricia Wrobel

INTRODUCTION

Dr. Boufford called the meeting to order and welcomed Council members, meeting participants and observers.

APPROVAL OF THE MINUTES OF FEBRUARY 19, 2026

Dr. Boufford asked for a motion to adopt the February 19, 2026, Minutes of the Public Health and Health Planning Council meeting. Dr. Watkins motioned for approval which was seconded by Dr. Berliner. The motion to adopt the minutes passed. Please refer to page 2 of the attached transcript.

REPORT OF DEPARTMENT OF HEALTH ACTIVITIES

Dr. Boufford next introduced Dr. McDonald to provide a Report of the Department of Health.

Report of the Department of Health

Dr. McDonald began by sharing that the Department of Health recently earned a Top Workplace Award through the Times Union. He noted that this recognition was significant for the department and reflected the positive transformation that had occurred since he became Commissioner in January 2023. During that time, the department had grown from approximately 4,000 employees to roughly 5,500 employees. He emphasized that no single individual was responsible for the achievement, crediting the collective efforts of staff and the strong support provided by Governor Hochul. Dr. McDonald stated that fostering a positive organizational culture has been essential to the department's success, explaining that employees who feel connected to a mission are more engaged and satisfied in their work.

Dr. McDonald next discussed the recent attention surrounding Hantavirus and explained its relevance to public health agencies in New York. He noted that the World Health Organization, the Centers for Disease Control and Prevention, and state and local health departments routinely collaborate on disease surveillance and response efforts. He explained that the strain currently receiving media attention is the Andes strain, which is commonly found in Argentina and Chile. The disease is well understood, with established recommendations focused on supportive care because no specific treatment exists. He reported that the Centers for Disease Control and Prevention was working with the U.S. State Department and international partners to repatriate seventeen American citizens from a cruise ship near Cape Verde. At present, there was no connection to New York State and no identified risk to New York residents.

Continuing his remarks on Hantavirus, Dr. McDonald explained that New York State remains engaged through ongoing communication with the Centers for Disease Control and Prevention and the World Health Organization's Global Outbreak Alert and Response Network. He clarified that while the Andes strain can spread from person to person, transmission requires prolonged, close personal contact and is not comparable to airborne diseases such as COVID-19. He emphasized that the virus is not easily transmitted and that public health officials continue to monitor the situation closely. Drawing on his previous experience working on the Navajo Reservation, Dr. McDonald discussed the history of Hantavirus in the United States. He recalled that the disease was first identified in the United States in 1993 following the death of a healthy Navajo adult in Arizona. He noted that CDC investigators worked closely with Navajo traditional leaders and healers, whose knowledge helped researchers better understand the disease and its connection to deer mice. During his time on the reservation, healthcare workers received orientation on Hantavirus and other region-specific diseases, including plague. He highlighted

this example as an illustration of the value of incorporating local and traditional knowledge into public health investigations.

Dr. McDonald then shifted to the Rural Health Transformation Program, emphasizing that it is a cooperative agreement with the Centers for Medicare and Medicaid Services rather than a traditional grant program. Through the agreement, New York State stands to receive approximately $212 million annually for five years if required benchmarks are met. He explained that special budget language is needed to allow the Department of Health to move quickly with contracts, as the standard review process through the Comptroller and Attorney General could take 13 to 18 months. Because all funds must be obligated by September 30, 2026, timely budget approval is critical. He noted that the Governor, Senate, and Assembly had recently reached a handshake agreement on the state budget, which could allow the department to move forward in the coming days. Dr. McDonald reviewed the program's four major focus areas: establishing coordinated rural health partnerships, strengthening rural communities and technology, building a sustainable rural healthcare workforce, and investing in technology innovation and cybersecurity. Funding allocations include approximately $77 million for rural health partnerships, $30 million for primary care and technology enhancements, $13 million for workforce development, and $79 million for technology and cybersecurity initiatives. He noted that extensive stakeholder engagement has already taken place and that implementation can proceed once the necessary budget provisions are approved.

Dr. McDonald noted that the Master Plan for Aging was completed and submitted in June 2024. He reported that eight state agencies are currently participating in steering committee meetings to guide implementation efforts. He highlighted the Direct Caregiver Flexibility Grant Program, which will provide $19 million annually over five years to strengthen the long-term care workforce through regional training centers and support hubs. He also noted the creation of a new Center for Hospice and Palliative Care within the Department of Health.

Dr. McDonald explained that many recommendations contained in the Master Plan for Aging do not require direct funding but instead rely on policy changes. Examples include expanding the use of Certified Medication Aides in nursing homes and allowing medical assistants to administer vaccines. He noted that New York remains the only state that does not permit medical assistants to administer vaccines and expressed hope that these reforms would advance during the current legislative session. He stated that such changes could help address workforce shortages while allowing healthcare workers to practice the skills for which they were trained. Dr. McDonald reported that the Department of Health currently administers 25 workforce programs and has committed approximately $570 million through March 2027 to workforce initiatives. These investments include loan repayment programs for physicians and nurses, career pathway programs, and training opportunities designed to attract more individuals into healthcare professions. He stated that the goal is to reverse the cycle of workforce shortages by increasing staffing levels, improving access to care, reducing burnout, and improving patient outcomes.

Dr. McDonald also highlighted recent research conducted by Dr. David Holtgrave and his team regarding medetomidine, a veterinary anesthetic increasingly found in the illicit drug supply. Their work was published in the New England Journal of Medicine and found that nearly one in four tested drug samples contained medetomidine. He explained that the Department of Health has issued alerts to healthcare providers and provided guidance on managing patients exposed to the substance, particularly those using fentanyl in combination with medetomidine. He emphasized that despite these emerging challenges, naloxone remains an important intervention. He also noted that Department of Health researchers publish more than 300 peer-reviewed articles annually.

Dr. McDonald informed members that they would soon review a regulatory package updating New York's list of reportable diseases. The proposed updates include adding several infectious diseases and organisms to laboratory reporting requirements, including blastomycosis, carbapenem-resistant organisms, Chronobacter infections, cytomegalovirus, Hendra virus, and Nipah virus. He noted that these updates would improve disease surveillance while minimizing additional burdens on local health departments.

Dr. McDonald also discussed proposed reporting requirements related to alpha-gal syndrome, an allergy to mammalian meat associated with bites from the Lone Star tick. Although the condition is not caused by an infectious organism, the department has determined that it has the authority to require reporting of laboratory findings associated with alpha-gal syndrome. Dr. McDonald explained that the Department of Health plans to combine laboratory reporting data with information from the All-Payer Claims Database to better estimate the prevalence of the condition in New York. He noted that Suffolk County has experienced a higher number of cases and that the dual-data approach could provide a more accurate picture of disease trends.

Dr. McDonald next recognized Black Maternal Health Week and discussed efforts to expand access to doulas across New York State. He highlighted outreach efforts in Brooklyn and explained that the department is working to increase the number of trained doulas, support Medicaid enrollment for doulas, and help them become credentialed with managed care organizations. He described doulas as non-clinical support professionals who assist individuals before, during, and after childbirth and noted that expanding access to these services remains a departmental priority. Dr. McDonald: Regarding the Medical Aid in Dying Act, Dr. McDonald reported that the department is currently developing regulations to support implementation of the law. He stated that the regulations are expected to be completed before the law takes effect on August 5, 2026.

Dr. McDonald also discussed preparations for major events taking place throughout New York State during the summer, including FIFA-related activities. He explained that the Department of Health has activated an incident management system and has spent the past year preparing for increased visitor activity. The department continues to coordinate with the New York City Department of Health, the Division of Homeland Security and Emergency Services, and other partners to ensure readiness for any public health concerns that may arise.

Lasty, Dr. McDonald introduced Darren Cohen as the Department of Health's new Chief Legal Officer. He explained that Kathy Marks has transitioned into a new role as his Special Advisor, where she is assisting with administrative decisions, the Northeast Collaborative, artificial intelligence implementation, and other strategic initiatives. Dr. McDonald praised Mr. Cohen's experience and contributions during his first six weeks with the department and expressed confidence in his leadership. He concluded his report by inviting questions from the council.

Dr. McDonald concluded his report and invited questions from the Council. Please see pages 3 through 18 of the transcript to view the complete report and members questions.

Dr. Boufford thanked the Commissioner for his report and turned to Dr. Fish and Ms. Deetz to provide the Report on the Activities of the Office of Healthcare Delivery.

Report of the Office of Health Care Delivery

Dr. Fish provided an overview of the organizational structure within the Office of Healthcare Delivery. He explained that the office includes the Office of Aging and Long-Term Care, the Office of Primary Care Health Systems Management, the Office of Health Facilities Management, and Medical Provider Management. Dr. Fish noted that Ms. Deetz serves as Deputy Director of the Office of Aging and Long-Term Care and that Mr. Hennessey leads the Office of Primary Care Health Systems Management. He further explained that the Office of Health Facilities Management oversees the state's veterans' homes as well as the Helen Hayes Rehabilitation Center in Haverstraw, New York.

Dr. Fish further explained that Medical Provider Management was separated from the Office of Primary Care Health Systems Management in January 2025. He noted that the office includes the Bureau of Narcotic Enforcement and the Office of Professional Medical Conduct. According to Dr. Fish, the reorganization was intended to distinguish practitioner-facing functions from facility-facing functions, as the other offices are primarily regulatory or operational in nature while Medical Provider Management focuses on physicians, healthcare workers, and other providers. Dr. Fish then introduced Val Deetz to provide updates from the Office of Aging and Long-Term Care.

Ms. Deetz reported that nursing home and adult care facility surveillance program leaders have been conducting visits throughout the state in a non-regulatory capacity to engage with providers. The purpose of these visits is to identify operational successes, challenges, innovative practices, and concerns. Ms. Deetz stated that the department is working collaboratively with providers to resolve issues, expand best practices, encourage innovation, and replicate successful models across facilities.

Ms. Deetz noted that the Center for Residential Surveillance continues to provide extensive educational programming. She noted that all training modules are publicly available through the New York State learning platform and are accessible to both the public and survey staff. Recent educational offerings included a three-part foundational series on Legionella tailored separately for nursing homes and adult care facilities. She added that upcoming webinars will focus on nutrition and social work, which are critical components of long-term care. Additional training planned for later in the year will address emergency preparedness and bed safety in response to increased use of bed rails.

Ms. Deetz also discussed efforts to improve efficiency and data reporting by transitioning providers from the Health Electronic Response Data System to the Survey Management and Response Tool platform. She explained that the new system reduces reporting burdens for providers while streamlining the submission of weekly surveys, including information related to bed census, demographics, and COVID-19 data. The Survey Management and Response Tool platform is being utilized across multiple long-term care provider types, including nursing homes, adult care facilities, licensed home care services agencies, and hospice agencies.

Ms. Deetz highlighted the work of the Center for Hospice and Palliative Care, which recently celebrated National Healthcare Decisions Day. She reported that the initiative included social media outreach, a YouTube video, an article published in the Empire Report, and an educational video focused on Medical Orders for Life-Sustaining Treatment.

Ms. Deetz further reported that the Office of Aging and Long-Term Care collaborated with Health Facilities Management to connect state veterans' homes with hospice agencies. This effort was undertaken to ensure that veterans residing in state-operated facilities have access to hospice and end-of-life care services when needed.

Ms. Deetz also announced that the Department partnered with adult care facility and assisted living industry representatives to secure approval of a State Plan Amendment. She explained that this amendment allows Medicaid Assisted Living Program participants to continue receiving assisted living services while simultaneously accessing hospice services. Previously, residents often had to disenroll from the assisted living program and leave their facility in order to receive hospice care. The amendment was designed to eliminate service barriers while ensuring clear delineation of Medicaid-covered services and preventing duplication of benefits.

Ms. Deetz stated that the Department recently completed the first phase of an educational study examining health equity within hospice care. She stated that the project is being conducted in partnership with student interns from the University at Albany and noted that additional findings will be presented during future Facilities and Services Committee meetings.

Ms. Deetz concluded her report, please see pages 19 through 21 of the transcript. Dr. Boufford thanked Dr. Fish and Ms. Deetz for their report and provided a report on the activities of the Public Health Committee

Report on the Activities of the Public Health Committee

Dr. Boufford reported on the activities of the Public Health Committee, noting that the committee serves on behalf of the Council to fulfill its statutory responsibility of overseeing the Prevention Agenda, New York State's health improvement plan. She explained that the Prevention Agenda is currently in its fourth cycle and has been significantly revised to include not only 23 priority health areas, but also five domains addressing social determinants of health. These domains reflect growing evidence supporting the impact of factors such as education, economic development, and community conditions on health outcomes.

Dr. Boufford explained that the Prevention Agenda is implemented through partnerships between local health departments, hospitals, and community organizations. Depending on local circumstances, these partnerships may operate at the county, regional, or municipal level. The goal is to engage a broad range of local stakeholders in addressing selected health priorities and improving community health outcomes. She noted that the current Prevention Agenda cycle covers the period from 2025 through 2030. She noted that hospitals were required under federal law to submit Community Health Needs Assessments and implementation plans by the end of December 2025. Although the state had hoped to align hospital and local health department planning cycles, the schedules remain slightly out of sync. Local health departments are now required to submit their plans by July 1, 2026. Approximately 30 to 35 percent of local health departments submitted plans by the end of December in collaboration with their local healthcare systems and hospitals. The remaining departments are being encouraged to continue working with local partners as they finalize their plans. Dr. Boufford stated that an updated report on progress will be presented at the Public Health Committee's June 23, 2026 meeting.

Dr. Boufford also discussed the committee's focus on community benefit reporting. She explained that nonprofit hospitals receive significant tax exemptions and, in return, are expected to invest in their communities through community benefit activities. The committee has been particularly interested in the community health improvement component of those activities, which closely aligns with the goals of the Prevention Agenda. Dr. Boufford reported that voluntary hospitals will now be asked to submit their federal Schedule H community benefit reports to the Department of Health at the same time they are submitted to the Internal Revenue Service. She noted that a separate reporting questionnaire is being developed for public hospitals, which are not required to submit Schedule H forms. The purpose of the questionnaire is to document community benefit activities undertaken by public hospitals. The Public Health Committee intends to review the questionnaire and work with the Department to identify opportunities to strengthen community health investments that support Prevention Agenda priorities.

Dr. Boufford reported on a presentation regarding the public health accreditation process. She noted that New York State was among the first and largest states to pursue voluntary public health accreditation several years ago and is now preparing for the next accreditation cycle. The committee heard from representatives of local health departments that have successfully completed accreditation, including Dr. Watkins' department. Discussion focused on both the benefits and challenges of accreditation, as well as lessons learned from the process.
Dr. Boufford explained that the Ad Hoc Committee was originally established as part of the requirements associated with public health accreditation. The committee discussed its continuing

role and future collaboration with the Department of Health as the state prepares for the next accreditation review cycle, which is expected to occur during 2027.

Dr. Boufford also highlighted the committee's ongoing focus on public health workforce development. She reminded members that the Council had previously identified maternal mortality as a priority issue and successfully used its convening authority to bring stakeholders together and increase awareness. Building on that model, the committee selected public health workforce development as another area of focus. Recent discussions explored strategies to strengthen the workforce, including the creation of a statewide academic network of schools and programs of public health, expansion of fellowship and internship opportunities, and other initiatives designed to increase visibility and support for public health careers. The committee plans to continue these discussions at its June meeting and identify specific action steps.

Dr. Boufford reported that the newly revitalized Prevention Agenda Ad Hoc Committee held a meeting the previous afternoon. She commended Mr. Waldenmaier, Dr. Whalen, Dr. Ali, and Department staff for their efforts in reorganizing and expanding the committee's membership. The committee now includes state and regional nonprofit organizations, professional associations, advocacy groups, and public agencies.

Dr. Boufford stated that 38 state and regional organizations and 14 state agencies participated in the meeting. In addition, more than 220 individuals attended virtually. She described the meeting as highly successful and emphasized the importance of building partnerships to support the Prevention Agenda. Dr. Boufford explained that the meeting focused on the five social determinant of health domains: economic stability; social and community context; neighborhood and built environment; healthcare access and quality; and education access and quality. Participants were assigned to discussion groups and had opportunities to contribute ideas in two separate domains before reporting back to the larger group. Representatives from longstanding Prevention Agenda partners, including the Office of Mental Health, the Office of Addiction Services and Supports, the New York State Office for the Aging, and the Department of State, participated alongside several newly engaged agencies.

Dr. Boufford advised that facilitators and rapporteurs were assigned to each discussion group and are currently compiling meeting notes and recommendations. The committee expects to review the findings at an upcoming Public Health Committee meeting and plans to reconvene the Ad Hoc Committee in September. Dr. Boufford stated that the long-term goal is to connect state and regional organizations with local Prevention Agenda partnerships involving hospitals and local health departments. By leveraging the resources and expertise of these organizations, communities will be better positioned to address health challenges and improve health outcomes. She noted that participants appeared enthusiastic about the opportunity to collaborate with the Department of Health. Dr. Boufford specifically highlighted the participation of representatives from the State Education Department and the Board of Regents, noting that education is one of the most important social determinants of health. She also acknowledged the involvement of agencies focused on economic development, transportation, and other sectors, describing their engagement as an important step toward addressing broader factors that influence community health.

Dr. Boufford concluded her report, please see pages 22 through 25 of the transcript

Dr. Boufford invited comments from fellow Council members regarding the report. Hearing none, she concluded her report and turned the meeting over to Mr. Robinson for the next agenda item.

PROJECT REVIEW RECOMMENDATIONS AND ESTABLISHMENT ACTIONS

Report of the Committee on Establishment and Project Review

Peter Robinson, Chair of Establishment and Project Review Committee

APPLICATIONS FOR CONSTRUCTION OF HEALTH CARE FACILITIES

CATEGORY 1: Applications Recommended for Approval – No Issues or Recusals, Abstentions/Interests

CON Applications

Residential Healthcare Facility – Construction

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	252188 C	Rosary Hill Home (Westchester County)	Contingent Approval

Mr. Robinson called application 252188. Mr. Robinson motioned for approval. Dr. Berliner seconded the motion. The motion passed. Please see pages 25 through 26 of the transcript.

CATEGORY 2: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Without Dissent by HSA
- ❖ Without Dissent by Establishment and Project Review Committee

NO APPLICATIONS

CATEGORY 3: Applications Recommended for Approval with the Following:

- ❖ No PHHPC Member Recusals
- ❖ Establishment and Project Review Committee Dissent, or
- ❖ Contrary Recommendations by HSA

NO APPLICATIONS

CATEGORY 4: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Establishment and Project Review Committee Dissent, or
- ❖ Contrary Recommendation by HSA

NO APPLICATIONS

CATEGORY 5: Applications Recommended for Disapproval by OHSM or Establishment and Project Review Committee - with or without Recusals

NO APPLICATIONS

CATEGORY 6: Applications for Individual Consideration/Discussion

NO APPLICATIONS

APPLICATIONS FOR ESTABLISHMENT AND CONSTRUCTION OF HEALTH CARE FACILITIES

CATEGORY 1: Applications Recommended for Approval – No Issues or Recusals, Abstentions/Interests

CON Applications

Ambulatory Surgery Centers – Establish/Construct

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	252226 B	Access Surg Care, LLC (New York County)	Contingent Approval
2.	261017 E	Dutchess Ambulatory Surgical Center, LLC d/b/a Dutchess Ambulatory Surgical Center (Dutchess County)	Approval

Mr. Robinson called applications 252226 and 261017. Mr. Robinson motioned for approval. Dr. Berliner seconded the motion. The motion passed. Please see page 26 of the transcript.

Diagnostic and Treatment Centers – Establish/Construct

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	252184 B	New Windsor Family Care, LLC (Orange County)	Contingent Approval
2.	261044 E	GAMMS LLC d/b/a Zelcare Family Health Network, LLC (Orange County)	Approval

Hospice Services – Establishment

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	252144 E	Hospice and Palliative Care Inc (Please see exhibit for list of Geographical Service Area)	Approval

Mr. Robinson called applications 252184, 261044 and 252144. Mr. Robinson motioned for approval. Dr. Berliner seconded the motion. The motion passed. Please see page 26 of the transcript.

Residential Healthcare Facilities – Establish/Construct

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	211102 E	Rockville Holdings Operating LLC d/b/a Rockville Skilled Nursing and Rehabilitation Center (Nassau County)	Contingent Approval

Home Care Service Agency Licensures

Changes of Ownership

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	231045 E	Medford Hamlet LLC d/b/a Medford Hamlet Home Care (Please see exhibit for list of Geographical Service Area)	Approval
2.	231252 E	1st Home Care Of NY Corp. (Please see exhibit for list of Geographical Service Area)	Approval
3.	241067 E	S & A Unified Home Care, Inc. (Please see exhibit for list of Geographical Service Area)	Approval
4.	241102 E	Kirenaga Home Care Manhattan Inc. d/b/a Synergy Homecare (Please see exhibit for list of Geographical Service Area)	Approval
5.	241125 E	Novel Home Health Care Services Of New York, Corp. (Please see exhibit for list of Geographical Service Area)	Approval
6.	251019 E	Carelink, Inc. (Please see exhibit for list of Geographical Service Area)	Approval

Mr. Robinson called applications 211102, 231045, 231252, 241067, 241102, 241125 and 251019. Mr. Robinson motioned for approval. Dr. Berliner seconded the motion. The motion passed. Please see page 27 of the transcript.

CATEGORY 2: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Without Dissent by HSA
- ❖ Without Dissent by Establishment and Project Review Committee

Diagnostic and Treatment Center – Establish/Construct

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	252207 B	Rosh Medical Management LLC d/b/a Rosh Medical Center (Kings County) Dr. Kalkut – Interest	Contingent Approval

Mr. Robinson called application 252207. Mr. Robinson noted for the record that Dr. Kalkut has an interest but was not present at the meeting. Mr. Robinson motioned for approval, Dr. Berliner seconded the motion. The motion passes with Dr. Kalkut's noted interest. Please see pages 21 and 22 of the transcript.

Home Care Service Agency Licensures

New Licensed Home Care Services Agencies

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	252172 E	PACE at Hudson Headwaters, Inc. (Please see exhibit for list of Geographical Service Area) Dr. Rugge - Interest	Approval

Mr. Robinson called application 252172. Mr. Robinson noted for the record that Dr. Rugge has an interest. Mr. Robinson motioned for approval, Dr. Berliner seconded the motion. The motion passes with Dr. Rugge's noted interest. Please see page 28 of the transcript.

CATEGORY 3: Applications Recommended for Approval with the Following:

- ❖ No PHHPC Member Recusals
- ❖ Establishment and Project Review Committee Dissent, or
- ❖ Contrary Recommendations by HSA

Residential Healthcare Facilities – Establish/Construct

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	232239 E	OLP SNF OPCO LLC d/b/a Our Lady of Peace Nursing Care Residence (Niagara County)	Contingent Approval

Mr. Robinson called application 232239. Mr. Robinson motioned for approval. Dr. Berliner seconded the motion. The motion passed with one member abstaining. Please see page 28 of the transcript.

CATEGORY 4: Applications Recommended for Approval with the Following:

- ❖ PHHPC Member Recusals
- ❖ Establishment and Project Review Committee Dissent, or
- ❖ Contrary Recommendation by HSA

NO APPLICATIONS

CATEGORY 5: Applications Recommended for Disapproval by OHSM or Establishment and Project Review Committee - with or without Recusals

NO APPLICATIONS

CATEGORY 6: Applications for Individual Consideration/Discussion

Residential Health Care Facility – Establish/Construct

	Number	Applicant/Facility	E.P.R.C. Recommendation
1.	261111 B	Transitional Living Community at The Center for Discovery (Sullivan County)	Application was presented at the May 7, 2026 Special Establishment and Project Review Committee Meeting

Mr. Robinson called application 261111. Mr. Robinson motioned for approval. Dr. Berliner seconded the motion. The motion passed. Please see page 29 of the transcript.

ADJOURNMENT

Dr. Boufford adjourned the public portion of the meeting and asked for a motion to go into Executive Session for the Report of the Committee on Health Personnel and Interprofessional Relations. Mr. Thomas seconded the motion. The motion was carried and the Council went into begin Executive Session. Please see page 32 of the transcript.

NEW YORK STATE DEPARTMENT OF HEALTH
PUBLIC HEALTH AND HEALTH PLANNING COUNCIL
FULL COUNCIL MEETING
May 7, 2026
ESP, CONCOURSE LEVEL, MEETING ROOMS 2-4 ALBANY
TRANSCRIPT

Dr. Boufford: Thank you. Thanks very much. I'd like to call to order the meeting of the Public Health and Health Planning Council and welcome our members, participants, and observers. As a reminder, I'll go through the reminders here for our audience viewing the public meeting via webcast. There is a form you need to fill out. If those of you that are here in person, it should be on the table outside the door. For those of you that are listening, please do go on the website of the department under certificate of need and download that form and send it in to Ms. Leonard.

I'd also like to remind council members, staff, and the audience, this meeting is subject to the open meetings law. It is broadcast over the internet. The webcasts are on the Department of Health website, and on-demand webcasts will be available no later than seven days after the meeting, for a minimum of 30 days, and then a copy will be retained in the department for four months.

I'm also welcoming the commissioner, Dr. McDonald. I just welcomed everybody else, and you came on over. So, anyway.

Dr. McDonald: Hi, how are you doing? Thank you.

Dr. Boufford: You're very welcome. So, some suggestions and ground rules for the meeting. Please keep yourselves on mute when you're not speaking, and obviously if your mic is open, papers are distracting, et cetera, for other noises. There is synchronized captioning, so please try to avoid talking over other individuals. First time you speak, you're asked to identify yourself and whether you're a member of the council. And I want to encourage the members, staff and public to join the department's certificate of need listserv, where there are regular set of updates on the status of various applications and their process. And there are printed instructions at the reference table outside on how to join.

Just a quick review of the agenda today. Department of Health reports, we'll hear first from Dr. McDonald, Commissioner McDonald, who will provide a report on the Department of Health activities. Dr. Fish and Ms. Deetz will provide a report on the activities of the Office of Healthcare.

I've got some contradictory information here. They don't run long-term care, so that's...

Ms. Leonard: So, it's going to be...

Dr. Boufford: Val's doing... Okay. So, Dr. Fish is not going to be... Okay, thank you very much. I didn't get that clear. Apologies. Ms. Deetz is going to provide a report on the activities of the Office of Aging and Long-term Care. I just saw Mr. Label come in, so maybe they'll have a tag team there. I'll provide an update on the activities of the public health committee and the ad hoc committee, which met yesterday.

And then project review recommendations and establishment actions. Mr. Robinson will be reporting on a number of CON applications that reviewed at the meeting of that committee. And just a little bit of the ground rules here for council members, to remind you that we do, in fact, batch applications under CON, and any of you, I hope you've had time to take a look at the agenda, and let me give you a few minutes if you would like to pull any of the applications out of the batch in which they sit and have them considered individually. Seeing no reaction from my colleagues, I'll assume that the batching holds for Mr. Robinson.

And next, I'd like a motion to adopt the February 19th meetings of the FBIC. May I have a motion? So, moved. Well, Mr. Berliner and Mr. Thomas moved and seconded. All in favor? Any opposed? Any abstentions? Those pass. And you also have been given the council meeting dates at the end of the materials here. I'd like a motion to adopt those meeting dates. I think I would add one for the public health committee on the 23rd of June. So, motion to R2. Dr. Watkins moved and Dr. Berliner seconded. All in favor of those dates, confirming the dates. Everyone. Any decline? Yes, Dr. Eisenstein?

Dr. Eisenstein: I just want to clarify on the calendar and the documents that you're referring to, it says the June meetings are in New York City. I think, is it correct they've been switched to Albany?

Ms. Leonard: That's the 27th.

Dr. Eisenstein: Oh, okay. I'm sorry.

Dr. Boufford: It's called advanced planning, here.

Dr. Eisenstein: It's the same dates.

Ms. Leonard: Now we know June is in...

Dr. Eisenstein: Thank you. My apologies.

Dr. Boufford: Yeah, the June meeting is in Albany. It's important to be aware of that. They also received proposals for revision of our bylaws, and I'd like a motion to adopt the revised council bylaws. Dr. Berliner moved. Mr. Thomas seconded. Any questions or concerns about the bylaws? I think Ms. Monroe had some questions, and my understanding is that Ms. Leonard has answered those questions satisfactorily. So, I think we're in good shape. I think everyone saw that email activity. So, all in favor, please, of the bylaw's revision. Any opposed, any abstentions? Bylaws revision passes. And now it's a pleasure to hear from Commissioner McDonald, who will update us since the last council meeting.

Dr. McDonald: Thanks, Dr. Boufford. Good to see everybody again today, and I see you've all found this meeting room, so we're across the hall as usual, here. So, the first thing I want to share with folks is that the New York State Department of Health last month earned a top workplace award, maybe something done through the Times Union. And I think I just want to get that out there.

Winning a Top Workplace Award, I think that's a big deal for the Department of Health. When I think about when I took over in January '23, we're a team of 4,000. Now we're a team of roughly 5,500, and the cultures really shifted. I think it is important to know that no one person was responsible for that. It was interesting to me just how this organization has transformed coming out of the pandemic. The governor was extremely supportive of the Department of Health. Anything I asked for, I got, and it's just been really nice.

And I think it's one of those things where organizational culture is really important to any organization. If you run a hospital, healthcare enterprise, you know that. If people don't feel comfortable at work, don't feel like they're part of a mission, it doesn't really matter what you do. But this is one of the things we see from our people, if they really feel like they're part of a mission, they're happy. And so, I'm excited about that.

I'd like to talk now a little bit more about something we've never talked about before, which is Hantavirus. Since Hantavirus is in the news, I thought I'd bring it to your attention a little bit from our perspective. You might be wondering, what does New York State Department Health have to do with a cruise ship somewhere off Cape Verde? And I just think I'd just talk a little bit about how public health works. So, this is normal. The World Health Organization works with CDC. CDC works with state and local health departments. So of course, I know what's going on a cruise ship in Cape Verde.

And I just want to talk a little bit about Hantavirus in general. The strain of Hantavirus that we're talking about is the Andes strain, A-N-D-E-S, which is common in Argentina and Chile. In other words, the disease Hantavirus occurs there not infrequently. And I just want to make sure this is clear. This particular strain is a known disease with known recommendations. There's no treatment for it. It's supportive care. And just important to have a perspective on this is, right now how we're working with CDC is, what CDC is doing is working with the state department, with other countries to how to get 17 American citizens repatriated to the United States. So that's something that we expect to occur in the next several days, which is what CDC tells us.

We do not see a nexus to New York state at the moment. The risk to the United States is really almost nothing. The risk of New York right now is nothing. There is no concern. But why do we care about this? I want to bring back a concept here. You might remember me talking a little bit about the Global Operator Alert and Response Network from the World Health Organization, that we joined earlier in the last year. So, we are on calls with them. We're on calls with CDC. This is all very normal. We're working through all this.

And I think it's just important to kind of just have a little context that the thing about the Andes strain that's capturing the news is its spread person to person. I think regrettably, when we think of person spread, your mind, if you're like the rest of us, drifts towards the pandemic, because that's what is fresh on our mind still. So, it's not contagious like that. It's not an airborne virus. It's sustained, prolonged, close, personal contact. Typically, a spouse would get from another spouse. So, it's not an efficient virus as far as transmission goes. So, we're keeping track of this scenario quite closely.

And then as a side note, some of you know, I used to work on the Navajo Reservation, and I bet there's someone in here who's a medical historian who knows a little bit about 1993, when Hantavirus was first described in the United States. And I share this with you. It was described in Arizona. It was described among the Navajo people, because a Navajo healthy adult passed away. And what was interesting about the 1993 experience is Hantavirus wasn't described in the United States prior to that.

But what was interesting, when CDC came, they worked with the Navajo traditional leaders and traditional healers and learned a little bit about it. Because what they had known among the Navajo people was, when there's a lot of rain in the spring, you have to be really careful about interacting with deer mice, because you don't want to interact with deer mice or with prairie dogs.

One of the things you should know is, when I worked on the reservation, we oriented everyone who came to us about Hantavirus because Hantavirus was something we saw there. Not commonly, but you had to be ready for it. If you missed it, you missed it, right? We oriented people about plague as well, because that happened there too. There was other diseases we oriented people about because it's a different part of the country. You see different diseases. This was all normal. It's still the case today.

I just shared that illustration. I thought it was really interesting how CDC in '93 listened to the traditional healers at the time, and it helped them isolate the Hantavirus, which was first described in the United States in 1993. Having said that, we're following closely with this, and we're just going to see if there's any role for us to play like the New York State Department of Health.

I'm going to shift now, just to touch base on the Rural Health Transformation Program. Keep in mind, it's the Rural Health Transformation Program. It is not a grant. It's a cooperative agreement with us and the Center for Medicaid and Medicare Services. We have $212 million coming each year for the next five years, if we meet what CMS has told us to do.

One of the things that we need to happen during this budget is that we've got what's called notwithstanding language. In other words, it would be impossible for the Department of Health to enter into contracts if we have to go through the usual controller review and attorney general review. That typically takes 13 to 18 months. So, you have to have all the money obligated by September 30th of this year, 26th. So, we have to really move on this stuff. Having said that, you heard the governor announced this morning at 9:00 with the assembly and the senate, a handshake agreement. So, we expect the budget to be resolved in the next several days or sometime next week. So, we'll see where that goes.

The Rural Health Transformation Program though, we're still working on it. We just need that language. But just to refresh your memory, there's four big areas we're working on. One is establishing coordinated rural health partnerships. We have $77 million planned for this year. Strengthening rural committees and technology, enhanced primary care, we have $30 million planned for that. Building a sustainable rural healthcare workforce, we have $13 million planned for that. And investing in technology innovation and cybersecurity enhancements, we have $79 million obligated for that. Keep in mind, we've done a lot of stakeholder engagement. We're doing a lot to get this moving in the right direction, and as soon as the budget's passed, it will just let us move forward, as long as that provision is in place.

I want to just talk a little bit about the Master Plan for Aging. As you know, last June, the Master Plan for Aging was completed and submitted, and that was great to see that. Right now, we are having what's happening next, which is eight state agencies are having their steering committee meetings. The first committee meeting was March 26th of this year, and there'll be more steering committee meetings as decided by the State Office for Aging, working with the Department of Health.

One of the things we did as part of the Master Plan for Aging is our direct caregiver flexibility grant. That's to help strengthen the long-term care workforce by establishing regional training centers and support hubs. It's $19 million a year for the next five years. We've also created a Center for Hospice and Palliative Care in the department. Cara Travis leads that.

There's other things that the department's doing on the Master Plan for Aging. Keep in mind, the Master Plan for Aging doesn't have a line item in the budget. It's really up to the legislature and other stakeholders to bring forward things from the Master Plan for Aging and see if they can procure funding for it. And some of the things we can do don't require funding. Like one of the concepts that came out of the Master Plan for Aging was some of the scope of practice changes we've been advocating for. One of the things we heard from nursing homes is, why can't we have certified medication aids pass meds in New York State nursing homes, like occurs in 38 other states, and like we do in New York and the assisted living and in the office of developmental disability. So, we're hoping this year that we get that across the finish line.

And of course, there are also proponents in the Master Plan for Aging of hoping medical assistants could administer vaccines. As many of you know, New York's the only state in the United States that doesn't allow a medical assistant to give a vaccine. The other 49 states have been doing this for quite some time. And these are just a few examples of certain things that are policy-related initiatives that actually don't have a budget item attached to it but really do provide some labor relief. We have a healthcare workforce shortage. Every state has a healthcare workforce shortage, but one of the things we have to do is catch up with other states and let people work with the skills they were trained to do.

And just about workforce in general, one of the focus areas I have for this year is workforce. We have 25 different workforce programs at the Department of Health. Dr. Carrie Rosamilia runs the Workforce Innovation Center for the Department of Health. But of our 25 workforce programs, we have $570 million committed between now and March 31st of 2027. That's committed money. In other words, some of it came out of the '24 budget, '25 budget, but that's implemented money.

Really trying to just, I think, stop the vicious cycle of a healthcare workforce shortage and create a virtuous cycle of a healthcare worker surplus. This is funds that are going to be used for loaner payment for physicians and nurses, but there's money in the career pathways training to help people get into healthcare. There's money to help more people get into care. There's a lot of resources that we have going on this year.

But really, it's to help stop the vicious cycle, because when you have healthcare worker shortage, you have access to care problems. You have quality of care problems, you just need more regulatory actions, more workplace violence. It's just, there's all these problems that occur. There's all this undue pressure on Medicaid. It just isn't helpful. What you really want to do is create a virtuous cycle. We have more healthcare professionals, better access to care. People can have better quality outcomes. Less burnout among healthcare workers. You just see the stability of workforce. So that's really what New York is working on, and that's good.

I want to shift to a different topic completely. I think many of you know Dr. David Holtgrave who works for the department as our emerging drug threat coordinator. He's also one of our senior policy advisors, but Dr. Holtgrave and his team did wonderful work working on just really looking at drug checking in a veterinary anesthetic called medetomidine. They published an article last month in the New England Journal of Medicine and really just looked at drug checking and just really identified how common medetomidine is becoming in our illicit drug supply. Almost one in four samples that were tested had that. Now keep in mind, they're not testing every sample, but one in four quite a bit.

So, what the Department of Health has done about this over the last year is, we sent out a health alert about this to our healthcare providers. One of the things we just sent out last week was, what do healthcare providers need to know about managing people who've had medetomidine? Because really, what you see most commonly is Its people who are taking fentanyl, but also medetomidine. And keep in mind, it changes people's cardiovascular status, so people need to know how to manage what might be some hypertension. And what are some remedies to do that. We still advise people to, of course, give Naloxone.

But I think it's just an example of there's a lot of scholarly work that occurs in New York State Department of Health. This may surprise you, but our department publishes over 300 peer-reviewed articles a year. I highlight just this one just because it's interesting and it made the New England Journal of Medicine, and it was in the media quite a bit too. So, I think that's good.

I do want to foreshadow a little bit. You're going to see a regulatory package coming up today. Dr. Luddow and her team have been working on this, and I just thank them so much for doing this, but every once in a while we have to just update the list of reportable diseases, and so you're going to be seeing some things that are going to come forward to you in the regulatory world. Some of these are a little bit more common, like blastocytes will become laboratory-reportable disease. Keep in mind, when it's a lab-reportable disease, the lab has the information. They just need to share it through us electronically. So not as much work on the part of anybody.

And one of the things we're really trying to be very careful is, you don't want to shift work to a local health department if you don't have to. Local health department's already doing a lot. But you'll see other information with other like carbapenem-resistant organisms are going to be included, some chronobacter, some other things about cytomegalovirus.

There's some that I think people haven't heard of before, which is Hendravirus. If you didn't know what Hendravirus was, I didn't either. I had to look it up myself. But just catching up on this. Nipovirus is another one. And Hendravirus is a Nipovirus, in case you're into the esoteric in medicine, but some of these rare diseases we need to know about.

One of the things that's going to come forward though, which is a little bit different for us is a different tick-borne situation here. And I'm going to call it a disease. We check with legal. We do have the regulatory authority to do this, but we're going to be recommending actually tick-borne disease. In other words, organisms that are going to lead towards causing what's called alpha-gal syndrome.

So, when you think about why people get alpha-gal syndrome, which is really, quite frankly, an allergy to meat, or any meat from a mammal, like beef. The thing is, you're not actually getting infected with a disease from the tick. It's the sugar that's actually transmitted from the saliva of the lone star tick, that causes an allergic reaction to people, which is persistent. And there's no real treatment for it, other than you have to avoid mammalian meat. And some people, of course, can have anaphylaxis for this. Others just have dyspepsia. But it's one of those things where it's occurring.

There's certain parts of New York where it's more common, like Suffolk County, so getting lab reportable information will give us a better idea of prevalence. But one of the things we're also going to do, which is just interesting, as you know, we have the All-Payer Claims Database. So just because someone has a positive lab test for the Alpha-16 galactose sugar, doesn't necessarily mean they're going to have alpha-gal syndrome. So, by

using the All-Payer Claims Database, which I expect to have some data on this by Labor Day, we'll have another way of actually seeing what the actual prevalence of this is in New York State and locate it.

Keep in mind, if it's in the All-Payer Claims Database, it means somebody paid for the care and a healthcare provider made the diagnosis. So, it's two different ways of actually looking at this, and I think it'll give a better estimate of prevalence of this. And in case you're curious, there's other jurisdictions in the country that do use the lab reportable disease, about 13. Most of them are different states. I don't know of anyone yet who's using both, though. I think our approach will be a little bit novel, but I think it'll give us a better idea of prevalence, and then hopefully better to give information to the public and advise people to avoid ticks.

There's no reason to get bit by a tick ever. I don't think anyone wants to be bit by a tick, but part of it's just making sure people know to keep an eye on this. Like when you're outside, which I want people to do, just make sure you look to make sure you're not carrying a tick with you. Keep in mind, ticks are not our friends. We're their food source, and we don't want to have tick bites on us, but it's important to keep on top of that.

Anyways, just a couple other topics to bring to your attention really quick, with Black Paternal Health Week was last month and Mother's Day's coming up. So just want to talk a little bit about some of the work we're doing. We did some work in Brooklyn with some community stakeholders to just help bring attention to the issue about doulas. Some of you might remember, I signed a standing order so someone could access a doula if they chose to do so through Medicaid.

One of the things we're trying to do is help more people be trained as doulas, help more people become enrolled in Medicaid as doulas, help them get credentialed with managed care company to become doulas. This is how the department can really reach out and provide better customer service. And I kind of said to some of the people who are running their own doula training agency that we can be your doula with Medicaid, because really, that's what a doula does, offer assistance and guidance. A doula is a non-clinical assistant to help someone when having a baby. They visit with people before they have the baby, when they have the baby, and after they've had the baby. And it's great to see that, and we're happy to see that's occurring here. So, I think that's great that we're doing that.

The medical aid in dying issue, I just want to talk a little bit about. We're working on putting regs together for that. My team is working on that. They're not going to be approved by you, they're approved by me, but I'm just letting you know we're working on the reg package for that. And I

think that'll be done by the time it gets in place. The law goes into effect August 5th of this year. Our reg should be done by then as well.

And then some of you are following this summer, there's going to be all these FIFA events. In other words, all these events that are going to be talked about... People are coming to watch all these FIFA events. We're getting ready for that. There's other things occurring this summer as well. Like in other words, there's a lot of things that people come to New York City for this year in other parts of the state, not the least, which is just FIFA.

But we have just stood up incident management system a few months ago. We've been planning on this for a year, but we're just making sure that as more people come to New York State, we're ready. We work with the City Health Department, Department of Homeland Securities and Emergency Services. But just so as more people come here, we're ready for some of the public health possibilities that might occur, so if there's something, we can respond quickly.

And then, last thing I want to do is want to make sure that you know who the person is to my right. This is Darren Cohen. Darren is our new chief legal. Kathy Marks did not go anywhere. Kathy is working in a part of the department who's actually assisting me now as my special advisor. She's helping me with doing some of the administrative decisions, giving me advice on administrative decisions we do that come through our administrative law judges. She's also helping with the Northeast Collaborative. She's helping with artificial intelligence implementation in the department as well and just helping with some other matters that are directly assisting me. Kathy's now working outside the New Rochelle office, which is really close to where she lives, which is good for her as well.

But it's really great to have Darren who's got a lot of experience working in legal, and he's only been here, gosh, I think six weeks, but I feel like he's been here forever. It’s just been great to see him the way he's hit the ground running, and there's been no shortage of complex legal situations for him to actually deal with. It was so great to see Darren to my right today.

With that, let me stop for just a minute and just see if there's any questions for me.

Dr. Boufford: Okay. Floor is open. Questions from council members? Mr. LaRue?

Mr. LaRue: Good morning, Commissioner. I actually have two questions. The first is related to PACE. So, a couple of years ago, new regulations came before

this committee, then they expired before they were implemented. Is that under review? Is there a process in place that that's going to be revisited?

Dr. McDonald: Yeah. So, for Program for All Care Inclusive for Elderly, which is what PACE stands for... Val, where are we in the reg package? I'm going to put Val on the spot because I know Val's right there.

Ms. Deetz: Hi Val Deetz. Hey, Scott. So, yes, they're under review, more to come. Hopefully we can provide a little bit more information at the upcoming FBIC meetings. Thank you.

Dr. McDonald: Okay, great. Thanks.

Mr. LaRue: Thank you. And then secondly, and completely different question, as it relates to assisted suicide, how does CMS fit into this, in terms of what was passed legislatively versus what CMS allows in different programs regulatorily? How does that get resolved if there's a conflict?

Dr. McDonald: Yeah. So, it's medical aid in dying, it doesn't have an obvious nexus with Center for Medicaid, Medicare Services. It's a state that's doing this. It's not going to be covered by third party payers, it is my understanding. So, I don't see the obvious nexus with them.

Mr. LaRue: Yeah. If we go back to PACE as an example, which is regulated by CMS, just when they look at those regulations, I encourage them to keep in mind any conflict there might be with PACE.

Dr. McDonald: Yep. I mean, keep in mind, well, CMS isn't looking at medical aid in dying regulations, because there's no... These are state regulations promulgated by us. And just to let you know, really, the law that made medical aid in dying come together is very prescriptive, so there's really not a lot of regulations we need to make. It's mostly about reporting. And regulations are a minimum standard, so don't expect to see a lot of requirements from us regarding what this is going to look like. Because really, the law itself was very prescriptive. I know it wasn't without controversy, but it was very prescriptive. So, our part is very minimal.

One of the things that the law talked about was making sure the unused narcotics were destroyed. That regulation's already existed through the Bureau of Narcotics Enforcement. So there really isn't... We didn't do anything there because it's already done. So, all good.

Dr. Boufford: Dr. Friedrich.

Dr. Friedrich: Yeah. Thank you, commissioner, for your update. You mentioned something using the All-Payer Database for this Alpha-16 galactose. Are

there other use cases? I always feel we are not getting the full story. I think over the last, I think, 13 years, the All-Payer Database has been built and it's such a great resource for many things. Can you elaborate a little bit on that?

Dr. McDonald: I'd love to. So, the All-Payer Claims Database, so just so people know, I think one of the first things I want to say is, when you hear the name All Payer, would you think that would include all payers? It doesn't. So just so you know, it doesn't include ERISA. So, it covers about 80% of payers. So, I want to get that out there.

Now, your question was, have we used it for anything else? And this is legitimate, right? It's been over a decade of existence. What are we using this for? So last year, we created a Parkinson's registry, and there's a webpage for the Department of Health where we actually determined the prevalence of Parkinson's disease in New York State. There's a dashboard, and that data came from the All-Payer Claims Database. Other places we've used it for, we have limited use public files for the All-Payer Claims Database for pharmacy costs that you can access on our website now as well. The other thing that's coming soon for the All-Player Claims Database is going to be looking at certain types of care settings.

So, there's a whole team of people that work on the All-Payer Claims Database. They're all led by Anne Skatine, who runs the Office of Health Systems Quality and Analytics. Because I think one of your points, which is this, would be helpful health economic information, and it is. Because one of the things about, I think that people struggle with is, when you go to procure anything in our culture, you have a good idea of what it costs. Not healthcare. And one of the things about healthcare is, it'd be better if we could actually see transparency in what things actually... What are we going to be charged, right? And so, this is something you get information for.

But the pharmacy data has been out for over a year through limited public use research files, so you can access that stuff and go explore it if you'd like to. Ann Skatine's the one who leads that, so if people have questions, you can reach out to the department. We're happy to make connections and answer other questions.

Dr. Boufford: Any other questions from council members? Yeah, Dr. Soffel.

Dr. Soffel: Good morning, Commissioner. Always a pleasure to see you. I have a comment and a question. Yesterday at the public health committee meeting, we had a really interesting presentation by your staff in the Office of Public Health about the challenges to building up the public health workforce and the many programs that they have implemented to

try to encourage people to come into public health. And one of our members actually observed that part of the challenge is that salaries in the public health field are so much dramatically lower than in other parts of healthcare, and anybody who's looking at a financial trade-off is unlikely to opt for the public health option. And so that's my comment, is that it is certainly something that should be part of the Department of Health conversations and budget conversations, because the state hires so many public health staff, and if the salaries are not viable for people who are trying to start a career, they're not going to go there.

My question was, I saw recently that the United States has declared the measles outbreak is over. What does that mean for New York? And could you sort of update us? How many cases did we see, and what was the resolution, and sort of where you think we are in terms of measles?

Dr. McDonald: Yeah. So, in 2025, New York State had 20 cases of measles. So far in 2026, we have had 10 cases of measles reported to New York State. So, keep in mind, it's May, so we're on pace to have a little bit more than last year.

When we get cases in New York State, our cases are generally imported from somewhere else, and they're really contained. So, what happens in New York State is, we have local health departments, we identify the case, contacts are identified. People who haven't been immunized are offered post-exposure prophylaxis if they're eligible. And we then manage this, right? So, you haven't seen measles take off in New York partly because our immunization rates are reasonable.

One of the things about New York, and I think this is just one of the important distinctions that separating New York from other states where you've seen these outbreaks. So, you've seen outbreaks in South Carolina, Utah, Texas, I mean, just... Oklahoma. You've just seen these massive outbreaks. The one thing that these states have in common is they have a religious exemption to the vaccine, and that is the key difference here. New York doesn't have a religious exemption. This was changed by the legislature and the governor years ago. And this is really one of the main things that go forward here.

When I say our immunization rates are reasonable, we still have people who are choosing not to give the vaccine, but you need it for school entry. What I see in New York a lot of times is people delaying the vaccine, which concerns me, because when you really think about who's more vulnerable for measles having a bad outcome, it's really our little ones. So, the reason why measles vaccine is given it 12 months, or 15 months is because the little ones are really vulnerable. And I think it's just important to keep in mind that the measles, mumps and rubella vaccine's been

around for, gosh, 60-plus years, and it's really the best protection people have out there.

As far as the country, I don't really want to comment on what Health and Human Services is saying. We kind of go to our own drum over here at the New York State Department of Health.

Dr. Boufford: Any other questions for the commissioner?

Dr. Rugge: I can't help myself.

Dr. Boufford: Dr. Rugge.

Dr. Rugge: I can't help but bring up the rural health transformation program and where it might go. As you said, it's a cooperative agreement between Washington and Albany.

Dr. McDonald: CMS.

Dr. Rugge: CMS. True. What's the relationship between organizations inside New York and the state government? Is that cooperative, or are they grants, or how?

Dr. McDonald: Oh, no. So, yeah. In other words, when I say cooperative agreement, that means high touch from CMS. That means weekly meetings, a lot of questions and making sure that we're doing everything they say we're doing, and we are doing everything they're supposed to be doing. And right now, CMS has been very helpful and it's going well.

When we issue money, then we have to make sure the money is spent wisely, as well. So just keep in mind, that's always true. Whether it's a grant or a cooperative agreement, if we as the New York State Department of Health give you a dollar, we need to know what you spent the dollar on. And just so you know, we're very careful about public dollars, right? And the controller audits us to make sure we're doing all this stuff right, as well.

So, if you're fortunate enough to get money through this rural health transformation program, you should expect that we are going to make sure you are accountable to spend the money wisely. That's true for every dollar we give, though. I mean, we pay very close attention to how the tax dollars are used.

Dr. Rugge: Just as a related question, there's an expectation of building collaborative relationships among different kinds of providers in rural areas. Does this mean all the rural regions and areas in the state, or there'll be a few trials?

Dr. McDonald: So really, it's a five-year program, and so all rural areas are eligible, but there's actually... One of the first parts of this I talked about was rural partnerships. So, keep in mind... And by the way, most of New York is a rural state. It's funny, I think too often people think of New York City as New York City and then everything is on 87, 90. And although that is a great part of New York, most of New York is rural. New York has 25 million trees and 20 million people. It is a rural state, right?

But one of the things about the partnership is, urban areas could partner with a rural area. You could see a scenario where in Erie County, for example, they might want to partner with somewhere, and Buffalo might want to partner with someone else. So, there's all these rural areas in New York. So, I think New York is like 46 rural counties. So, we're really quiet a rural state.

Dr. Rugge: 47.

Dr. McDonald: 47. I forgot one, right? I don't know which one I forgot, but we're a very rural state here, so I expect to be a lot of partnership with this. And I think it's... $212 million is nothing to sneeze at. And I'll tell you, one of the things I've heard so many times from just rural counties is, "Could you throw us a bone?" And I think this is great. So hopefully we'll get the language we need in the budget and we can move forward. I know Dr. Fish and his team and Karen Madden have been working feverishly in all this work. We're chomping at the bit to get going here.

Dr. Rugge: Just a fun final observation, and that is, what makes this especially important in rural areas are the Medicaid cuts, that we have to find new ways of working together, new ways of sharing experience than previously, because otherwise we can have medical deserts in big areas.

Dr. McDonald: Yeah. I'm worried about that. I mean, we are ready for what's coming, just so you know. And I'll talk more about this next time I come. But we're doing a lot of extremely intentional work to try to protect everybody as much as possible if they need Medicaid to stay on Medicaid, and we're trying to keep as many people insured as possible. HR1 was something we didn't support. We think the federal government could have handled this much better, but they didn't. But we are doing everything we can with our Office of Health Insurance Programs team and Mayor [inaudible 00:48:36] and others have just done a lot of work to get ready.

So, when we get the guidance the end of June of this year about what this work requirement's going to look like, and keep in mind, there are 14 exceptions to that, but I'll talk to you next time about how we've done this in a very detailed way. We'll have more specific details to announce then as well. But we're going to do our best to keep as many people insured as

possible. It's healthcare for people. It's stunning, this is what our federal government chose to go after, but nothing they do surprises me anymore.

Dr. Boufford: Any other questions?

Dr. Farrell: Yes. I have two, so I'm asking for others.

Dr. Boufford: Okay.

Dr. Farrell: Yes, thank you. Thank you. We're on a roll here. Dr. McDonald, the social care networks, they were slow to roll out, but we're really picking up speed and just so concerned that indeed, it's all going to end however many months in the future. Is there any thought about whether we might be able to extend or be able to continue this important work that we're doing with community-based organizations?

Dr. McDonald: So, social care networks are part of the 1115 Amendment, which does expire March 31st of 2027. CMS's posture right now is if you're going to do another 1115 amendment, it has to be budget neutral. So, we're looking at this. One of the things we have to try to figure out... You're right. And by the way, you're right that it was slow to start, but that's not a fault of the social care networks. I want to get that right up front. We have to go through contracting. They had to do stuff together. But they are making progress. So, I'm keeping track of what they're doing. But there's, the social care networks do a lot of important work. They're doing work that helps people stay out of those expensive rooms that we deliver care in. So obviously, it's important to us. We're going to see what's possible. I'm being as non-committal as I can to you because I can't promise spending money I don't have, but obviously it's important to us and I follow it closely.

Dr. Boufford: I have a couple follow-up questions to my colleagues' opening questions. First, on the issue of the Rural Transformation Initiative, is there funding for, or significant engagement for local health departments? Because it strikes me where pushing their prevention agenda issues, local health departments are in partnership with the healthcare providers, and in the rural counties, it's probably even more effective in many ways because the partnerships are more cohesive than in some of the larger urban areas.

Dr. McDonald: So, there's no specific funding that says this local health department gets this much money. It's possible, though. In other words, if local health departments partner... Because one of the things that we tried to do when we built the Rural Health Transformation Program was allow flexibility in New York, understanding that the needs of certain parts of New York aren't the same as other parts of New York. So, if the partner was going to be a local health department, then yes, that could occur. So, it's really one

of those things where this particular program for the federal government isn't designed to support local health departments, but there could be possibilities for them to get funding here.

Dr. Boufford: Could it be more explicit in the state language relative to at least inclusion, significant inclusion of local health?

Dr. McDonald: So, we're doing what we can do. I want to make sure this is really clear. We cannot do anything in this program that CMS doesn't authorize us to do, and it's a high touch program. And obviously, we're big fans of local health departments, and no one knows their needs... I mean, I've never heard a local health department say, "All good, plenty of money here." Never heard that. So, we understand that need, to be sure.

Dr. Boufford: Okay. My second question was following on Dr. Soffel's question earlier. We did have a really robust conversation about public health workforce, and as you may recall, the council each year not only fulfills our role in overseeing the prevention agenda but also selects one issue of concern that we try to work with your staff to kind of raise the profile, raise visibility. And there has been budgetary support by the governor for the healthcare workforce, personal healthcare workforce, but none really for the broader public health workforce.

And I think other than the salary issue, which Denise raises, I think one of the questions we heard yesterday was that a number of things like the Public Health Fellowship Program and others will sunset or will be expiring this summer or next fall because the money had come from the federal government. I wondered what your thoughts about department support or advocacy around the next budget cycle. This one, obviously, is done, but just some thinking about that.

Dr. McDonald: Yeah. I'll say this about the health department salaries. Government is never going to compete with the private sector. We are just not. And no one goes into public health for fame or fortune. Our salaries have improved quite a bit, though. When I think about when I started, there's been a number of pay grades in particular that have gone up quite a bit. We are not going to be competitive with the private sector for the amount of money they can offer, though. I mean, we just aren't.

Having said that, I've actually gotten quite a bit of support. If you look at state agencies, one of the things my colleagues at Division of Budget tell me is our average salary is higher than other state agencies. I think of that as more of a point of pride than anything else. But we do get people who are recruited to work for us more for mission than money, and yet, people need money to live.

Having said that, we are recruiting, you know what I mean? I don't have a lot of openings right now. I mean, when I started in '23, it was so many openings, they said, "Just hire who you want." Now I have, I think, 80 openings right now. And when we get people applying for jobs, we get a lot of resumes. So, we're recruiting. I think it's like, we could always... I'll always advocate for more funding, but one of the things I have to be conscious about is what does the budget look like for the following year?

I heard the same budget director you talk about for our years, and I don't think the out years so far look as rosy as this year did based on some of the things this federal government is doing. So, I'm approaching every tax dollar like it's got to be spent very carefully. And the governor's always been very supportive of me. She's really been a real champion of science and public health. I couldn't ask for more support. So, we'll see what happens.

Dr. Boufford: So, I think I want to go back to the non-salary question, which I think is an important one, which you addressed. I appreciate that. But some of these programs that were sort of pipeline programs to prepare are expiring.

Dr. McDonald: The Public Health Fellowship, that one has unsettled. We do have other programs though, right? In other words, we support a lot of interns from the School of Public Health in Albany, now called the College of Integrating Health Sciences. We have about $600,000 committed each year so we can hire interns who are graduate students and doctoral candidates as well. So that exists. And of course, the state has the Excelsior Fellow program, and we have several Excelsior Fellows working for us role. So, there's different paths of people to enter public health through that non-traditional route. So, I mean, I just saw a bunch of letters going out this morning for new Excelsior Fellows getting their appointments this morning. So that was exciting for me to see.

Dr. Boufford: Okay. Thanks very much. Any other questions for the commissioner? As always, thank you so much for being with us.

Dr. McDonald: My pleasure.

Dr. Boufford: And you're welcome to stay as long as you can.

Dr. McDonald: Well, I can stay right now and go upstairs. So, thanks, everybody. Have a good day.

Dr. Boufford: Thank you so much. Yeah, thanks so much. All right. The next item on the agenda is a report from the Office of Healthcare Delivery. I just acknowledged Dr. Fish is here, but my understanding is Ms. Deetz is going to be presenting on the issue of Aging and Long-term Care area.

Dr. Fish: Yes. And just to organize folks, to remind folks about our organizational structure. So, we have the Office of Healthcare Delivery, in which now the Office of Aging and Long-term Care exists, our Office of Primary Care Health Services Management. Val is Deputy Director for OALTC, Office of Aging and Long-Term Care. Mark Hennessey, to my right, you stepped away, Office of Primary Care Health Systems Management. We also have two other offices in the Office of Healthcare Delivery. The third is the Office of Health Facilities Management. So, you may recall that the state operates for veterans' homes, as well as Helen Hayes Rehabilitation Center in Haverstraw, New York. So that's the...

Dr. Boufford: That's really helpful. This is new, and I think part of my confusion anyway, so that's super helpful. Thank you.

Dr. Fish: Yeah. And then the fourth is medical provider management. We broke out separately outside of the office of Primary Care Health Systems Management. This happened a year ago, January of 2025. Our Bureau of Narcotic Enforcement and our Office of Professional Medical Conduct. And why did we do that? Because they are practitioner-facing as opposed to facility-facing. The other offices are more regulatory in function, or operational, and that office is around doctors and healthcare workers and providers. So, with that, I'm going to turn it over to Val Deetz. We have a history of alternating kinds of reports between the hospital side and the long-term care side. And so, this time falls to Val, so I appreciate her updates. So over to Val Deetz.

Ms. Deetz: Thanks, Dr. Fish. Thank you, Dr. Boufford. Good morning, everyone. I'm Val Deetz. I'm the deputy director of the Office of Aging and Long-term Care within the Office of Healthcare Delivery. A couple of updates. I know you have a written report, so I won't go straight into that, but I do want you to know that our nursing home and adult care facility surveillance program leaders have been making their rounds around the state in a non-regulatory capacity to touch base with our providers out there, find out operationally what's working, what's not working, innovations that they may be endeavoring and any concerns that they may be having, so that we can work together in a non-regulatory fashion and try to help them with either resolving issues that may have come up, expanding best practices and model innovation concepts they may have, and then replicating the best practices as well.

We also do a lot of teaching in our Center for Residential Surveillance. All of our modules are posted publicly and available to both the public and our survey staff on www.nylearnsph.com. Recently, we did a three-part foundational series on Legionella, one set for nursing homes and the other set for adult care facilities. We have additional webinars coming up on nutrition and social work, which are some of the foundational aspects of

both nursing home and adult facility care. Later on, this year, we'll be working on emergency preparedness training and webinar series, as well as bed safety, as we are starting to see a rise in the use of bed rails.

Improving efficiency and data reporting, removing from the old HERDS reporting, which was the Health Electronic Response Data System, to the new SMART platform, which is the Survey Management and Response Tool. What this does is it creates less of a burden when the providers are submitting their weekly surveys, including bed census, demographics, COVID information, across all provider types in long-term care, nursing homes, adult care facilities, licensed home care services and hospice agencies.

I'm also proud to talk a little bit, and Dr. McDonald mentioned it briefly, about our Center for Hospice and Palliative Care, which last month did a great big celebration for National Healthcare Decisions Day, in which there were a great deal of social media posts. There was a YouTube video that was shared. There was an article in the Empire Report and an educational video that was released on Medical Orders for Life Sustaining Treatment.

We are also proud to say that we have worked across our office with our health facilities management partners that oversee the veterans' homes, and we have worked to connect our veterans' homes with hospice agencies in order to provide and ensure that hospice services end of life care are available for our veterans of our facilities.

We also partnered with our adult care facility and assisted living industry partners, submitted and received approval of a state plan amendment, which effectively allows us, for the first time ever, to continue Medicaid assisted living program services and provide hospice services while that person still resides in the Medicaid assisted living program, also known as ELP. So, we're very proud of that.

Previously, ELP residents would either have to disenroll and oftentimes leave the adult care facility. Now they have the opportunity to stay. The state plan amendment was submitted in response to a need just to make sure there was no duplication of Medicaid services, and that each of the programs had clear expectations of what services were being provided by what sector.

And then last, we just finished our first phase of an educational study on health equity in the hospice space, and we look forward to reporting a little bit more on that in future FBIC meetings, but we are working with our student interns from the university at Albany in this project. I think that's it. Dr. Boufford, thank you.

Dr. Boufford: Any questions or comments from the council members?

Ms. Monroe: I have one.

Dr. Boufford: Please, Ms. Monroe.

Ms. Monroe: Thank you for that report. Just on this last study, when you're looking at health equity, are you looking at it as a staffing issue or as a patient issue? Where are you looking at whether or not the hospice program is addressing health equity?

Ms. Deetz: Yep. So, the first area that we are focused on was language and religious barriers to access. So, as soon as we... Can you hear me, Ann? Sorry.

Dr. Boufford: Only when your mic is near your mouth.

Ms. Deetz: So again, focusing on our first phase was on language and religious barriers to hospice care and access to hospice care. And as we move forward, we'll continue to provide you information on what's our next goal, and that'll be in subsequent written reports.

Ms. Monroe: So, you're looking at both staff and patients?

Ms. Deetz: Correct. Utilization, and barriers to that utilization.

Dr. Boufford: Okay. All right. Any other questions or comments? Yeah, Dr. Lim.

Dr. Lim: I actually have a question about another section of the department report, and I think it's probably for Dr. Fish, just really quickly. I was very interested to see, so there's new regulations for community paramedicine. Are those living yet, or if not, when will they be effective?

Dr. Fish: Yeah, we're still working through those and working on that, but we are excited about that. They've been in development for the development, so working through the various stages of approval, but soon.

Dr. Lim: And they won't be coming through FBIC for approval per se. Doesn’t it come through codes?

Dr. Fish: Correct.

Dr. Lim: Okay.

Dr. Fish: That's right.

Dr. Boufford: Any other questions? Okay, seeing none. I will call on myself to deliver the public health committee report, put on a different hat. We had a full day yesterday. Just a reminder to the council, the public health committee really acts on your behalf to fulfill our statutory responsibilities for oversight of the prevention agenda, which is the state health improvement plan. We're now in the fourth cycle of the prevention agenda, and it has been modified quite significantly for this cycle to address not only particular priority areas, 23, I think, exactly, which are more in the immediate purview of local health departments and the state health department, but also five domains, which were the first time the CDC has issued a sort of... Felt that there was strong enough evidence based to focus on social determinants of health, such as in the educational, economic development and other spaces. So those are both articulated as part of the new prevention agenda.

And the idea for the prevention agenda is it is led by partnerships between the local health department and the local hospitals in communities, sometimes at county level, and sometimes counties collaborate, and sometimes at local level. And the idea is for them to pull together as many partners as possible at the local level to advance the priority areas that they select for the work that they will be doing.

And so, this next cycle is to cover 2025 to 2030. Through federal law, the hospitals had to submit their community health needs assessment and service plans by the end of December of this past year. We had tried to get the cycle in sync with local health department submissions. We missed a beat, but we'll hopefully get back in order in a year or so. But the local health departments, their deadline is now July 1st. We learned yesterday that about 30, 35% of the departments did submit by the end of December in conjunction with their local healthcare delivery systems or hospitals, and the others are being encouraged to collaborate with their local hospitals and systems as they modify and finalize their own plans, which they'll be submitting in July. And so, we were pleased to learn the progress there. We do have a meeting on June 23rd, and so we'll be hearing near, almost final report on that work.

The other issues that we discussed in that meeting were the issue of community benefit reporting. The public health committee has indicated that they want to really focus on not, within the context of, if you might call it, the portfolio of the prevention agenda, the issue of community benefit, which is really the obligation, if you will, of voluntary organization of nonprofits in the state who are relieved of paying income tax, sales tax and real estate taxes in order to invest in their communities, hospitals being the largest nonprofit sector in the state and nationally, certainly get a lot of attention. And there has been new requests that the

Schedule Hs, which are submitted by the hospitals to the Internal Revenue Service, be submitted to the department and voluntary.

Well, you learned yesterday as well, thanks to Dr. Fish, he was kind enough to come and present this and discuss it, that the plan for July 1st is the due date for the submission that the voluntary hospitals will be asked to submit to your office, Doug, their Schedule Hs as they are submitting them to the federal government. There is also a separate questionnaire being created for the public hospitals who do not have an obligation to submit to IRS, to have them answer a set of questions that would articulate what they are doing in terms of community benefit.

And our interest in the public health committee is around a category of that work, which is called the community health improvement section, which is pretty much aligned with the goals of the prevention agenda. So, we have had a lot of good discussion with Dr. Fisher's office, and the plan is that we will, hopefully, maybe even by the June meeting, we'll be able to take a look at the document that the public hospitals are being asked to complete as kind of a baseline for further discussion for the next cycle, which will be due next July 27th, to really focus on the specific items that are relevant to our concerns, relative to community evidence-based investments in local health improvement aligned with the prevention agenda. So, we're happy about that prospect and we'll be busy doing that.

The other presentation we had was on the public health accreditation process. New York State was one of the first states and first large states, I think, to seek voluntary accreditation about five, six years ago. That cycle is now coming around again, and the state will be submitting for statewide certification. We had a good discussion with a number of local health departments who are also certified. Dr. Watkins' department is certified, and what that process was like and what the positives and challenges were in doing that. He was the star yesterday with everybody. He showed a picture of him with a plaque for being recognized.

But I think one of the important links here, so we will, the public health committee will be tracking that process very closely. And it sort of segues into the other report I'll give in a minute. I want to finish up the other agenda item on public health workforce. But when the original voluntary accreditation was pursued, one of the requirements is to have a public advisory committee, and that is the origin of the ad hoc committee. So, the ad hoc committee for the prevention agenda reflects that entity, which is required for voluntary accreditation. So, we had a discussion of that and what we might wish to do or need to do in terms of working with the department to prepare for that process, which I think is fall '27 through into the summer of '27, is the next sort of decision-making cycle. So, we'll be working on that.

And then, as Denise mentioned, we did have a very good discussion on the public health workforce issues. That is the one priority area, if you recall, the council had identified maternal mortality a few years ago. And we'd like to think that the work we did there really involves bringing people together, having panels, having public sessions, using our, if you will, bully pulpit to raise visibility of issues that are important.

And so, we had decided that public health workforce was one of the issues that we wanted to work on, and we had a good discussion strategically about some of the options on a call to action that we might make, that we might enable and work with the department on, including trying to think about developing an academic network of schools and programs of public health statewide there that does not exist, even though there is one for medical and nursing, medical deans and dental deans, et cetera, talking about some of the fellowship programs, internship programs, and others that need to be supported. So, we will be bringing that conversation back at our June meeting to think about what the priority action steps might be to support the department in advancing the visibility and importance of the public health workforce.

Yesterday afternoon was the first meeting of the newly revitalized ad hoc committee for the prevention agenda. And I really had a good time. It was a really, really, really interesting meeting. Thanks to Mark Waldenmaier and Liza Whalen, and their staff, Zara Ali, have done a fantastic job really, it's not an easy task to take... An ad hoc committee, to remind you, is the state level organizations of nonprofits, professional associations, advocacy groups, and they're state and regional to some degree, and sort of taking a look at who was in charge two years ago, three years ago, which was the last time it was updated, and finding out very meticulously who gets the letter, who are they asking for designees, et cetera.

So, they did a fantastic piece of work in getting that done, and we had 38 state level state and regional level organizations convened yesterday afternoon along with 14 state agencies. And Colleen advised me this morning that we had over 220 people online listening to the meeting. So, it was really, really exciting in terms of developing these partnerships.

It was an active meeting, really focusing on the sort of five social determinants areas, which are economic stability, social and community context, neighborhood and built environment, healthcare access and quality, and education access and quality. And everybody at the meeting had a chance to sit in on two of those domains. We had 30 minutes for each domain and then a report out at the end. And I have to say it was really exciting. We've had core partnerships to the prevention agenda historically with Office of Mental Health, OASIS and NYSOFA and the Department of State, and they were represented, but bringing in these

other agencies is really crucial to getting any leverage in these other, broader determinants of areas.

And so, that material will be pulled together. Thanks to staff and the department, we had facilitators at each of the tables and rapporteurs who are putting minutes together, and we'll have that report hopefully for the public health committee when they reconvene. And our plan would be to reconvene the ad hoc committee in September.

The goal of that group is to say, okay, you all are state and regional organizations. Many of you have local members, you have local divisions, you have local infrastructure. We want you to hook up with the counties or communities or cities with the local health department and hospital partnerships to sort of expand the leverage on addressing health problems in your communities. And I think folks were really quite responsive, and I think, excited to be invited really by the department to collaborate.

I have to mention one thing that was especially terrific, because one of the major social determinants of health, probably the number one, is education, and we had representation from the Department of Education and the Board of Regents, which was spectacular, and they were really, really excited to be invited. Along with other agencies that I don't want to... Economic development, transportation and others, which was great.

So, invite any of my colleagues that might want to comment. Obviously, you can tell I was enthusiastic about it. Okay, great. So, we'll move on then, and the next item is to turn it over to the established committee, Mr. Robinson.

Mr. Robinson: Thank you very much. As Dr. Boufford mentioned at the beginning of the meeting, we will be batching these applications.

Ms. Monroe: Is your mic on?

Mr. Robinson: Pardon me?

Ms. Monroe: Is your mic on?

Mr. Robinson: It is, but I need to stay close to it. Thank you, Ms. Monroe for that admonition. So, just a reminder, you can pull out, ask that we address an individual application separately, so please feel free to do that. Otherwise, I'm just going to move along. Okay. This is the first batch, which concludes only one application. Application 252188C, Rosary Hill Home, Westchester County, decertifying 13 residential healthcare facility beds, and perform renovations to modernize the facility. The department and the

committee recommend approval with conditions and contingencies, and I so move.

Dr. Boufford: Motion, Dr. Berliner, motion and second from Dr. Watkins. Any comments, questions? All in favor? Aye. Any opposed? Any abstentions? Onward, Mr. Robinson.

Mr. Robinson: Okay. On we go. These are applications for ambulatory surgery centers. Application 25226B, Access Surgical Care LLC in New York County, establish and construct a multi-specialty ambulatory surgery center at 4778 Broadway, New York, and certify lithotripsy outpatient services. The Center will specialize in cardiology, vascular surgery, facial plastic reconstructive surgery, GI, general surgery, ophthalmology, orthopedics, otolaryngology, pain management, and urology. The department and the committee recommend approval of conditions and contingencies, with an expiration of the operating certificate five years from the date of issuance.

And application 261017E, Dutchess Ambulatory Surgery Center, LLC, doing business as Dutchess Ambulatory Surgical Center in Dutchess County. This is to transfer 6.66% ownership interest from the 1315 current members to one new member. Department and committee recommend approval with the condition. I move both applications.

Dr. Boufford: I'll get a second, Dr. Berliner. Any comments, concerns, questions from the council members? Seeing none, I'll approve the voting. All in favor? Any against? Any abstentions? No. Motion passes.

Mr. Robinson: Okay. Continuing with our batching. 252184B, New Windsor Family Care LLC in Orange County, transferring 99% ownership interest from one withdrawing member to one new member and certify medical services, especially primary care. Department and committee recommend approval with a condition and a contingency.

261044E, Gamms LLC, doing business as Zelle Care Family Healthcare Network, LLC in Orange County, transferring 25% ownership interest from the three current members to one new member. Department and committee recommend approval with a condition. Application 252144E, Hospice and Palliative Care Inc. This is to merge Hospice and Palliative Care Inc and the Hospice of Chenango County, Inc, with HPCI being the surviving operating entity. Department and committee recommend approval with a condition. And I moved that batch.

Dr. Boufford: Okay. Second, Dr. Berliner. Any comments, questions from the council members? Seeing none. All in favor? Any opposed? Any abstentions? Motion passes.

Mr. Robinson: On we go. 21102E. Rockville Holdings Operating, LLC, doing business as Rockville Skilled Nursing and Rehab Center in Nassau County, establishing Rockville Holding Operating, LLC, doing business as Rockwell Skilled Nursing and Rehabilitation Center. As the new operator of Rockville Skilled Nursing and Rehabilitation Center, which is a 66-bed residential healthcare facility located at 50 Main Avenue in Rockville Center. Here, the department is recommending approval with a condition and contingencies.

Moving on, including a change of ownership, 231045E, Medford Hamlet, LLC, doing business as Medford Hamlet Home Care, transferring 66.667% ownership interest from two deceased members to two existing members and three new members. Department and committee are recommending approval with a condition.

Application 231252E, First Home Care of New York Corp, transferring 90.1% ownership interest from one withdrawing shareholder to the remaining shareholder. Department and committee recommend approval with a condition.

241067E, SNA Unified Home Care, Inc, transferring 90.1% membership of one shareholder to the remaining corporate shareholder. Department and committee recommend approval with a condition.

Application 241102E. Kyranga... Kyronaga Home Care in Manhattan Inc, doing business as Synergy Home Care, transferring 100% ownership interest to a new shareholder LLC. Department and committee recommend approval with a condition.

241125E, Novel Home Healthcare Services of New York Corporation, transferring 75.25% ownership interest from one shareholder to three current shareholders and one new shareholder. Again, department and committee recommend approval with a condition.

Application 251019E, CareLink, Inc, transferring 80.2% ownership interest from one withdrawing shareholder to the two remaining shareholders. Department and committee recommend approval with a condition.

I move the batch.

Dr. Boufford: Okay. Second, Dr. Berliner. Any questions, comments from council members? Seeing none. All in favor? Aye. All opposed. Any abstentions? Motion passes.

Mr. Robinson: Continuing on with diagnostic and treatment centers, 252207B, Roche Medical Management LLC, doing business like Roche Medical Center in Kings County. Dr. Calcutt, who is not here, declared an interest, established and constructed a new diagnostic and treatment center at 670 Flushing Avenue in Brooklyn. Department and committee recommend approval with conditions and contingencies. I moved that application.

Dr. Boufford: Second, Dr. Berliner. Any comments, questions from council members? Seeing none. All in favor? Any opposed? Any abstentions? Motion passes.

Mr. Robinson: Application 252172E, Pace at Hudson Headwaters, Inc. Interest expressed by Dr. Rugge, establish a licensed home care services agency to serve individuals enrolled in the PACE program. Department and committee recommend approval with a condition. I'm going to continue on.

Application 23239E, OLPS and FOPOCO, LLC, doing business as Our Lady of Peace Nursing Care residence in Niagara County. This is to establish OLPS and FOPOCO, LLC as the new operator of a 250-bed residential healthcare facility currently operated by our Lady of Peace, Inc at 5285 Lewiston Road in Lewiston Department, and committee recommend approval with condition and contingency. I'll note here that one member abstained from the committee vote. And I moved that batch.

Dr. Boufford: Okay. Second, Dr. Berliner. Any comments or questions for staff? Seeing none. All in favor? Aye. Any opposed? Any abstentions? Motion passes. Oh, one abstention. Mr. LaRue.

Mr. Robinson: And finally, the application we heard at the special committee meeting this morning, application 26111B, transitional living community at the Center for Discovery in Sullivan County, establish and construct a new 40 bed residential healthcare facility at 195 Lake Louise Marie Road in Rockville. The department recommended approval with conditions and contingencies, and this morning the committee did as well, and I so move.

Dr. Boufford: Okay. Second, Dr. Berliner. Any comments or questions from council members? All in favor? Aye. Opposed? Any abstentions? Seeing none, the motion passes. Thank you, Mr. Robinson.

Mr. Robinson: Thank you. And with that, I conclude the report of the establishment and project review committee.

Dr. Boufford: Thank you. Next meetings, not for '27', for '26' are at the bottom. And I would just add that the public health committee is scheduled to meet on June 23rd, which is the day before the next council meeting. And I think we will now move into executive session. Do I adjourn and move into it?

All right. I'll adjourn Public Health and Health... I'm sorry. Ms. Monroe has a question.

Ms. Monroe: This is for EPRC. At our last meeting, we had quite a contentious discussion about an applicant that was in some people's minds doing unsupported work, and would we bring them into Article 28? And I think we deferred that decision. And my question is, deferred to when?

Mr. Robinson: The department, I think, is considering that. Ms. Glock, is that you that... No?

Ms. Ngwashi: Are you talking about which? Hyphen care.

Mr. Robinson: Do you remember the application?

Ms. Ngwashi: Was it the one that was for alternatives?

Mr. Robinson: Yes.

Ms. Leonard: Okay. So, it is.

Dr. Fish: Yeah. This is Doug Fish from Department of Health. Yeah. I think you're referring to the Hype Care application, where there was conversation about outcomes and how we would know if they were successful. So, yeah, we have taken that back, given them the charge, and they will be coming back at a future meeting. I think Colleen, is it scheduled for... Do we know which meeting yet at this point? Okay.

Ms. Monroe: Okay. Thank you.

Dr. Boufford: Okay. Dr. Berliner, do you have a... Somebody else here had something. It was on the same issue, I guess. For the good of order, any other business that people would like to raise, or any other issues or questions they'd like to raise? It didn't mean to rush the adjournment. I'm seeing none. I will now adjourn the meeting of the Public Health and Health Planning Council, and we'll now move into executive session. Can I have a move into move into executive session, please? I'll move it. Seconded by Mr. Thomas, just for diversity there, Dr. Berliner. All right. And so, we'll take... Those that are not involved in the executive session would be asked to leave the room, and we will convene an executive session to discuss professional approval matters. Okay? And Hugh, you're the lead on this? Okay.

Ms. Monroe: Well, I'm going to say hi to Denise.

Mr. LaRue: Dr. Boufford.

Dr. Boufford: Sir.

Mr. LaRue: While we were waiting for the transition, just ask a question. Has the prevention committee looked at the Master Plan for Aging for where there's overlap...

SUMMARY OF EXPRESS TERMS

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by sections 572, 573, and 576 of the Public Health Law, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, as follows:

Part 19 of Title 10 is repealed and a new Subpart 58-6 is added to Title 10 as follows:

Section 58-6.1 establishes definitions used in the Subpart.

Section 58-6.2 establishes the requirements for a laboratory director certificate of qualification. These requirements are concordant with Federal requirements for a clinical laboratory director under Title 42, Section 493 of the Code of Federal Regulations.

Section 58-6.3 establishes the duties and responsibilities of a laboratory director.

Section 58-6.4 establishes the requirements for a technical director certificate of qualification. These requirements are consistent with Federal requirements for a clinical laboratory technical supervisor under Title 42, Section 493 of the Code of Federal Regulations.

Section 58-6.5 establishes the duties and responsibilities of a technical director.

Section 58-6.6 establishes criteria for the denial of a certificate of qualification.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by sections 572, 573, and 576 of the Public Health Law, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, as follows:

Part 19 of Title 10 is repealed and a new Subpart 58-6 is added to Title 10, to read as follows:

Section 58-6.1 Definitions:

(a) Acceptable Laboratory means a facility, operating lawfully, that meets the definition of a clinical laboratory or blood bank as defined in section 571 of the Public Health Law and which has a laboratory director and technical director(s) who meet or would meet the requirements of this Subpart.

(b) Accredited means having the approval (accreditation) conferred on schools, institutions, or programs by an accrediting agency or association recognized by the United States Secretary of Education and verified as such by the department.

(c) Board-certified means having completed all requirements set forth by an accrediting board acceptable to the department, including a passing score on any qualifying examination and completion of all the requirements for recertification whenever the certifying board mandates recertification, provided such requirements are determined by the department to provide the applicant with the ability to effectively discharge the

responsibilities described in this Subpart and Subpart 58-1 of this Title. The department shall make available a list of all boards that are recognized.

(d) Category means an area, field, or discipline of laboratory medicine or laboratory science in which a technical director certificate of qualification is issued. The department may issue technical director certificates of qualification in a specified subpart of a category, including but not limited to, a subcategory, technology, method, or specific procedure, based on the applicant's education, training, and experience and the applicant's ability to demonstrate that tests performed under their direction generate reliable results. The department shall make available a list of categories in which technical director certificates of qualification are issued; minimum qualifications for each category; and the corresponding categories of testing authorized by a laboratory permit.

(e) Dentist means an individual who is licensed and currently registered to practice dentistry in the jurisdiction in which they practice and is not subject to any disciplinary or non-disciplinary order by the applicable jurisdiction except as otherwise allowed by the department.

(f) Department means the New York State Department of Health.

(g) Earned Doctoral Degree means a doctor of philosophy, doctor of science, or equivalent degree as determined by the department.

(h) Experience means post-doctoral employment or voluntary participation in an acceptable laboratory where the applicant performed, supervised, or directed testing of human specimens. Teaching experience directly related to a medical technology program,

clinical laboratory sciences program, or a clinical laboratory section of a residency program may be considered acceptable experience.

(i) Laboratory Director means the individual responsible for the operation of a clinical laboratory or blood bank including the duties outlined in section 58-6.3 of this Subpart.

(j) Physician means an individual who is licensed and currently registered to practice medicine in the United States or in another jurisdiction in which they intend to act as a laboratory director or technical director and who is not subject to any disciplinary or non-disciplinary order by the applicable state or country except as otherwise allowed by the department.

(k) Post-doctoral means education or training following conference of a doctor of medicine (MD), doctor of osteopathic medicine (DO) or doctor of dental surgery (DDS), doctor of dental medicine (DMD) or earned doctoral degree.

(l) Training includes participation in a residency, fellowship, or post-doctoral position, or participation in a training course approved by a board acceptable to the department.

(m) Technical Director means the individual responsible for the technical and scientific operations of the clinical laboratory or blood bank for one or more categories of testing, including the duties outlined in section 58-6.5 of this Subpart.

Section 58-6.2 Laboratory Director Certificate of Qualification

(a) Certificate required. An individual serving as a laboratory director of a clinical laboratory or blood bank must hold a laboratory director certificate of qualification issued

after the department has determined that the applicant meets the requirements specified in this section and has demonstrated, in accordance with this section and section 58-6.3 of this Subpart, that they possesses the character, competence, training, and ability to direct the operation of a clinical laboratory or blood bank and ensure the proper supervision or performance of test procedures, adherence to the department's clinical laboratory standards, and accurate reporting of findings of tests.

(b) An applicant for a laboratory director certificate of qualification must submit a complete application in such form and manner as required by the department, provide payment of the application fee, and supply such additional information as may be required by the department. The applicant must demonstrate that board certification and laboratory management training occurred within the previous 10 years or they have served as a laboratory director in an acceptable laboratory within the previous 10 years. A laboratory director certificate of qualification is valid for two years.

(c) An individual seeking renewal of a laboratory director certificate of qualification must apply no later than 60 days prior to expiration of the current certificate in such form and manner as required by the department and provide payment of the application fee. Renewal applicants must present evidence of directorship experience within the previous 10 years to maintain certificate eligibility.

(d) To qualify for, and maintain, a laboratory director certificate of qualification, the applicant shall:

(1) be a physician who is currently certified by:

(i) the American Board of Pathology in anatomic pathology or clinical pathology, or both; or

(ii) the American Osteopathic Board of Pathology in anatomic pathology or laboratory medicine/clinical pathology, or both; or

(2) be a physician with two years of experience supervising high complexity clinical testing and have at least 20 credit hours in clinical laboratory operations training to include training in the responsibilities outlined in this section; or

(3) (i)

(*a*) hold an earned doctoral degree in a relevant biological, chemical, medical technology, clinical laboratory science, or medical laboratory science major; or

(*b*) hold an earned doctoral degree and have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology, clinical laboratory science, or medical laboratory science; or

(*c*) hold an earned doctoral degree and have an approved thesis or research project in biology, chemistry, medical technology, clinical laboratory science or medical laboratory science related to laboratory testing for the diagnosis, prevention, or treatment of any disease, or the assessment of a health condition, or for identification purposes; and

(ii) be currently certified by one of the following boards:

(*a*) American Board of Bioanalysis;

(*b*) American Board of Clinical Chemistry;

(*c*) American Board of Forensic Toxicology;

(*d*) American College of Histocompatibility and Immunogenetics, formerly the American Board of Histocompatibility and Immunogenetics;

(*e*) American Society for Clinical Pathology Board of Certification; Diplomate in Medical Laboratory Immunology;

(*f*) American Board of Medical Genetics and Genomics, formerly the American Board of Medical Genetics;

(*g*) American Board of Medical Laboratory Immunology;

(*h*) American Board of Medical Microbiology;

(*i*) National Registry of Certified Chemists; and

(iii) have at least two years of laboratory training or experience, including experience directing or supervising high complexity testing; and

(iv) have at least 20 credit hours in clinical laboratory operations to include training in the responsibilities outlined in this section; or

(4) in the categories of parentage/identity and/or forensic identity testing, hold an earned doctoral degree in a relevant science and have at least four years of laboratory training or experience including at least two years of experience directing or supervising testing.

(e) An individual holding a certificate of qualification prior to the implementation of this regulation who does not meet the qualifications in this section and is serving as the laboratory director of a facility permitted under article 5, title 5 of Public Health Law at the time the regulation becomes effective may continue to serve as the laboratory director

where currently employed until January 1, 2027. Such individuals must immediately meet the requirements in this section if they seek employment as the laboratory director of another laboratory after implementation of this regulation.

(f) An individual holding a certificate of qualification prior to the implementation of this regulation who does not meet the qualifications in this section and is not serving as a laboratory director of a facility permitted under article 5, title 5 of the Public Health Law at the time the regulation becomes effective may not renew their certificate as a laboratory director certificate of qualification.

Section 58-6.3 Laboratory director responsibilities

(a) The laboratory director shall have the training and/or experience and capability to discharge the following responsibilities:

(1) ensure standards of performance are established for all laboratory testing systems in conformance with the department's clinical laboratory standards of practice;

(2) ensure a safe laboratory environment for personnel and the public;

(3) ensure all work performed in the laboratory is monitored to ensure that medically reliable data are generated;

(4) ensure that a process is established to verify performance characteristics, including but not limited to accuracy and precision, for all test systems;

(5) ensure that a policy is established to monitor staff adherence to approved standard operating procedures;

(6) ensure that the laboratory, when applicable, is enrolled in a proficiency testing program acceptable to the department for the testing performed and that the laboratory adheres to the proficiency testing program's administrative and technical requirements as well as department standards for proficiency testing;

(7) ensure that the laboratory reviews all proficiency testing reports received and investigates and takes remedial and corrective actions when an unacceptable or unsatisfactory result is identified;

(8) ensure that the laboratory participates in monitoring and evaluating the quality and suitability of services rendered, within the context of a quality management system, regardless of where the testing is performed;

(9) ensure that a procedure for control of nonconformities is established that complies with the department's clinical laboratory standards of practice;

(10) ensure that reports of test results include pertinent information required for the interpretation of laboratory data;

(11) ensure consultation is available to the laboratory's clients regarding the significance of laboratory findings;

(12) ensure that sufficient qualified personnel are employed with documented education, training, and/or experience to supervise, perform, and report the work of the laboratory;

(13) ensure that policies and procedures are established for monitoring staff to assess competency and, whenever necessary, to provide remedial training to improve skills;

(14) ensure that a current, accurate, and complete procedure manual is available to all personnel;

(15) specify in writing the responsibilities and duties of all laboratory personnel;

(16) maintain an effective working relationship with applicable accrediting and regulatory agencies, administrative officials, and the medical community;

(17) set goals, develop, and allocate resources within the laboratory; and

(18) provide effective administrative direction of the laboratory, in conjunction with the individual(s) responsible for financial management of the laboratory, to ensure adequate resources are available to operate the laboratory in a manner consistent with all State and Federal requirements.

Section 58-6.4: Technical Director Certificate of Qualification

(a) Certificate required. An individual serving as a technical director of a permit category at a facility permitted under article 5, title 5 of the Public Health Law must hold a technical director certificate of qualification issued after the department has determined that the applicant meets the requirements specified in this section, and has demonstrated, in accordance with this section and section 58-6.5 of this Subpart, and that the applicant

possesses the character, competence, training, and ability to direct the technical and scientific operations of a clinical laboratory or blood bank.

(b) An applicant for an initial technical director certificate of qualification for one or more categories must submit a complete application in such form and manner as required by the department, provide payment of the application fee, and supply such additional information as may be required by the department. Applicants must present evidence of experience within the previous 10 years in each category for which a certificate is sought. A technical director certificate of qualification is valid for two years.

(c) An individual seeking an amendment of a technical director certificate of qualification to add one or more categories or to amend or remove a limitation to an existing category must submit a complete application in such form and manner as required by the department, provide payment of the application fee, and supply such additional information as may be required by the department. Applicants must present evidence of experience within the previous 10 years in each category sought.

(d) An individual seeking renewal of a technical director certificate of qualification must apply no later than 45 days prior to expiration of the current certificate in such form and manner as may be required by the department and provide payment of the application fee. Renewal applicants must present evidence of experience within the previous 10 years in each category sought to maintain certificate eligibility.

(e) Boards for technical director certificate of qualification acceptable to the department are:

(1) American Board of Bioanalysis:

(i) Bioanalyst Clinical Laboratory Director (ABB(BCLD))

(ii) High Complexity Laboratory Director (ABB(HCLD))

(iii) Public Health Laboratory Director (ABB(PHLD))

(iv) Andrology Laboratory Director (ABB(ALD))

(2) American Board of Clinical Chemistry:

(i) Clinical Chemistry (ABCC(CC))

(ii) Toxicological Chemistry (ABCC(TC))

(iii) Molecular Diagnostics (ABCC(MD))

(3) American Board of Dermatology:

(i) Dermatology (ABD)

(ii) Dermatopathology (ABD(DP))

(4) American Board of Forensic Toxicology (ABFT)

(5) American Board of Internal Medicine in Hematology (ABIM(Hem))

(6) American Board of Oral and Maxillofacial Pathology (ABOMP)

(7) American Board of Medical Genetics and Genomics, formerly the American Board of Medical Genetics:

(i) Clinical Biochemical Genetics (ABMGG(CBG))

(ii) Laboratory Genetics and Genomics (ABMGG(LGG))

(8) American Board of Medical Laboratory Immunology (ABMLI)

(9) American Board of Medical Microbiology (ABMM)

(10) American Board of Pathology:

(i) Anatomic Pathology (ABPath(AP))

(ii) Blood Banking and Transfusion Medicine (ABPath(BB/TM))

(iii) Clinical Pathology (ABPath(CP))

(iv) Dermatopathology (ABPath(DP))

(v) Molecular Genetic Pathology (ABPath(MGP))

(vi) Medical Microbiology (ABPath(MMB))

(11) American Osteopathic Board of Internal Medicine in Hematology (AOBIM(Hem))

(12) American Osteopathic Board of Pathology:

(i) Anatomic Pathology (AOBPath(AP))

(ii) Clinical Pathology/Laboratory Medicine or Laboratory Medicine (AOBPAth(LM))

(iii) Dermatopathology (AOBPath(DP))

(13) American Society for Clinical Pathology Board of Certification; Diplomate in Medical Laboratory Immunology (ASCP(DMLI))

(14) National Registry of Certified Chemists:

(i) Clinical (NRCC(CC))

(ii) Toxicological (NRCC(TC))

(f) Eligible applicants for a technical director certificate of qualification must be a physician or hold an earned doctoral degree from an accredited institution in a relevant chemical, biological, clinical laboratory, medical technology, or medical laboratory science. Applicants must meet the requirements for each category sought as outlined in this subdivision. In addition to any training and/or experience specified in this

subdivision, the applicant must demonstrate that relevant experience was obtained within the previous 10 years.

(1) Andrology. Eligible applicants must demonstrate two years of post-doctoral training and/or experience in andrology in an acceptable laboratory or hold board certification through ABPath(CP); AOBPath(LM) supplemented by six months of training and/or experience in andrology at an acceptable laboratory; ABB(ALD); ABB(BCLD) supplemented by six months of training and/or experience in andrology at an acceptable laboratory; ABB(HCLD) with successful completion of the ABB examination in andrology or supplemented by six months of training and/or experience in andrology at an acceptable laboratory; ABCC(CC) supplemented by one year of training and/or experience in andrology at an acceptable laboratory; or NRCC(CC) supplemented by one year of training and/or experience in andrology at an acceptable laboratory.

(2) Bacteriology, Mycobacteriology, Mycology, Parasitology and/or Virology. Eligible applicants must demonstrate two years of post-doctoral training and/or experience in an acceptable laboratory in the respective category of microbiology for which they are applying or hold board certification through ABPath(CP); AOBPath(LM); ABPath(MMB); ABMM; ABB(PHLD); ABB(BCLD); or ABB(HCLD) with successful completion of the ABB examination in Microbiology, Public Health Microbiology, and/or Molecular Diagnostics; or ASCP(DMLI).

(3) Blood Banking Collection – Comprehensive. Eligible applicants must be a physician and demonstrate two years of training and/or experience in the

collection and testing of blood, with at least one year of experience in collection and testing for the purpose of allogeneic transfusion.

(4) Blood Banking Collection – Limited. Eligible applicants must be a physician and hold board certification through ABPath (BB/TM); ABPath(CP); AOBPath(LM); ABIM(Hem) or AOBIM(Hem).

(5) Blood Lead. Eligible applicants must demonstrate at least two years of post-doctoral training and/or experience at an acceptable laboratory or hold board certification through ABCC(CC) or ABCC(TC).

(6) Blood pH and Gases, Clinical Chemistry, Endocrinology, or Fetal Defect Markers. Eligible applicants must demonstrate two years of post-doctoral training and/or experience in the respective category for which they are applying at an acceptable laboratory or be board-certified through ABPath(CP); AOBPath(LM); or ABCC(CC).

(7) Cellular Immunology. Eligible applicants must demonstrate two years of post-doctoral training and/or experience in cellular immunology in an acceptable laboratory or hold board certification through ABMLI; ASCP(DMLI); ABB(BCLD) supplemented by at least one year of post-doctoral training and/or experience in flow cytometric methods at an acceptable laboratory, or with successful completion of an ABB examination in Diagnostic Immunology and Hematology and supplemented by six months of training and/or experience in flow cytometric methods at an acceptable laboratory; ABB(HCLD) supplemented by one year of post-doctoral training and/or experience in flow cytometric methods at an acceptable laboratory, or with successful completion of an ABB

examination in Hematology and supplemented by at least six months of training and/or experience in flow cytometric methods at an acceptable laboratory; or ABCC(CC) supplemented by one year of post-doctoral training and/or experience in flow cytometric methods at an acceptable laboratory.

(8) Clinical Toxicology. Eligible applicants must demonstrate two years of post-doctoral training and/or experience in toxicology at an acceptable laboratory or hold board certification through ABPath(CP); AOBPath(LM); ABCC(TC); or ABCC(CC) with at least six months of toxicology confirmatory testing experience at an acceptable laboratory. Eligible applicants holding board certification through ABCC(CC) without six months of confirmatory testing experience may be limited to qualitative testing.

(9) Cytogenetics. Eligible applicants must demonstrate four years of post-doctoral training and/or experience in human genetics in an acceptable laboratory, at least two of which are in clinical cytogenetics.

(10) Cytopathology. Eligible applicants must be a physician and hold board certification through ABPath(AP) or AOBPath(AP).

(11) Diagnostic Immunology. Eligible applicants must demonstrate two years of post-doctoral training and/or experience in diagnostic immunology in an acceptable laboratory or hold board certification through ABPath(CP); AOBPath(LM); ABPath(MMB); ABCC(CC); ABMLI; ABMM; or ASCP(DMLI).

(12) Forensic Identity. Eligible applicants must demonstrate two years of post-doctoral training and/or experience in forensic identity testing in an acceptable laboratory.

(13) Forensic Toxicology. Eligible applicants must demonstrate at least two years of post-doctoral medico-legal toxicology training and/or experience at an acceptable laboratory or hold board certification through ABFT.

(14) Genetic Testing. Eligible applicants must demonstrate two years of post-doctoral training and/or experience in human genetic testing in an acceptable laboratory or hold board certification through ABCC(MD); AMBGG(CBG); or ABMGG(LGG).

(15) Hematology. Eligible applicants must demonstrate two years of post-doctoral training and/or experience in hematology in an acceptable laboratory or hold board certification through ABPath(CP); AOBPath(LM); ABIM(Hem) including or supplemented by 1 year of training and/or experience in hematology at an acceptable laboratory; or AOBIM(Hem) including or supplemented by one year of training and/or experience in hematology at an acceptable laboratory.

(16) Histocompatibility. Eligible applicants must demonstrate four years of post-doctoral training and/or experience in histocompatibility in an acceptable laboratory; or demonstrate two years post-doctoral training and/or experience immunology and two years post-doctoral training and/or experience in histocompatibility in an acceptable laboratory.

(17) Histopathology – General. Eligible applicants must be a physician and hold board certification through ABPath(AP) or AOBPath(AP).

(18) Histopathology – Dermatopathology. Eligible applicants must be a physician and hold board certification through ABPath(AP), ABPath(DP), AOBPath(AP), AOBPath(DP), ABD or ABD(DP).

(19) Histopathology – Oral Pathology. Eligible applicants must be a physician and hold board certification through ABPath(AP) or AOBPath(AP). Dentist applicants must hold board certification through ABOMP.

(20) Immunohematology. Eligible applicants must demonstrate two years of post-doctoral training and/or experience in immunohematology in an acceptable laboratory or hold board certification through ABPath(CP); ABPath(BB/TM); or AOBPath(LM).

(21) Oncology – Molecular and Cellular Tumor Markers. Eligible applicants must demonstrate two years of post-doctoral training and/or experience in oncology testing in an acceptable laboratory or hold dual board certification through ABPath(AP) and ABPath(MGP); dual board certification through ABPath(CP) and ABPath(MGP); ABCC(MD); or ABMGG(LGG).

(22) Parentage/Identity Testing. Eligible applicants must demonstrate two years of post-doctoral training and/or experience in parentage testing in an acceptable laboratory.

(23) Therapeutic Substance Monitoring/Quantitative Toxicology. Eligible applicants must demonstrate two years of post-doctoral training and/or experience in quantitative toxicology at an acceptable laboratory or hold board certification through ABPath(CP); AOBPath(LM); ABCC(CC); ABCC(TC).

(24) Trace Elements. Eligible applicants must demonstrate two years of post-doctoral training and/or or direct experience with methods based on analytical atomic spectrometry in an acceptable laboratory.

(25) Transfusion Services. Eligible applicants must be a physician and hold board certification through ABPath(BB/TM); ABPath(CP) supplemented by six months of training and/or experience in transfusion medicine at an acceptable blood bank; ABIM(Hem) supplemented by six months of training and/or experience in transfusion medicine at an acceptable blood bank; or AOBIM(Hem) supplemented by six months of training and/or experience in transfusion medicine at an acceptable blood bank.

(26) Transplant Monitoring. Eligible applicants must demonstrate two years of post-doctoral training and/or experience in transplant monitoring testing in an acceptable laboratory or hold board certification through ABCC(MD).

(g) An individual holding a certificate of qualification prior to the implementation of this regulation who meets the qualifications in this section and is serving as an assistant director of a clinical laboratory permitted under article 5, title 5 of the Public Health Law at the time the regulation becomes effective may continue to serve as an assistant director and must apply for a technical director certificate of qualification upon the next renewal.

(h) An individual holding a certificate of qualification prior to the implementation of this regulation who is not serving as an assistant director of a clinical laboratory permitted under article 5, title 5 of the Public Health Law at the time the regulation becomes effective must apply for a technical director certificate of qualification upon the next

renewal. If such individual seeks to serve as a technical director prior to the next certificate renewal, they may so serve.

Section 58-6.5: Technical Director Responsibilities

(a) The technical director shall have the training and/or experience and capability to discharge the following responsibilities:

(1) selecting test methodology and devices that are capable of accurate and reliable results;

(2) defining, implementing, and monitoring of the performance characteristics of all testing procedures in conformance with the department's clinical laboratory standards of practice;

(3) enrolling and ensuring participation in a proficiency testing program acceptable to the department for the testing performed;

(4) establishing of a quality program appropriate for the testing performed that monitors, evaluates, and ensures the quality and appropriateness of services rendered throughout the testing process;

(5) ensuring appropriate corrective actions are taken prior to the release of patient test results when test systems are not functioning in accordance with established performance characteristics;

(6) providing training and continuing education to laboratory staff;

(7) ensuring that competency of testing personnel is assessed by supervisor-qualified staff following, at a minimum, the procedures and frequency prescribed by the department, and providing remedial training as necessary; and

(8) selecting all reference laboratories for services not offered by the laboratory.

(b) In cytopathology, the technical director, in addition to the responsibilities in subdivision (a) of this section, must:

(1) meet the requirements in section 58-6.4(e)(10) of this Subpart;

(2) establish the workload limit for each individual examining slides;

(3) reassess the workload limit for each individual examining slides at least every six months and adjust as necessary;

(4) ensure that each individual examining gynecologic preparations participates in an Federal Health and Human Services (HHS) approved cytology proficiency testing program, and achieves a passing score; and

(5) if responsible for screening cytology slide preparations, document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.

Section 58-6.6: Denial of Certificate of Qualification

(a) In determining whether to deny an application for a **laboratory director certificate of qualification**, in whole or in part, the department shall consider the applicant's education, experience, and licensure as required in section 58-6.2 of this Subpart; the applicant's demonstrated ability to discharge the responsibilities set forth in section 58-6.3 of this Subpart; the character and competence of the applicant and the laboratory or laboratories directed; and any other factors the department considers relevant, including but not limited to the following:

(1) prior sustained charges of administrative violations of state or Federal laws, rules, and regulations related to the provision of health care services, or reimbursement for such services, against the applicant individually or any laboratory directed by the applicant;

(2) conviction of any crime, including but not limited to, any offense relating to the furnishing of, or billing for, laboratory services and medical care, services, or supplies, or which is considered an offense involving theft or fraud;

(3) false representation or omission of any material fact in making an application in any state or city of the United States for any license, permit, certificate, or registration related to a profession or business, or in making an application for a certificate of qualification or laboratory permit to New York State;

(4) submission of a laboratory permit application which conceals an ownership or controlling interest by any person who otherwise would be ineligible for a permit;

(5) failure to supply additional documentation of training and/or experience, pursuant to a written request for such documentation, in the course of applying for a laboratory director certificate of qualification;

(6) on the part of any laboratory, category, or subcategory directed by the applicant, a pattern of repetitive failures of required proficiency testing performance in one or more proficiency testing categories, excluding failure for administrative reasons such as late result submission;

(7) on the part of any laboratory, category, or subcategory directed by the applicant, a pattern of deficiencies on onsite inspection, especially in areas of quality control, quality assurance, laboratory management, and handling of regulated medical waste and radioactive materials, including refusal or inability to produce records as requested by department employees, which deficiencies are not corrected from inspection to inspection or which recur at each inspection despite written notice of violations by a state or Federal licensing or auditing agency and which jeopardize the quality of test results and resulting patient care, even if interim corrections have occurred;

(8) on the part of any laboratory, category, or subcategory directed by the applicant, performance of any laboratory procedures not authorized by the laboratory permit issued pursuant to article 5, title V of the Public Health Law; or operation or direction of a laboratory without a permit; or continuing operation or failure to notify the department after a change in director, ownership, or location has voided the permit;

(9) on the part of any laboratory, referral of specimens collected in New York State to laboratories which do not possess a New York State permit;

(10) on the part of any laboratory, knowing acceptance of specimens or requisitions for laboratory examination from, or issuance of reports to, a person or persons not authorized by law to submit such specimens or requisitions, or receive such reports;

(11) on the part of any laboratory issuance of reports on laboratory work, including both patient samples and proficiency testing, actually performed in another laboratory, without designating the fact that the examinations or procedures were performed in another laboratory; and/or testing and reporting results on unsatisfactory specimens as defined by the department, including unlabeled specimens or specimens of insufficient quantity to conduct the analyses requested;

(12) on the part of any laboratory, failure to establish and ensure that employees follow procedures for disposal or handling of specimens or infectious or radioactive medical waste, in violation of applicable state or Federal laws, rules and regulations, or in a manner which endangers the public, the laboratory's employees, or the environment;

(13) employment of unqualified or unlicensed technical personnel or an insufficient number of such personnel;

(14) failure of the applicant to be responsible for adequately supervising laboratory personnel to ensure the proper performance of all tests conducted in the laboratory; and

(15) any other factor having a direct bearing on the applicant's ability to provide or supervise the provision of high quality laboratory services, or to ensure compliance with statutory and regulatory requirements.

(b) In determining whether to deny an application for a **technical director certificate of qualification** in whole or in part, the department shall consider the applicant's education, experience, and licensure as required in section 58-6.4 of this Subpart; the applicant's demonstrated ability to discharge the responsibilities set forth in section 58-6.5 of this Subpart; the character and competence of the applicant and the laboratory or laboratories directed; and any other factors the department considers relevant, including, but not limited to:

(1) prior sustained charges of administrative violations of state or Federal laws, rules, and regulations related to the provision of health care services or reimbursement for such services, against the applicant individually;

(2) conviction of any crime, including, but not limited to, any offense relating to the furnishing of, or billing for, laboratory services and medical care, services, or supplies, or which is considered an offense involving theft or fraud;

(3) false representation or omission of any material fact in making an application in any state or city of the United States for any license, permit, certificate, or

registration related to a profession or business, or in making an application for a certificate of qualification or laboratory permit to New York State;

(4) failure to supply additional documentation of training and/or experience, pursuant to a written request for such documentation, in the course of applying for a technical director certificate of qualification;

(5) on the part of any category, or subcategory directed by the applicant, a pattern of repetitive failures of required proficiency testing performance in one or more proficiency testing categories, excluding failure for administrative reasons such as late result submission;

(6) on the part of any category, or subcategory directed by the applicant, a pattern of deficiencies on onsite inspection, that demonstrate an inability to effectively discharge the responsibilities outlined in section 58-6.5 of the Subpart, including refusal or inability to produce records as requested by department employees, which deficiencies are not corrected from inspection to inspection or which recur at each inspection despite written notice of violations by a state or Federal licensing or auditing agency and which jeopardize the quality of test results and resulting patient care, even if interim corrections have occurred;

(7) on the part of any laboratory, category, or subcategory directed by the applicant, failure to establish and ensure that employees follow procedures for disposal or handling of specimens or infectious or radioactive medical waste, in violation of applicable state or Federal laws, rules and regulations, or in a manner which endangers the public, the laboratory's employees, or the environment;

(8) any other factor having a direct bearing on the applicant's ability to provide or supervise the provision of high quality laboratory services, or to ensure compliance with statutory and regulatory requirements.

(c) If an application for a certificate of qualification is denied, the applicant shall be given written notice of the proposed denial, stating the reason or reasons for the denial. Such notice shall be sent by certified mail and shall be a final determination to be effective 30 days from the date of the notice unless a hearing is requested pursuant to subdivision (d) of this section.

(d) Subsequent to notice of the proposed denial of an application for a certificate of qualification, the applicant may request a hearing on the proposed denial by submitting a written request for a hearing to the department within 10 days of the date of the notice. Submission of a request for a hearing within 10 days shall stay any action to deny the application for a certificate of qualification, pending the department's decision following the hearing on such proposed denial.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The Department of Health's (Department) authority to prescribe the criteria for issuing a Certificate of Qualification is established in Section 573(1) of the Public Health Law (PHL). Part 19 of Title 10 of the Official Compilation of Codes, Rules, and Regulations of the State of New York (10 NYCRR) was originally adopted in 1979 to describe the standards by which the Department will evaluate whether a person possesses the character, competence, training, and ability to direct operation of a clinical laboratory located in or accepting specimens from New York State or a blood bank located in or collecting, processing, storing, or distributing blood products in New York State, as specified in Section 573(2) of the PHL. The Department proposes the repeal of Part 19 and the addition of Subpart 58-6 of Title 10 to amend the standards by which a person is evaluated for eligibility to serve as a laboratory director and/or technical director responsible for the proper operation of a clinical laboratory.

Legislative Objectives:

Section 573 of the PHL authorizes the department to establish minimum qualifications for individuals issued a certificate of qualification. This serves to ensure safety and reliability of procedures and tests performed at clinical laboratories and blood banks serving the people of New York. The proposed addition of Subpart 58-6 to Title 10 of the New York Codes, Rules and Regulations is consistent with that goal in that they set the groundwork to require oversight by a board-certified individual at all facilities

in the future, maintain New York's commitment to ensuring the highest level of category-specific technical leadership at every facility, expand the ability of qualified individuals to obtain certification, and improve access to the information contained in the legislation.

Needs and Benefits:

Section 572 of the PHL prescribes that a Certificate of Qualification be issued, authorizing an individual to act as a director of a clinical laboratory located in or accepting specimens from New York State or a blood bank located in or collecting, processing, storing, or distributing blood products in New York State. Subpart 58-6 of 10 NYCRR establishes the standards by which the Department evaluates whether an individual possesses sufficient training and/or experience to effectively direct the operation of a clinical laboratory or blood bank and the expertise to ensure accurate reporting of test findings.

Sustained approval of the Department's exemption from Centers for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvement Amendments (CLIA) is conditional on revision of State regulations to require that all laboratory directors are board-certified. Previously, applicants for a Certificate of Qualification were required to demonstrate general laboratory management experience, such as management of resources (e.g., budget allocation, staffing, etc.), implementation of a quality management system, development of standard operating procedures, etc.; and expertise in one or more category(ies) of practical laboratory testing as defined in the

Part. Certification by a board recognized by the Federal Health and Human Services (HHS) was but one pathway to obtain a Certificate of Qualification; applicants may also qualify based solely on experience. Federal CLIA regulations require that a laboratory director be a physician or earned doctoral degree holder who is certified by a board recognized by the Federal HHS; there is no experience pathway for an earned doctoral degree holder. This revision complies with Federal CLIA regulations by generating two certificates of qualification, the Laboratory Director Certificate of Qualification (LDCQ) and the Technical Director Certificate of Qualification (TDCQ). The LDCQ must be a physician or an individual holding an earned doctoral degree; who is certified by an HHS-recognized board; has at least two years of laboratory training or experience, including experience directing or supervising high complexity testing; and has at least twenty credit hours of continuing education in clinical laboratory operations, per the new CLIA regulations effective December 28, 2024. The TDCQ maintains New York's commitment to ensuring technical direction by a physician or earned doctoral degree holder with a minimum of two year of post-doctoral training and/or experience specific to the category for which they are applying.

To preserve continuity of leadership at a clinical laboratory permitted under Article 5, Title 5 of PHL at the time this proposed rule is adopted, an individual who does not meet the qualifications for an LDCQ may continue to serve as the laboratory director where currently employed until January 1, 2027. Such individuals must immediately

meet the qualifications for an LDCQ if they seek employment as the laboratory director of another laboratory after this revision goes into effect.

The certifying boards recognized in this proposed revision were expanded to include the American College of Histocompatibility and Immunogenetics (ACHI), the American Society for Clinical Pathology (ASCP) Board of Certification (BOC) Diplomate in Medical Laboratory Immunology (DMLI), the American Board of Medical Genetics and Genomics (ABMGG), additional certifications by the American Board of Bioanalysis (ABB) and the American Board of Clinical Chemistry (ABCC), and specific certifications by the National Registry of Certified Chemists (NRCC).

This proposed revision will also specify LDCQ requirements for paternity and forensic testing, which are not subject to Federal CLIA regulations.

Costs:

Costs to Regulated Parties

Applicants must pay an application fee for each type of Certificate requested, namely the Laboratory Director Certificate of qualification (LDCQ) and the Technical Director Certificate of Qualification (TDCQ). The application fee is established in section 573 of New York State Public Health Law. Legislation was recently passed that increased the application fee from $40.00, as established in 1993, to $150.00.

Costs to the Agency, State and Local Governments

This proposed rule will increase the volume of applications received and processed by the Department, as many existing Certificate of Qualification holders will now be required to apply separately for a Laboratory Director Certificate of qualification (LDCQ) and a Technical Director Certificate of Qualification (TDCQ). This will therefore increase labor costs; however, the application fee will offset the increased costs to the Department. This proposed rule will not increase costs to local governments.

Local Government Mandates:

The proposed regulations impose no new mandates on any county, city, town or village government; or school, fire or other special district.

Paperwork:

Applicants for a Certificate of Qualification must apply on forms approved by the Department. Applicants requesting both a LDCQ and a TDCQ must apply using separate forms. LDQQ applicants must also submit a curriculum vitae, and proof of physician licensure and/or earned doctoral degree, and proof of current board certification. TDCQ applicants must submit, in addition to the documents listed for a LDCQ, a third party letter of experience that includes specific details about the dates of employment/training, type of training and experience acquired, methods and techniques of test procedures used, and volume of testing personally performed, supervised, and/or directed.

Duplication:

This proposed rulemaking will create the Laboratory Director Certificate of Qualification, with the same qualifications as for the laboratory director of laboratories performing high complexity testing under Federal rules. This is necessary to ensure that the Department will continue to meet the requirements to obtain an exemption from CLIA regulations as described above.

Alternatives:

There were no significant alternatives to the current proposal to consider. The Department must make these revisions to ensure that the Department will continue to meet the requirements to obtain an exemption from CLIA regulations as described above. Loss of the CLIA exemption would result in costly duplicative State and Federal oversight for clinical laboratories residing in New York. Affected laboratories would be required to apply for approvals at both the State and Federal levels, submit to on-site inspections to both regulatory entities and pay applicable registration fees to both regulatory entities.

Federal Standards:

Title 42, Chapter IV, Subchapter G, Part 493, Subpart M, Section 493.1443 of the Federal Code of Regulations (CFR) describes the qualifications for directors of laboratories performing high complexity testing. This proposed rulemaking will create two Certificates of Qualification, the Laboratory Director Certificate of Qualification (LDCQ) and the Technical Director Certificate of Qualification (TDCQ). The LDCQ adheres

specifically to the Federal laboratory director qualifications. The requirement that an individual be a physician or earned doctoral degree holder with a minimum of two year of post-doctoral training and/or experience specific to the category for which they are applying to qualify for a TDCQ is more stringent than the qualifications for the role of technical supervisor at the Federal level.

Compliance Schedule:

The Department of Health will expect regulated parties to comply with the proposed regulation upon renewal of their existing Certificate of Qualification. Current Certificate of Qualification holders who are certified by a board recognized under Federal rules will qualify for a Laboratory Director Certificate of Qualification (LDCQ). Certificate of Qualification holders who are currently serving as the laboratory director of a facility holding a clinical laboratory permit issued by the Department, and who do not meet the requirements for a LDCQ, will be allowed to continue serving in that role until January 1, 2027. The Department expects that current Certificate of Qualification holders will qualify for a Technical Director Certificate of Qualification (TDCQ), unless the applicant fails to meet the recent experience requirements.

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STATEMENT IN LIEU OF REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

No Regulatory Flexibility Analysis is required pursuant to section 202-b(3)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendment, that it will not have an adverse impact on small businesses and local governments.

STATEMENT IN LIEU OF

RURAL AREA FLEXIBILITY ANALYSIS

A Rural Area Flexibility Analysis for these amendments is not being submitted because the amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

JOB IMPACT STATEMENT

Nature of Impact:

The proposed revisions to Part 19 and Subpart 58-6 will adversely impact job opportunities for individuals seeking employment as a clinical laboratory director who do not hold certification through a recognized accrediting board. However, the same individuals may be eligible to serve as technical directors of clinical laboratories.

Categories and Numbers Affected:

The job category affected is clinical laboratory director. There are approximately 665 clinical laboratories in New York holding or applying for a clinical laboratory permit; approximately 85 of those laboratories have named a laboratory director who would not meet the requirements set forth in these revisions.

Regions of Adverse Impact:

The proposed revisions are applicable to all regions of the State.

Minimizing Adverse Impact:

The proposed revisions to Part 19 and Subpart 58-6 will bring the State into compliance with Federal regulations for clinical laboratory directors established in Title 42 of the Code of Federal Regulations. This is necessary to ensure that the Department of Health continues to meet the requirements to maintain an exemption from the Federal requirements such that the Clinical Laboratory Evaluation Program remains the primary accrediting authority in New York for clinical laboratories. Failure to make these

revisions could result in the denial of that exemption in 2027, which would create duplicative laboratory oversight programs in New York. There is no available mechanism to minimize the anticipated adverse impact.

Self-Employment Opportunities:

Not applicable.

SUMMARY OF EXPRESS TERMS

The regulatory proposal would repeal and replace all sections within Part 16 of Title 10 of the New York Codes, Rules and Regulations (NYCRR), as described in more detail below.

Section 16.1 is updated to correct references to other agencies and persons exempted under Title 10 of the Code of Federal Regulations (CFR) Part 30.

Section 16.2 is updated to include numerous new definitions used in 10 CFR Part 30, as well as other definitions related to new technologies, updated units and clarification of terms.

Section 16.4 updates appendix references, including changing the reference from 10 NYCRR Part 16 to application sections within 10 CFR Part 30.

Section 16.5 updates responsibilities for radiation safety to include acceptance testing and annual program review requirements.

Section 16.6 makes updates to the requirements for evaluating prior occupational doses and removes provisions on planned special exposures. The term “eye dose” is replaced by “lens dose.”

Section 16.7 updates dose limits for members of the public to reflect current Title 10 CFR references and outdated language is removed or updated.

Section 16.10 is amended to update inspection schedules, add Certified Radiation Equipment Safety Officer (CRESO) program requirements, and update requirements for surveys and testing of sealed sources.

Section 16.11 is updated to reflect changes in terminology for personnel monitoring and to clarify dose limits.

Sections 16.12, 16.13 and 16.15 are all updated to reflect 10 CFR Part 30 references instead of references to 10 NYCRR Part 16, as well as to clarify the actual language and phrasing used within these sections.

Section 16.14 is updated to require recording of high patient doses from fluoroscopy and notification of referring physician and instructions to patient.

Sections 16.16 and 16.17 are updated for compatibility with 10 CFR Part 30 requirements.

Section 16.19, concerning limitations on application of radiation to humans, is updated to reflect changes in the use of radioactive materials especially therapeutic sources.

Section 16.22 is updated to remove the requirement for mammography screening programs to teach breast self-examination.

Section 16.23 is updated to require quality assurance (QA) programs for advanced modality dental and podiatry, to require radiation safety policies regarding patient fluoroscopy doses and neonatal imaging, to update specifications for modern imaging modalities, and to update breast imaging QA requirements.

Section 16.24 is updated to reflect updates to QA requirements and verification of radiation therapy treatments.

Section 16.26 is updated to incorporate by reference the current federal regulation from the U.S. Nuclear Regulatory Commission (NRC).

Sections 16.40 and16.41 are updated to reflect new fee schedules and to incorporate NYS Department of Labor (DOL) fee categories.

Section 16.50 is updated to correctly reference the New York City Department of Health and Mental Hygiene (NYC DOHMH), change registration periods to allow more flexibility, and include commercial requirements previously listed within DOL regulations.

Section 16.51 is updated to include several items in the prohibited uses of radiation equipment, and half-value layer tables were updated to be current with federal manufacturing requirements (21 CFR Part 1020) for equipment listed in sections 16.52 through 16.70 of Title 10 of the NYCRR.

Sections 16.52, 16.54 and 16.55 are updated to include specifications for hand-held units and Cone Beam Computed Tomography (CBCT) as well as updates to filtration requirements. Requirements for gonadal shielding have also been removed.

Section 16.53 is updated to include changes for handheld intra-oral radiographic equipment.

Section 16.58 is updated to include new specifications for display of air kerma and minimum source to skin distance, to be consistent with federal manufacturing requirements (21 CFR Part 1020). Language has also been added allowing for an alternative dose reduction method to be used in lieu of wearing lead equivalent garments by all persons working the fluoroscopy room.

Sections 16.60 and 16.61 are updated to reflect current technologies and therapy equipment operated at potentials over and below 60 kV.

Section 16.65 is a new section regarding CBCT quality assurance, physicist testing, and accreditation requirements.

Section 16.101, concerning licensure, is updated to incorporate references to the CFR. Although no additional requirements are being added, elements of 10 CFR Part 31 and the Appendices to Part 16 are now included herein.

Section 16.102 is updated to add a paragraph authorizing the Department to inspect a facility prior to the issuance of a license and adds a paragraph requiring an emergency plan for licensees that possess large amounts of dispersible radioactive material. This was previously codified in DOL regulations under 12 NYCRR Part 38. This section also adds conditions for consortiums to share accelerator produced isotopes.

Section 16.103, concerning licensing requirements for radioactive materials, incorporates by reference various provisions within 10 CFR Parts 30, 40, and 70 for licensing requirements. Currently these requirements are only incorporated into license conditions but not NYS regulations.

Section 16.104 adds requirements on portable gauge security, consortiums, and breakthrough limits for generators.

Section 16.109 adds reciprocity agreement provisions with other Agreement States, which were previously codified in DOL regulations within 12 NYCRR Part 38. This new section will also

allow a licensee to pay a fee to work in New York for up to 180 days each year, instead of only allowing licensees to work 30 days each year but at no charge.

Section 16.112 is updated to add requirements for increased security for certain amounts of radioactive material, as required by 10 CFR Part 37.

Sections 16.113 and 16.114 add requirements for decommissioning and financial assurance.

Section 16.123 updates medical use requirements for specific licenses for certain medical uses of byproduct materials, to be compatible with Federal regulations.

Section 16.124 is a new section that adds manufacturing requirements for licenses to manufacture or transfer certain items containing radioactive material.

Section 16.125 is a new section that adds additional requirements for the manufacture, preparation or transfer for commercial distribution of medical drugs containing radioactive material.

Section 16.126 adds a new requirement for sealed source and device registration.

Section 16.127 adds a new section governing licenses for industrial radiography as well as radiation safety requirements for industrial radiographic operations.

Section 16.128 adds a new section for well logging.

Section 16.129 adds a new section for panoramic irradiators.

Pursuant to the authority vested in the Commissioner of Health by section 7 of Part B of Chapter 58 of the Laws of 2006, Part 38 of Title 12 (Labor) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby repealed, and pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Section 225 of the Public Health Law, sections 16.0 through 16.200 of Part 16 of Title 10 (Health) of the NYCRR are hereby repealed and replaced, to be effective upon filing a Notice of Adoption in the New York State Register, to read as follows:

Part 16 - Ionizing Radiation

Section 16.0 Introductory note.

This Part applies to all radiation equipment and radioactive material within the jurisdiction of the New York State Department of Health. Sections of this Part set forth under the heading "General Provisions" (sections 16.1-16.26) contain provisions applicable to radiation equipment operators and persons in possession of radioactive materials, including general radiation protection requirements.

Sections of this Part set forth under the heading "Radiation Equipment" (sections 16.50-16.63) contain the registration provisions for radiation equipment in general, and additional radiation protection requirements applicable only to specific radiation equipment.

Sections of this Part set forth under the heading "Licensing of Radioactive Materials" (sections 16.100-16.123) contain the licensing provisions for radioactive materials, i.e., byproduct

material, source material, special nuclear material in quantities not sufficient to form a critical mass, naturally occurring radioactive materials, and accelerator-produced radioactive material. Section 16.150, "Radon testing and reporting", contains provisions applicable to firms performing radon measurements and mitigations in the State of New York.

Section 16.200, "Material incorporated by reference," provides a list of federal rules and regulations also related to the regulation of ionizing radiation.

GENERAL PROVISIONS

16.1 Applicability and inapplicability of this Part.

(a) Applicability. Except as otherwise provided in subdivision (b) of this section, this Part applies to any person who transfers, receives, possesses or uses any radiation source in this State. The types of installations to which this Part is generally applicable are described in the definition of "radiation installation" in section 16.2 of this Part.

(b) Inapplicability.

(1) This Part does not apply to any common or contract carrier operating within this State to the extent that such carrier is subject to regulation as provided for by law by the United States Department of Transportation or other agencies of the United States or agencies of the State of New York, other than the Department of Health, having jurisdiction.

(2) The licensure requirements contained in sections 16.100 through 16.110 and sections 16.120 through 16.123 of this Part shall not apply in a county, part-county or city health district having a population of more than 2,000,000 people, provided that such health district has established its

own substitute licensure requirements with respect to radiation sources located within such health district and transferred, received, possessed or used by persons other than the State and its institutions or other facilities and provided that such substitute licensure requirements are submitted to the State Department of Health prior to their effective date and are acceptable to the State Department of Health as consistent with the corresponding requirements of this Part.

(3) Persons described in 10 CFR 30.12 & 30.13, are exempt from this Part to the same extent provided for in 10 CFR 30, as revised and implemented in full on October 16, 2020.

(4) All discharges of wastes to the environment are subject to the provisions of the Environmental Conservation Law with particular reference to article 17 (water pollution control), article 19 (air pollution control) and article 27 (collection, treatment and disposal of refuse and other solid waste) thereof, and to all pertinent rules and regulations of the State Department of Environmental Conservation, including its permit requirements.

(c) Communications. Except as otherwise provided for in this Part or authorized by the department, all applications, notifications or other communications filed pursuant to this Part shall be addressed to the New York State Department of Health, Bureau of Environmental Radiation Protection, Empire State Plaza, Albany, NY 12237, by telephone (518) 402-7550, facsimile (518) 402-7554 or email to berp@health.ny.gov. Registrants and licensees authorized to operate pursuant to article 28 of the Public Health Law may comply with adverse event reporting required by this Part by electronic filing with the department via the New York Patient Occurrence and Tracking System (NYPORTS).

16.2 Definitions.

(a) As used in this Part, unless the context indicates otherwise, the terms below shall have the following meanings:

(1) “A_1” means the maximum activity of special form radioactive material permitted in a Type A package. “A_2” means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are either listed or may be derived in accordance with the procedure prescribed in 10 CFR 71 appendix A, as revised and implemented in full on November 30, 2021.

(2) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

(3) "Accelerator-produced radioactive material" means any material made radioactive by a particle accelerator.

(4) "Acceptance Test" is an evaluation of medical equipment and software to verify proper function prior to clinical use. Acceptance testing includes but is not limited to image quality, radiation dose, and radiation protection.

(5) "Accessible surface" means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

(6) "Activity" means the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

(7) “Acute” means a single radiation dose or chemical exposure event or multiple radiation dose or chemical exposure events occurring within a short time (24 hours or less).

(8) "Adult" means a legally competent individual 18 or more years of age.

(9) "Agreement State" means any state with which the United States Nuclear Regulatory Commission or the United States Atomic Energy Commission has entered into an effective agreement under section 274b of the Atomic Energy Act of 1954, as amended.

(10) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

(11) "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations:
(i) in excess of the derived air concentrations (DACs) specified in appendix B to 10 CFR 20, as revised and implemented in full on December 19, 2002, or
(ii) to such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

(12) “Air kerma” or “AK” means kerma in air (see definition of Kerma (under paragraph (99) of this subdivision.)

(13) “Air kerma rate” or “AKR” means the air kerma (see definition of Kerma (under paragraph (99) of this subdivision) per unit time.

(14) “Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

(15) “ALARA” (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this Part as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

(16) “Alert” means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

(17) "Aluminum equivalent" means the thickness of aluminum affording the same attenuation, under specified conditions, as the material in question.

(18) "Annual limit on intake" or “ALI” means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in appendix B to 10 CFR 20, as revised and implemented in full on December 19, 2002.

(19) "Annually" means either at intervals not to exceed 1 year or, once per year at about the same time each year (plus or minus 1 month).

(20) "Assigned Protection Factor” or “APF” means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly trained and fitted users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

(21) "Atmosphere-supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere and includes supplied-air respirators (SAR’s) and self-contained breathing apparatus (SCBA) units.

(22) “Authorized licensing authority” means the New York State Department of Health, the New York City Department of Health and Mental Hygiene, an Agreement State, or the United States Nuclear Regulatory Commission.

(23) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive material (which have not been technologically enhanced) including radon (except as a decay product of source or special nuclear material); and global radioactive fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include radiation from radioactive materials (source, byproduct or special nuclear material) regulated by an authorized licensing authority.

(24) "Becquerel" or “Bq” means the SI unit of activity. One becquerel is equal to one disintegration or transformation per second (s^{-1}).

(25) "Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of this Part, "radiobioassay" is an equivalent term.

(26) "Bone densitometer" means a device intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and

adjacent tissues. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(27) “Broad scope license” or “specific license of broad scope” means a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purposes. This type of license is subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee’s radiation safety committee.

(28) “Byproduct material” means:

(i) any radioactive material, except special nuclear material, yielded in, or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material;

(ii) the tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes; however, underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

(iii) any discrete source of radium-226 produced, extracted, or converted for extraction for use for a commercial, medical, or research activity;

(iv) any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction for use for a commercial, medical, or research activity;

(v) any discrete source of naturally occurring radioactive material, other than source material, that is extracted or converted after extraction for use in a commercial medical or research activity that the Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security is extracted or converted after extraction for use in a commercial, medical, or research activity.

(29) "Calendar quarter" means not less than 12 consecutive weeks or more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method used to determine calendar quarters for purposes of this Part except at the beginning of a calendar year.

(30) “Calibration” means the determination of:

(i) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or

(ii) the strength of a source of radiation relative to a standard.

(31) "C-arm fluoroscope" means a fluoroscopic x-ray system in which the image receptor and the x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship.

Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

(32) “Certified radiation equipment safety officer" or “CRESO” means an individual who meets the requirements in section 16.10(d) of this Part and who holds an unexpired certificate as a radiation equipment safety officer issued by the department.

(33) "CFR" means Code of Federal Regulations.

(34) "Class" or “lung class” or “inhalation class” means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days.

(35) "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

(36) "Collimator" or “collimating device” means a device or mechanism by which the x-ray or gamma-ray beam is restricted in size.

(37) “Commissioner" means the Commissioner of Health of the State of New York.

(38) "Committed dose equivalent" or "$H_{T,50}$" means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

(39) "Committed effective dose equivalent" or "$H_{E,50}$" is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \Sigma\ W_T\ H_{T,50}$).

(40) "Cone" means a device used to indicate beam direction and establish a minimum source-surface distance. It may or may not incorporate a collimator.

(41) "Consortium" means an association of medical use licensees and a positron-emission tomography (PET) radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a medical facility.

(42) "Constraint" or "dose constraint" means a value above which specified licensee actions are required.

(43) “Controlled area” means any area the access to which is controlled for the purpose of protecting individuals from exposure to radiation and radioactive material but shall not mean any area used as residential quarters. Controlled area is synonymous with restricted area.

(44) "Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

(45) "Curie" means a unit of activity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} disintegrations per second (2.22×10^{12} disintegrations per minute).

(46) “Dead-man switch” means a switch, button or foot pedal which terminates beam exposure when pressure is released.

(47) "Declared pregnant worker" means a person who has voluntarily informed the licensee or registrant, in writing, of their pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant worker withdraws the declaration in writing or is no longer pregnant.

(48) "Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the license.

(49) "Decommissioning plan" means a written document that includes the licensee's planned procedures and activities for decommissioning of the facility or site.

(50) "Deep dose equivalent" or "H_d" which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

(51) "Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

(52) "Department" means the New York State Department of Health and includes its duly authorized representatives, except for the reference to 10 CFR 30.12, as revised and implemented on November 30, 2021, in section 16.1 of this Part, for which Department means the U.S. Department of Energy.

(53) "Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 percent by weight of the total uranium present.

(54) "Derived air concentration" or "DAC" means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of this Part, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in table 1, column 3, of appendix B to 10 CFR 20, as revised and implemented in full on December 19, 2002.

(55) "Derived air concentration-hour" or “DAC-hour” means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may use 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

(56) “Discrete source” means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

(57) "Diagnostic type protective tube housing" means x-ray tube housing so constructed that the leakage radiation at a distance of one meter from the source does not exceed 1 millisievert (100 milliroentgens) in one hour when the tube is operated at its maximum continuous rated current for the maximum rated tube potential.

(58) "Diaphragm" means a device or mechanism by which the x-ray or gamma-ray beam is restricted in size.

(59) “Disposable respirator” means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator

are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

(60) “Distinguishable from background” means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials assessed with adequate measurement technology, survey, and statistical techniques.

(61) "Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent. For purposes of this Part, "radiation dose" is an equivalent term.

(62) “Dose area product” or “DAP” is the absorbed dose multiplied by the corresponding x-ray beam cross-sectional area. Units are expressed as $Gy \cdot cm^2$.

(63) “Dose commitment” means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.

(64) "Dose equivalent” or “H_T” means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

(65) "Dose limits" means the permissible upper bounds of radiation doses established in accordance with this Part. For purposes of this Part, "limits" is an equivalent term.

(66) "Dose monitor unit" or "DMU" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

(67) "Dosimetry processor" means a person that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

(68) "Effective dose equivalent" or "H_E" is the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum W_T H_T$).

(69) "Embryo/fetus" means a developing human organism from conception until the time of birth.

(70) "Entrance or access point" means any location through which an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

(71) “Explosive materials” means any chemical compound, mixture, or device which produces substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

(72) “Exposure” means either:

(i) being exposed to ionizing radiation or to radioactive materials; or

(ii) the quotient of dQ by dm where “dQ” is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass “dm” are completely stopped in air. The special unit of exposure is the roentgen R. One roentgen is equal to 0.000258 coulomb per kilogram of air.

(73) “Exposure rate” means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

(74) “External dose” means that portion of the dose equivalent received from any source of radiation outside the body.

(75) “Extremity” means any hand, elbow, arm below the elbow, foot, knee or leg below the knee.

(76) "Facility" means the location within one building, vehicle, or under one roof and under the same administrative control:

(i) at which the possession, use, processing or storage of radioactive material is or was authorized; or

(ii) at which one or more radiation-producing machines or radioactivity-inducing machines are installed or located. "Facility" may also mean multiple such locations at a site or part of a site.

(77) "Filter" means material placed in the useful beam to change beam quality in radiation producing equipment.

(78) "Filtering facepiece (dust mask)" means a negative pressure particulate respirator with either a filter as an integral part of the facepiece or the entire facepiece being composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

(79) "Final status survey" means the survey of the facility or site after decommissioning activities have been completed during which the determination is made by the licensee that the facility or site meets the department’s release criteria.

(80) "Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

(81) "Fit Test" means the use of a protocol to qualitatively evaluate the fit of a respirator on an individual.

(82) “Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities” means nuclear reactors, nuclear fuel reprocessing plants, uranium

enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

(83) “General License” means a license issued pursuant to the terms and conditions of sections 16.101 or 16.103 of this Part. General licenses are effective without the filing of an application with or the issuance of a licensing document by the department.

(84) “Gray” or “Gy” means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram. One gray is equal to 100 rad.

(85) “Half value layer” or “HVL” means the thickness of a specified substance which, when introduced into the path of a beam of radiation, reduces the exposure rate by one-half.

(86) “Health officer having jurisdiction” means the commissioner or the commissioner’s designee, or the public health officer of the appropriate county or part-county health department or the New York City Department of Health and Mental Hygiene, or the director of a state, regional, area or district office of public health.

(87) "Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

(88) "High radiation area" means any area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose

equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates. For purposes of this Part, rooms or areas in which diagnostic x-ray systems are used for healing arts purposes are not considered high radiation areas.

(89) "Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

(90) “Human use” as used in this Part is equivalent to “medical use”.

(91) “Image receptor” means any device which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformation. Image receptors may include but are not limited to radiographic film with or without cassette, a phosphorescent screen, a computed radiography system (CR), a direct digital radiography system (DR), or scintillation camera.

(92) “Individual” means any human being.

(93) "Individual monitoring" means the assessment of:

(i) dose equivalent:

(*a*) by the use of individual monitoring devices or

(*b*) by the use of survey data; or

(ii) committed effective dose equivalent:

(*a*) by bioassay or

(*b*) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours.

(94) "Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of this Part, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescence dosimeters (TLDs), optically stimulated luminescent dosimeters (OSLDs), pocket ionization chambers, and personal (lapel) air sampling devices.

(95) “Inherent filtration” means the filtration permanently in the useful beam: it includes the window of the x-ray tube and any permanent tube or source enclosure.

(96) “Inspection” means an official examination or observation including, but not limited to, reviews of records, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the department.

(97) “Interlock” means a mechanical, electrical or software barrier or device, arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

(98) “Internal dose” means that portion of the dose equivalent received from radioactive material taken into the body.

(99) “Kerma” means the quantity as defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dEtr by dm, where dEtr is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of material; thus K = dEtr/dm, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as "air kerma."

(100) “Kerma Area Product” or “KAP” is the air kerma multiplied by the corresponding X-ray beam cross-sectional area. Units are expressed as $Gy \cdot cm^2$.

(101) “Kilovolt” or “kV” means a unit of electrical potential equal to 1000 volts. “Kilovolt peak” or “kVp” means the crest value in kilovolts of the potential difference of a pulsating generator. When only one-half of the wave is used, the value refers to the useful half of the wave.

(102) “Lead equivalent” means the thickness of lead affording the same attenuation, under specified conditions, as an equivalent material used for the same purpose.

(103) “Leakage radiation” means all radiation coming from within the source or tube housing except the useful beam.

(104) "Lens dose equivalent" or “LDE” applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

(105) "License" means a radioactive material license issued by the department in accordance with the regulations adopted by the department. There are two types of licenses: general and specific. Unless otherwise specified, the type of license referred to in this Part will be a specific license.

(106) “Licensed material” means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by an authorized licensing authority.

(107) “Licensed Medical Physicist” or “LMP” means an individual who is authorized to practice medical physics in the appropriate subspecialty pursuant to article 166 of the Education Law. In addition, an “Authorized Medical Physicist” or “AMP” means a licensed medical physicist who meets the requirements of paragraph 16.123(b)(2) of this Part.

(108) “Licensee” means any person who is licensed by the department in accordance with this Part or who possesses any radioactive material that is subject to the licensure requirements of this Part.

(109) “Limits” has the same meaning as dose limits as defined in paragraph (65) of this subdivision.

(110) "Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

(111) “Lost or missing licensed material” means licensed material whose location is unknown by the licensee. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot by readily traced in the transportation system.

(112) “Lot Tolerance Percent Defective” means the poorest quality in an individual inspection lot that should be accepted, expressed as “percent defective.”

(113) “Medical use” means the intentional internal or external administration of ionizing radiation to human beings under the order or direction and supervision of individuals specified in section 16.19 of this Part.

(114) “Member of the public” means any individual who is not receiving an occupational dose.

(115) “Minor” means an individual less than 18 years of age.

(116) “Monitoring” means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of this Part, radiation monitoring and radiation protection monitoring are equivalent terms.

(117) “Monitor Unit” has the same meaning as Dose Monitor Unit as defined in paragraph (66) of this subdivision.

(118) “Natural radioactivity” means radioactivity of naturally occurring nuclides.

(119) “Nationally tracked source” is a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in appendix E of 10 CFR 20, as revised and implemented in full on December 19, 2002. In this context, a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

(120) "Negative pressure respirator (tight fitting) " means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

(121) “Nonstochastic effect” means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of this Part, a “deterministic effect” is an equivalent term.

(122) "NORM" means any naturally occurring radioactive material. It does not include accelerator produced, byproduct, source, or special nuclear material.

(123) “Nuclear Regulatory Commission” or “NRC” means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

(124) “Occupational dose” means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under 10 CFR 35.75, as revised and implemented on August 14, 2007, from voluntary participation in medical research programs, or as a member of the public.

(125) “Operator” means any person conducting the business or activities carried on within the radiation installation or legally possessing administrative control of a radiation source whether as owner, lessee, contractor or otherwise.

(126) “Package” means the packaging, together with its radioactive contents, as presented for transport.

(127) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and discharging the resultant particulate or

other radiation into a medium as energies usually in excess of 1 MeV. For purposes of this definition, "accelerator" is an equivalent term.

(128) “Person” means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of the State, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of the foregoing, but shall not include federal government agencies.

(129) “Personnel monitoring equipment” has the same meaning as individual monitoring devices as defined in paragraph (94) of this subdivision.

(130) "Phantom" means an object behaving in essentially the same manner as components of human anatomy, in both material and shape appropriate for the purpose, with respect to absorption or scattering of ionizing radiation.

(131) "Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

(132) "Possess" means to acquire or take responsibility for radiation sources without regard for legal ownership.

(133) "Powered air-purifying respirator” or “PAPR” means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

(134) “Professional practice" means the practice of medicine, dentistry, podiatry, osteopathy or chiropractic.

(135) “Professional practitioner” means any individual licensed or otherwise authorized under State Education Law to engage in a professional practice as defined in this section.

(136) "Pressure demand respirator" means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

(137) "Principal activity" means an activity authorized by license which is essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use, or disposal and activity incidental to decontamination or decommissioning are not principal activities.

(138) “Principal individual” means a person primarily or ultimately liable for control of radioactive materials or radiation equipment regulated under this Part.

(139) “Protective apron” means an apron made of radiation attenuating material(s), used to reduce exposure to radiation.

(140) “Protective barrier” means a barrier of radiation attenuating materials(s) used to reduce useful beam and/or stray radiation to the degree required to assure compliance with sections 16.6 and 16.7 of this Part.

(141) “Protective glove” means a glove made of radiation attenuating material(s) used to reduce radiation exposure.

(142) "Public dose" means the dose received by a member of the public from exposure to sources of radiation released by the licensee or registrant, or to any other source of radiation under the control of the licensee or registrant. Public dose does not include occupational dose, dose received from background radiation from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under 10 CFR 35.75, as revised and implemented on August 13, 2007, or equivalent, or dose from voluntary participation in medical research programs.

(143) "Qualitative fit test” or “QLFT” means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual’s response to the test agent.

(144) “Quality factor” or “Q” means the modifying factor (listed in tables 1004(b).1 and 1004(b).2 of 10 CFR 20.1004, as revised and implemented on May 21, 1991) that is used to derive a dose equivalent from an absorbed dose.

(145) "Quantitative fit test" or "QNFT" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

(146) "Quarter" has the same meaning as Calendar Quarter, as defined in paragraph (29) of this subdivision.

(147) "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray). One millirad equals 0.001 rad.

(148) "Radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of this Part, ionizing radiation is an equivalent term. Radiation, as used in this Part, does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

(149) "Radiation Area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

(150) "Radiation equipment" means any equipment or device that can emit radiation by virtue of the application thereto of high voltage.

(151) “Radiation installation” means a place, facility or mobile unit where radiation equipment in operable condition is located, used or is intended to be used or where radioactive material is transferred, received, possessed or used, including hospitals; medical, dental, chiropractic, podiatry, or veterinarian institutions, clinics or offices; industrial facilities; educational institutions; commercial, private or research laboratories performing diagnostic procedures or handling equipment or material for medical use; or any trucking, storage, messenger or delivery service establishment. Radiation installations shall also include, any place, facility or mobile unit where radiation is administered intentionally to a human. The limits of the contiguous radiation installation area shall be as designated by the operator.

(152) “Radiation safety officer” shall mean a principal individual who, under the authorization of the operator of a radiation installation, administers a radiation protection program in accordance with section 16.5 of this Part and who is qualified by training and experience in radiological health to evaluate the radiation hazards of such installation and administer such radiation protection program.

(i) For human use radiation equipment installations, the radiation safety officer (RSO) shall be:

(*a*) a professional practitioner as defined in section 16.2 of this Part, practicing within their professional practice as defined in this section; or,

(*b*) a physicist certified by the American Board of Health Physics or the American Board of Radiology in a branch of physics related to the type of radiation sources in the installation, or, an individual with equivalent training and experience as determined by the department.

(ii) For non-human use radiation equipment installations, the radiation safety officer shall be:

(*a*) a veterinarian for veterinary installations; or,

(*b*) a physicist certified by the American Board of Health Physics, the American Board of Radiology, or, an individual with equivalent training and experience as determined by the department; or,

(*c*) a researcher determined by the institution as qualified by training and experience for installations using only x-ray diffraction and fluorescence analysis equipment.

(iii) For licensed non-human use radioactive materials installations, the radiation safety officer shall be:

(*a*) an authorized user named on the radioactive materials license issued by this department; or,

(*b*) a physicist certified by the American Board of Health Physics or the American Board of Radiology in a branch of physics related to the type of use of radioactive material in the installation, or, an individual with equivalent training and experience as determined by the department; or

(*c*) an individual who, under the authorization of the operator of a radiation installation, administers a radiation protection program in accordance with section 16.5 of this Part and who is qualified by training and experience in radiological health to evaluate the radiation hazards of such installation and administer such radiation protection program.

(iv) For a license that authorizes human use, the radiation safety officer shall be

(*a*) an individual that meets the training and experience requirements in paragraph 16.123(b)(10) of this Part; and

(*b*) an individual who is also:

(*1*) an authorized user named on the radioactive materials license issued by this department or;

(*2*) a physicist certified by the American Board of Health Physics or the American Board of Radiology in a branch of physics related to the type of use of radioactive material in the installation; or

(*3*) an individual with equivalent training and experience as determined by the department.

(153) “Radiation source” means any radioactive material or any radiation equipment.

(154) “Radioactive material” means any solid, liquid, or gas that emits radiation spontaneously.

(155) “Radioactivity” means the transformation of unstable atomic nuclei by the emission of radiation.

(156) “Radiobioassay” has the same meaning as bioassay, as defined in paragraph (25) of this subdivision.

(157) "Radon" means the radioactive noble gas radon 222.

(158) “Reference man” means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

(159) “Registrant” means any person who is registered with the department or is legally obligated to register with the department pursuant to this Part.

(160) “Registration” means registration with the department in accordance with this Part.

(161) “Rem” is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem=0.01 sievert).

(162) “Research and development” means:

(i) theoretical analysis, exploration, or experimentation; or

(ii) the extension of investigative findings and theories of scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

(163) "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee’s control. This includes all radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at a site as a result of routine or accidental releases of radioactive materials at such site and previous burials at the site, even if those burials were made in accordance with the provisions of this Part.

(164) “Respiratory protective device” means an apparatus, such as a respirator, used to reduce an individual’s intake of airborne radioactive material.

(165) “Restricted area” means any area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. A restricted area does not include areas used as residential quarters. "Restricted area" as used in this Part is synonymous with "controlled area."

(166) “Roentgen” means the special unit of exposures. One roentgen R equals 2.58×10^{-4} coulombs per kilogram of air (see definition of Exposure (under paragraph (72) of this subdivision)).

(167) “Sanitary sewerage” means a system of public sewers for carrying off waste and refuse, but excluding sewage treatment facilities, septic tanks and leach fields owned or operated by the licensee or registrant.

(168) “Scattered radiation” means radiation whose direction has been altered during passage through matter. (It may have been modified also by a decrease in energy.)

(169) “Sealed source” means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

(170) "Sealed Source and Device Registry" or "SSDR" means the national registry that contains the registration certificates, maintained by the Nuclear Regulatory Commission (NRC), that summarize the radiation safety information for sealed sources and devices, and describe the licensing and use conditions appropriate for the product.

(171) "Self-contained breathing apparatus" or "SCBA" means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

(172) "Shallow dose equivalent" or "Hs", which applies to the external exposure of the skin of the whole body or the skin of an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

(173) "Shutter" means an adjustable device fixed to the radiation source housing to intercept or collimate the useful beam.

(174) "SI" means an abbreviation of the International System of Units.

(175) "Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

(176) "Site" means the area contained within the boundary of a location under the control of persons generating or storing radioactive materials.

(177) “Site area emergency” means events that may occur, are in progress or have occurred that could lead to a significant release of radioactive material and that may require a response by offsite response organizations to protect persons offsite.

(178) “Site boundary” means that line beyond which the land or property is not owned, leased, or otherwise controlled by a licensee or registrant.

(179) “Source material” means:

(i) uranium or thorium, or any combination thereof, in any physical or chemical form; or

(ii) ores that contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium, or any combination of uranium and thorium. Source material does not include special nuclear material.

(180) “Source of radiation” means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

(181) “Source-skin distance” or “source-surface distance” means the distance measured along the central ray from the center of the front surface of the source (x-ray focal spot or sealed radioactive source) to the surface of the irradiated object.

(182) “Special form radioactive material” means radioactive material which satisfies the following conditions:

(i) it is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
(ii) the piece or capsule has at least one dimension not less than 5 millimeters (0.197 inch); and
(iii) it satisfies the additional requirements specified in section 71.4, Special form radioactive material, of 10 CFR 71, as revised and implemented in full on November 30, 2021 (see section 16.200 of this Part).

(183) “Special nuclear material” means:
(i) plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or
(ii) any material artificially enriched by any of the foregoing but does not include source material.

(184) “Special nuclear material in quantities not sufficient to form a critical mass” means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: for each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all kinds of special nuclear material in combination shall not exceed 1. For

example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{\text{175 (grams contained U-235)}}{350} + \frac{\text{50 (grams U-233)}}{200} + \frac{\text{50 (grams Pu)}}{200} = 1$$

(185) "Specific License" means a license for byproduct material issued pursuant to sections 102 through 123 of this Part. A specific license also means a similar license issued by the New York City Department of Health and Mental Hygiene, the United States Nuclear Regulatory Commission or any Agreement State.

(186) “State” means the State of New York, unless the context of this Part clearly indicates that a different meaning is intended.

(187) “Stochastic effect” means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a function of dose without threshold. Hereditary effects and cancer incidences are examples of stochastic effects. For purposes of this Part, probabilistic effect is an equivalent term.

(188) “Stray radiation” means the sum of leakage and scattered radiation.

(189) "Supplied-air respirator” or “SAR” or airline respirator means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

(190) “Survey” means an evaluation of the radiological conditions and potential hazards incidental to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements or calculations of levels of radiation or concentrations of radioactive material present.

(191) “Therapeutic type protective tube housing” means:

(i) for x-ray therapy equipment not capable of operating at 500 kVp or above, an x-ray tube housing so constructed that the leakage radiation at one meter from the source does not exceed one roentgen in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential; or

(ii) for x-ray therapy equipment capable of operation at 500 kVp or above, an x-ray tube housing so constructed that leakage radiation at one meter from the source does not exceed 0.1 percent of the useful beam dose rate at one meter from the source for any of its operating conditions.

(192) "Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

(193) “Total effective dose equivalent” or “TEDE” means the sum of the effective dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

(194) “Unrestricted area” means an area, access to which is neither limited nor controlled by the licensee or registrant.

(195) “U.S. Department of Energy” means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 42 U.S.C. 5814, effective January 19, 1975) and transferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

(196) “Unrefined and unprocessed ore” means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

(197) “Use” as used in radioactive materials licenses means to employ or apply radioactive materials for the licensed purpose. It shall include instruction of, and responsibility for, technical and support staff members. It does not include training others in the techniques of use of radioactive materials for the purpose of qualifying for licensure. In licenses authorizing human use of radioactive materials “use” will also include:

(i) ordering or directing the administration of radiation of radioactive materials to humans, including the method or route of administration;
(ii) actual use of, or direction of, technologists or other paramedical personnel in the use of radioactive material;
(iii) regular review of the progress of patients receiving therapy and modification of the originally prescribed dose as warranted by the patient's reaction to radiation therapy.

(198) “Useful beam” means the radiation that passes through the source or tube-housing port and the aperture of the collimating device when the exposure switch or timer is activated.

(199) "User seal check" means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check. For purposes of this Part “fit check” is an equivalent term.

(200) "Very high radiation area" means any accessible area in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a radiation source or 1 meter from any surface that the radiation penetrates. (Note: At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts)).

(201) “Waste” means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in subparagraphs (ii), (iii), and (iv) of the definition of byproduct material set forth in this section.

(202) “Waste handling licensees” means persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive wastes.

(203) “Week” means 7 consecutive days starting on Sunday.

(204) “Weighting factor” or “W_T” for an organ or tissue means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of W_T are:

Organ or Tissue	W_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03

Bone surfaces	0.03
Remainder	0.30[1]
Whole Body	1.00[2]

[1] 0.30 results from 0.06 for each of 5 "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.

[2] For the purpose of weighting the external whole-body dose (for adding it to the internal dose), a single weighting factor, w_T=1.0, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

(205) “Whole body” means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

(206) "Worker" means an individual engaged in activities under a license or registration issued by the department and controlled by a licensee or registrant but does not include the licensee or registrant.

(207) “Working level” or “WL” means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 130,000 MeV of potential alpha particle energy. The short-lived radon daughters are, for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

(208) “Working level month” or “WLM” means an exposure to 1 working level for 170 hours. (2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.)

(209) “Year” means the period of time beginning in January used to determine compliance with the provisions of this Part. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

16.3 Granting exemptions or variations. The department may, upon either the application of any interested person or the department's own initiative, grant an exemption or variation from any requirement of this Part when the department finds that such exemption or variation will not result in an undue danger to life or property from radiation hazards.

16.4 Exemption of certain radiation sources from the requirements of this Part. A person is exempt from the requirements of this Part to the extent that such person transfers, receives, possesses, installs, operates or uses:

(a) Any of the radioactive materials~~,~~ or items containing radioactive material in accordance with the provisions in 10 CFR 30.14, 30.15, 30.18, 30.19, 30.20, 30.21(a), (b) and (d), 30.22(a), all as revised and implemented in full on October 16, 2020, and 10 CFR 40.13, as revised and implemented in full on January 14, 1961.

(b) Radiation equipment constructed so that it cannot emit radiation at a level greater than 0.005 mGy (0.5 milliroentgen) per hour, measured two inches or five centimeters from the surface, and averaged over an area of 1.55 square inches or 10 square centimeters as certified by the manufacturer of the device; provided, however, that such exemption shall not apply to the testing or servicing of such equipment during its production.

(c) Radiation equipment during its storage, shipment, retail sale or other similar use during which such equipment is not connected to a voltage source and does not emit radiation.

16.5 Responsibility for radiation safety. No person shall operate or permit the operation of a radiation installation, nor shall a person operate, transfer, receive, possess, or use or permit the operation, transfer, receipt, possession or use of any radiation source unless that person:

(a) achieves occupational doses, and doses to any member of the public, as low as is reasonably achievable (ALARA). Such effort shall include, to the extent practicable, the use of procedures and engineering controls which are based on sound radiation protection principles;

(b) develops, documents, and implements a radiation protection program commensurate with the scope and extent of the radiation activities engaged in by the radiation installation. This program shall be designed to ensure compliance with the provisions of this Part;

(c) provides a radiation safety officer as described in section 16.2 of this Part. The radiation safety officer shall be delegated authority to ensure the implementation of this radiation protection program and shall be responsible for the day-to-day conduct of the program;

(d) provides for a radiation safety committee to administer the radiation protection program in hospitals, and broad scope licensees and in accordance with section 16.123(d) of this Part. The committee shall include the facility operator or a person with the authority to act on behalf of the facility operator, and representation from departments within the facility where radiation sources are used. The committee shall approve all uses of radiation-producing equipment and radioactive materials within the facility; shall review the activities of the radiation safety officer annually; and shall review the radiation protection program at least annually. The committee or any subcommittee shall also oversee the administration of a quality assurance program, as required by subdivision (e) of this section;

(e) provides a quality assurance program for diagnostic and therapeutic uses of radiation producing equipment and radioactive materials pursuant to sections 16.23, 16.24 and other applicable sections of this Part;

(f) ensures that all personnel involved in planning for or administering radiation doses to humans, or in the use of radiation producing equipment or radioactive materials for other purposes, are supervised, and are instructed as described in subdivision (c) of section 16.13 of this Part, and are competent to safely use such radiation equipment or other radiation sources and services;

(g) ensures that radiation equipment is used only for those procedures for which it is designed;

(h) ensures that acceptance testing of all medical and chiropractic diagnostic equipment, and treatment and planning equipment for radiation therapy, and all associated software, is performed before first use of such equipment on humans by a licensed medical physicist or other individual authorized by law or regulation. Such testing will also be performed following reassembly or major upgrade; and

(i) conducts, or causes to be conducted, an annual review of the radiation protection program content and implementation.

16.6 Occupational dose limits.

(a) Occupational dose limits for adults

(1) No person shall transfer, receive, possess, or use any radiation source so as to cause any individual adult to receive an occupational dose from all sources of radiation that exceeds any of the following limits:

(i) An annual limit, which is the lesser of:

(*a*) The total effective dose equivalent being equal to 0.05 Sv (5 rem); or

(*b*) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.50 Sv (50 rem).

(ii) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities which are: [note that any reference to eye dose is equivalent to lens dose]

(*a*) A lens dose equivalent of 0.15 Sv (15 rem), and

(*b*) A shallow dose equivalent of 0.50 Sv (50 rem) to the skin of the whole body or to the skin of any extremity.

(2) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the department. The assigned deep dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow dose equivalent must be the dose averaged over the contiguous 10 square centimeters of the skin receiving the highest exposure.

(i) The deep dose equivalent, lens dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purposes of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of the individual monitoring are unavailable.

(ii) When a protective apron is worn pursuant to section 16.58 of this Part, by physicians during x-ray fluoroscopic procedures and monitoring is conducted as specified in section 16.11(b)(1) of this Part, the effective dose equivalent for external radiation may be determined for these individuals as follows:

(*a*) When only one individual monitoring device is used and it is located at the neck outside the protective apron, the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

(*b*) When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep

dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

(3) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in table 1 of appendix B to 10 CFR 20, as revised and implemented in full on December 19, 2002, and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits.

(4) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by any individual to 10 milligrams in a week. (*See* footnote 3 of appendix B to 10 CFR 20, as revised and implemented in full on December 19, 2002).

(5) The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. The licensee or registrant shall determine the occupational radiation dose received during the current year. In complying with this requirement, a licensee or registrant may accept a record of the occupational dose that the individual received during the current year, or from the individual's employer(s) for work involving radiation exposure during the past year, that discloses the nature and the amount of any occupational dose that the individual received during the current year. If the licensee or registrant is unable to obtain complete records of an individual's current accumulated occupational dose, the licensee or registrant shall assume that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure.

(b) Compliance with requirements for summation of external and internal dose.

(1) If the licensee or registrant is required to monitor pursuant to both subdivisions (a) and (d) of section 16.11 of this Part, the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to subdivisions (a) or (d) of section 16.11 of this Part, then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses by meeting one of the conditions specified in paragraph (2), and the conditions in paragraphs (3) and (4) of this subdivision. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

(2) Intake by inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit and any one of the following does not exceed unity:

(i) the sum of the fractions of the inhalation ALI for each radionuclide; or

(ii) the total number of derived air concentrations-hours (DAC-hours) for all radionuclides divided by 2,000; or

(iii) the sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, W_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10 percent of the maximum weighted value of H_{50}, that is, $W_T H_{T,50}$ per unit intake for any organ or tissue.

(3) Intake by oral ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee or registrant shall account for this intake and include it in demonstrating compliance with the limits.
(4) Intake through wounds or absorption through skin. The licensee or registrant shall evaluate and account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to this paragraph.

(c) Determination of external dose from airborne radioactive material.
(1) Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud (*See* 10 CFR 20 appendix B, footnotes 1 and 2, as revised and implemented in full on March 14, 2023).
(2) Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

(d) Determination of internal exposure.
(1) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required under section 16.11 of this Part, take any of

the following measurements as may be necessary for timely and appropriate detection and assessment of intake of radioactivity by individuals:

(i) concentrations of airborne radioactive materials in work areas; or

(ii) quantities of radionuclides in the body; or

(iii) quantities of radionuclides excreted from the body; or

(iv) combinations of these measurements.

(2) Unless respiratory protective equipment is used, as provided in section 16.26 of this Part, or the assessment of intake is based on bioassays, the licensee or registrant shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

(3) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee or registrant may:

(i) use that information to calculate the committed effective dose equivalent, and, if used, the licensee or registrant shall document that information in the individual's record; and

(ii) upon prior approval of the department, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and

(iii) separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide (*See* 10 CFR 20, appendix B, as revised and implemented in full on March 14, 2023) to the committed effective dose equivalent.

(4) If the licensee chooses to assess intakes of Class Y material using the measurements given in subparagraphs (ii) or (iii) of paragraph (1) of this subdivision, the licensee or registrant may

delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by sections 16.15(b) or 16.15(c) of this Part. This delay permits the licensee or registrant to make additional measurements basic to the assessments.

(5) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

(i) the sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from 10 CFR 20, appendix B, as revised and implemented in full on March 14, 2023, for each radionuclide in the mixture; or

(ii) the ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

(6) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

(7) When a mixture of radionuclides in air exists, a licensee may disregard certain radionuclides in the mixture if:

(i) the licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in subdivision (a) of this section and in complying with the monitoring requirements in section 16.11(d) of this Part; and

(ii) the concentration of any radionuclide disregarded is less than 10 percent of its DAC; and

(iii) the sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

(8) When determining the committed effective dose equivalent, the following information may be considered:

(i) In order to calculate the committed effective dose equivalent, the licensee or registrant may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

(ii) When the ALI (and the associated DAC) is determined by the nonstochastic organ dose limit of 0.50 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), (the stochastic ALI,) is listed in parentheses in 10 CFR 20, appendix B, table 1, as revised and implemented in full on March 14, 2023. The licensee or registrant may, as a simplifying assumption, use the stochastic ALIs to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALIs, the licensee or registrant shall also demonstrate that the limit in clause (a)(1)(i)(b) of this section is met.

(e) Occupational dose limits for minors. The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in subdivision (a) of this section.

(f) Dose equivalent to an embryo/fetus.

(1) The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant worker, does not exceed 5 mSv (0.5 rem). (*See* section 16.14(d) of this Part for recordkeeping requirements).

(2) The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant worker so as to satisfy the limit in paragraph (1) of this subdivision.

(3) The dose equivalent to an embryo/fetus shall be taken as the sum of:

(i) the deep dose equivalent to the declared pregnant worker; and

(ii) the dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant worker during the entire pregnancy period.

(4) If by the time the worker declares pregnancy to the licensee or registrant, the dose to the embryo/fetus exceeded 5 mSv (0.5 rem), the licensee or registrant shall be deemed to be in compliance with paragraph (1) of this subdivision if the additional dose equivalent to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

16.7 Radiation dose limits for individual members of the public.

(a) Dose limits for individual members of the public.

(1) Each licensee or registrant shall conduct operations so that:

(i) the dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with 10 CFR 35.75, as revised and implemented on August 13, 2007, does not exceed 0.02 mSv (0.002 rem) in any one hour; and

(ii) the total effective dose equivalent to individual members of the public from the licensed operation, or registered equipment operation, does not exceed 1 mSv (0.1 rem) in a year, exclusive of dose contribution from background radiation, from any administration the individual has received, from exposure to individuals administered radioactive material and released under

10 CFR 35.75, as revised and implemented on August 13, 2007, from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with section 16.8 of this Part.

(2) If the licensee permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

(3) Notwithstanding subparagraph (ii) of paragraph (1) of this subdivision, a licensee may permit visitors to an individual who cannot be released, in accordance with 10 CFR 35.75, as revised and implemented on August 13, 2007, to receive a radiation dose greater than 0.1 rem (1 mSv), but not exceeding 0.5 rem (5 mSv) if the authorized user, as defined in section 16.123 of this Part, has determined before the visit that it is necessary and appropriate.

(4) A licensee or license applicant may apply for prior department authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). The licensee or license applicant shall include the following information in this application:

(i) demonstration of the need for and the expected duration of operations in excess of the limit in subdivision (a) of this section;

(ii) the licensee's program to assess and control dose within the 0.5 rem (5 mSv) annual limit;

(iii) the procedures to be followed to maintain the dose as low as is reasonably achievable; and

(iv) any additional information requested by the department.

(5) The department may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

(6) If radioactive materials are released into the air or water by any person in such a manner that the radioactive materials may be reconcentrated in the environment or may be added to any other

radioactive materials released to the environment, the department may restrict the release by such person to assure that the limits set forth in this Part are not exceeded.

(b) Compliance with dose limits for individual members of the public.

(1) The licensee or registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in subdivision (a) of this section.

(2) A licensee or registrant shall maintain records of measurements and calculations used to demonstrate compliance with the annual dose limits in subdivision (a) of this section.

(3) A licensee shall show compliance with the annual dose limits in subdivision (a) of this section by:

(i) demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual dose limit; or

(ii) demonstrating that:

(*a*) the annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in 10 CFR 20, appendix B, table 2, as revised and implemented in full on March 14, 2023; and

(*b*) if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in a year.

16.8 Waste disposal. Disposal and transportation of radioactive waste shall be governed by the New York State Department of Environmental Conservation as set forth in 6 NYCRR Parts 380 and 381.

16.9 Professional practitioners and related provisions.

(a) Nothing in sections 16.6 through 16.16 of this Part shall limit any human use of radiation in diagnostic or therapeutic procedures pursuant to section 16.19 of this Part, provided that with respect to use of radioactive material on humans, such use is in accordance with a specific or general license issued under this Part, or an exemption therefrom.

(b) Each professional practitioner who administers, inserts, or implants an amount of radioactive material into a patient in such quantities that the patient cannot be released under 10 CFR35.75, as revised and implemented on August 13, 2007, shall require that the patient wear a wrist band. The wrist band shall bear the radiation symbol, the quantity and type of radioactive material administered, inserted or implanted and the date on which such quantity was measured.

(c) Radioactive cadavers.

(1) If any patient containing radioactive material, which was administered for therapeutic purposes, dies it shall be the responsibility of the physician who pronounces such patient as dead to notify immediately the physician in charge of the case or their designated representative.

(2) No person shall commence any autopsy on any cadaver that contains radioactive material in a quantity that exceeds five millicuries, which was administered for therapeutic purposes, without first having consulted with and being advised by the radiation safety officer for the licensee or, if

they are not available, the physician responsible for the administration of the radioactive material. If neither is available, their designated representative may serve.

(3) A radioactivity report on every cadaver containing more than five millicuries of radioactive material which was administered for therapeutic purposes shall be completed by the radiation safety officer or the physician responsible for the administration of the radioactive material or their designated representatives. The report must include: the name and address of the hospital; the name of the deceased; the name, address and telephone number of the next of kin; the name, address and telephone number of the funeral home to which remains will be sent; the radionuclide involved, the approximate activity on the day of the report and the physical form; the location of the radioactive materials in the body and the external rate at the body surface closest to the source; the precautions to be observed during autopsy or handling of the body by the funeral director; and the name of the person who prepared the form. This report shall accompany the body (whether autopsied or not) when it is surrendered to the funeral director. The licensee shall retain a copy of the radioactivity report for a period of three years for review by the department.

(d) Provide notification of suspected radiation related illness as required by section 16.15(f) of this Part.

16.10 Inspections, surveys, checks and tests; vacating installations; securing radiation sources.

(a) Each person who possesses any radiation source shall make, or cause to be made, the applicable surveys required under this section and such additional surveys as may be necessary for them to comply with other sections in this Part, to determine the magnitude and extent of

radiation levels and concentrations or quantities of radioactive material in areas including the subsurface, and as the department may direct in order to evaluate the extent of the radiation hazard or potential radiation hazards of the radiation levels and residual radioactivity that may be present. Each person who possesses any radioactive material not in a sealed source for which surveys are required shall provide or have available appropriate calibrated and operable instruments capable of detecting and measuring radiation and radioactive contamination. Records of surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning in accordance with this Part.

(1) Any radiation installation subject to the registration requirements of section 16.50(a) of this Part shall be inspected periodically to assure compliance with this Part and the maintenance of radiation exposures as far below the limits set forth in this Part as is reasonably achievable. Inspections shall be made at a frequency as specified in subparagraph (i) of this paragraph, The inspection shall be performed in a manner and reported in writing on a form prescribed by the department. The person who makes the inspection shall include in such report all recommendations necessary to accomplish compliance with this Part, and to reduce radiation exposure as far below the limits set forth in this Part as reasonably achievable. The inspection shall be made by the department, the New York City Department of Health and Mental Hygiene or, as the department shall direct, by the appropriate county or part-county health officer having jurisdiction or by a certified radiation equipment safety officer. Such county or part-county health officer or the New York City health commissioner shall make the inspection only under an inspection program that is certified by the department in writing as approved and in effect. They may make the inspection or have it made by a duly authorized representative approved for

such purpose by both such health officer and the department. The operator of an installation required to be inspected by a certified radiation equipment safety officer, shall be solely responsible for having all such required inspections made.

(i) The department shall establish a schedule of inspection frequencies and make this available to regulated entities and other interested parties. This schedule may be adjusted for cause or administrative purposes by the department. Initial inspections should occur within the first year of operations.

(ii) The CRESO (certified radiation equipment safety officer), or the health officer having jurisdiction, as the case may be, shall furnish the inspection report, signed by the person who made the inspection, to the operator of the installation and a copy thereof to the department in accordance with the instructions of the prescribed form.

(2) Radiation installations wherein radioactive materials are handled or installed which will have any readily accessible area in which there is reasonable expectation that a radiation level will exist in excess of two millirems in any one hour shall be surveyed during the initial operation and whenever any change is made in the installation or its use that might increase the radiation level to which a person could be exposed.

(3) Accessible areas and equipment within radiation installations wherein radioactive material not contained in a sealed source is handled or installed shall be surveyed at least once a month for radioactive contamination unless a shorter interval is specified in a license issued pursuant to this part. Radioactive contamination of surfaces shall be kept ALARA using Appendix 16-A, Table 7 of Part 16 of Title 10 (Health) of the NYCRR, or as otherwise specified on a radioactive materials license.

(4) Depleted uranium components, and each sealed or plated sources, containing radioactive material other than Hydrogen-3, with a half- life greater than 30 days and in any form other than gas, shall be tested for leakage prior to initial use and at successive intervals thereafter not to exceed six months or a longer interval as specified in the sealed source and device registry, except as noted below:

(i) That each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed three months or as specified in the sealed source and device registry.

(ii) Notwithstanding the periodic leak test required by this paragraph, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta, neutron, and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

(iii) Except for alpha sources, the periodic leak test required by this paragraph shall not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer. In the absence of the delivery of a certificate by the transferor to the transferee indicating that a test pursuant to the applicable provisions of this Part was made within six months prior to the transfer, the source shall not be used until tested for leakage.

(5) Additional requirements for leak tests:

(i) If there is reason to suspect that a sealed source may be damaged, or is leaking, such source shall be tested for leakage before further use.

(ii) The test sample shall be taken from selected accessible surfaces of the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored. For teletherapy and/or irradiator sources, the selected accessible surfaces should be those surfaces on

which one might expect contamination (if there were to be leakage) to accumulate and shall include the inner surface of the most frequently used treatment cone or beam collimating device. The test sample shall be taken with the source in the "off" position. The leak test technique shall be capable of detecting:

(*a*) the escape of radon at the rate of 37,000 Bq (0.001 microcurie) or more per 24 hours for sealed radium sources; or

(*b*) 185,000 Bq (0.005 microcurie) or more of removable radioactivity from all other sealed sources and depleted uranium shields, collimators, etc. Detection of a leak in any sealed source in excess of the sensitivity levels set forth in this paragraph shall result in immediate suspension of the use of such source until such source is decontaminated and repaired or disposed of in accordance with section 16.8 of this Part. Records of leak test results shall be kept in units of microcuries per test sample and maintained for inspection by the department.

A leaking source report shall be submitted to the department for each source found to be leaking in excess of the above sensitivity levels within five days of detection of the leak and shall describe the equipment involved, the test results and the corrective action taken. The reporting requirements are listed in section 16.15(e) of this Part.

(6) Protective devices such as interlocks, safety switches, fume hoods, filters and trapping devices for radioactive gases, shall be tested regularly and maintained in good repair and proper operating condition.

(b) Each person shall perform surveys of the area wherein radioactive material is or has been stored as necessary to demonstrate to the department that the area of the licensee’s facility meets

the criteria in section 16.113of this Part for unrestricted release. This section only applies to decommissioning of buildings and/or license termination.

(c) Each person who possesses any radiation source shall secure such source against its unauthorized removal from its place of storage or use. The following additional restrictions apply to noncontrolled areas:

(1) Radiation sources stored in a noncontrolled area shall be stored in a locked facility in the original shipping container, or a container providing equivalent radiation protection. Such a facility may be a cabinet, a safe or a room, providing the facility is locked at all times when no activities are in progress relating to the use of the radiation sources.

(2) Radiation sources in a noncontrolled area and not in storage shall be tended to under the constant surveillance and immediate control of the licensee or registrant.

(3) Security requirements for portable moisture density gauges. Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(d) Certified Radiation Equipment Safety Officer (CRESO). A certification as a radiation equipment safety officer shall be issued by the department. Eligibility for renewal of a certificate shall be based on a work record as a certified radiation equipment safety officer that is in conformance with the regulations of the department. The certificate may be revoked for cause by the department on due notice.

(1) The requirements for certification as a radiation equipment safety officer are as follows:

(i) at least 18 years of age at the time of application; and

(ii) good moral character; and

(iii) graduation from a regionally accredited college or university, or one recognized by New York State, with a bachelor's degree in physical or natural science, mathematics or engineering; or four years of satisfactory full-time paid experience in radiation protection or control; or an equivalent combination of the education and experience specified in this clause; and

(iv) successful completion, after meeting the requirements of subparagraphs (i), (ii), and (iii) of this paragraph, of an examination prescribed by the department; and

(v) at least three years of satisfactory full-time paid experience in radiation protection or control including at least one year of experience dealing with radiation equipment, with the provision that up to two years of graduate training in physical or natural science, mathematics or engineering may be substituted on a year for year basis for the required experience except for the one year of experience in radiation protection or control dealing with radiation equipment. Verification of employment, experience, and education must be provided upon department request.

(vi) Individuals must have available calibrated test equipment appropriate for the types of equipment inspected. Records of calibration must be submitted to the department as requested.

(2) The department may accept in lieu of the requirements of subparagraphs (iii) and (iv) of paragraph (1) of this subdivision a certificate in radiation protection or control issued by the American Board of Health Physics, the American Board of Radiology or the American Board of Medical Physics.

(3) A person meeting all requirements of paragraph (1) of this subdivision except the experience or experience substitute requirement of subparagraph (v) of paragraph (1) may be certified as a

radiation equipment safety officer with the restriction that they perform surveys only under the supervision of a certified radiation equipment safety officer who meets the requirements of subparagraph (v).

(4) The Radiation Safety Officer for a facility may not act as CRESO for the same facility.

(e) Instrumentation. Each person required to perform a survey by this Part shall be provided with or have available appropriate calibrated and operable instruments capable of detecting and measuring radiation.

16.11 Personnel monitoring.

(a) External radiation sources. Each licensee and registrant shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee or registrant. Each person who possesses any radiation source shall supply and require the proper use of appropriate, calibrated and operable individual monitoring devices by:

(1) adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in paragraph (1) of section 16.6(a) of this Part; and

(2) minors likely to receive, in 1 year, from radiation sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem), a lens dose equivalent in excess of 1.5 mSv (0.15 rem), or a shallow dose equivalent to the skin or to the extremities in excess of 5mSv (0.5 rem);

Minors and declared pregnant workers likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in section 16.6 of this Part; and

(3) declared pregnant worker likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem) (Note: All of the occupational doses in section 16.6 of this Part continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded); and

(4) individuals entering a high or very high radiation area, or operating fluoroscopy equipment; and

(5) as required by section 16.127 of this Part for individuals conducting industrial radiography operations (10 CFR 34.47, as revised and implemented on March 18, 2020) and as required by section 16.129 of this Part for irradiator operators (10 CFR36.55, as revised and implemented on March 18. 2020)

(b) A person supplying personnel monitoring devices to individuals as required by subdivision (a) of this section shall ensure that the individuals wear such devices as follows:

(1) An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure.

(2) An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant worker, pursuant to section 16.6(h)(1) of this Part, shall be located at the waist under any protective apron worn by the worker.

(3) An individual monitoring device used for monitoring the lens dose equivalent shall be located at the neck outside any protective apron worn by the individual, or at an unshielded location closer to the eye.

(4) An individual monitoring device used for monitoring the dose to the extremities shall be worn on the extremity likely to receive the highest exposure. The device shall be oriented to measure the highest dose to the extremity being monitored.

(c) All personnel monitoring devices, except for direct and indirect reading dosimeters and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and which are supplied pursuant to subdivision (a) of this section, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

(1) holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(2) approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximate the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(d) Intake of radioactive material. Each licensee shall perform all appropriate measurements of those specified in section 16.6(d)(1) of this Part which will enable them to determine the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(1) Adults likely to receive, in one year, an intake in excess of 10 percent of the applicable ALI(s) in 10 CFR 20, appendix B, table 1, columns 1 and 2, as revised and implemented in full on March 14, 2023.

(2) Minors likely to receive, in one year, a committed effective dose equivalent in excess of 0.50 mSv (0.05 rem).

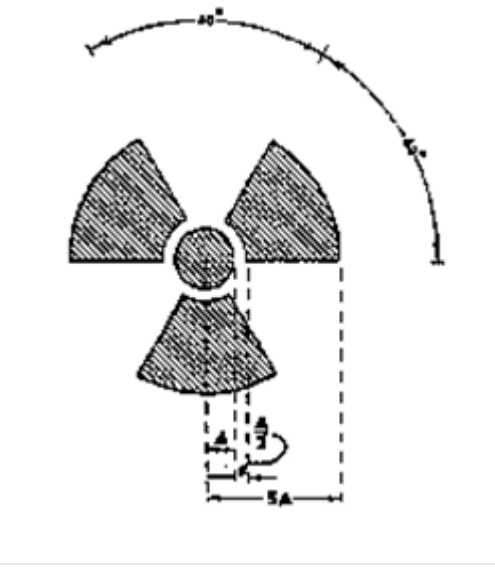
(3) Declared pregnant worker likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.50 mSv (0.05 rem).

16.12 Radiation symbol, signs, labels, and control devices.

(a) Standard radiation symbol. Unless otherwise authorized by the department, the symbol prescribed by this section shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design and shall be as illustrated below:

(1) Cross-hatched area is to be magenta, or purple, or black.

(2) The background is to be yellow.



(3) Exception to color requirements for standard radiation symbol. Notwithstanding the requirements of subdivision (a) of this section, licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

(4) Additional information on signs and labels. In addition to the contents of signs and labels prescribed in this Part, the licensee or registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

(b) (1) Posting requirements.

(i) Posting of radiation areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA".

(ii) Posting of high radiation areas. The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA".

(iii) Posting of very high radiation areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA".

(iv) Posting of airborne radioactivity areas. The licensee or registrant shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA".

(v) Posting of areas or rooms in which licensed material is used or stored. The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in 10 CFR 20, appendix C, as revised and implemented in full on March 14, 2023, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)".

(2) Exceptions to posting requirements.

(i) A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight hours, if each of the following conditions is met:

(*a*) the sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this Part; and

(*b*) the area or room is subject to the licensee's or registrant's control.

(ii) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to paragraph (1) of this subdivision provided that the patients that could be released from licensee control pursuant to section 16.123 of this Part.

(iii) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.

(iv) A room or area is not required to be posted with a caution sign because of the presence of a diagnostic x-ray system used solely for healing arts purposes.

(c) Labeling of containers and radiation equipment.

(1) The licensee or registrant shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL". The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(2) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

(3) Each registrant shall ensure that radiation equipment is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

(4) Exemptions to labeling requirements. A licensee or registrant is not required to label:

(i) containers holding licensed material in quantities less than the quantities listed in 10 CFR 20, appendix C, as revised and implemented in full on March 14, 2023; or

(ii) containers holding licensed material in concentrations less than those specified in 10 CFR 20, appendix B, table 3, as revised and implemented in full on March 14, 2023; or

(iii) containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this Part, (e.g., laboratory containers, such as beakers, flasks, and test tubes, used transiently in laboratory procedures (i.e., for a period of a few hours) in the presence of an authorized user); or

(iv) containers when they are in transport and packaged and labeled in accordance with the regulations of the United States Department of Transportation; or

(v) containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

(vi) installed manufacturing or process equipment, such as chemical process equipment, piping, and tanks.

(d) Control of access to high radiation areas.

(1) The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

(i) a control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or

(ii) a control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(iii) entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

(2) In place of the controls required by paragraph (1) of this subdivision for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(3) The licensee or registrant may use alternative methods for controlling access to high radiation areas found by the department to be effective at accomplishing such control.

(4) The licensee or registrant shall establish the controls required by paragraphs (1) and (3) of this subdivision in a way that does not prevent individuals from leaving a high radiation area.

(5) The licensee or registrant is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with section 16.17 of this Part, provided that:

(i) the packages do not remain in the area longer than 3 days; and

(ii) the dose rate at 1 meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.

(6) The licensee is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in this Part and to operate within the ALARA provisions of the licensee's or registrant's radiation protection program.

(7) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in this paragraph if the registrant has met all the specific requirements for access and control specified in other applicable sections of this Part, such as those regulating x-ray equipment in the healing arts and particle accelerators.

(e) Control of access to very high radiation areas.

(1) In addition to the requirements in paragraph (2) of this subdivision, the licensee or registrant shall institute additional measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 Gy (500 rad) or more in 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation, or to irradiators as described in subdivision (f) of this section.

(2) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in paragraph (1) of this subdivision if the registrant has met all the specific requirements for access and control specified in other applicable sections of this Part, such as those regulating radiation equipment in the healing arts or particle accelerators.

(f) Control of access to very high radiation areas -- irradiators.

(1) This subdivision applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. This subdivision does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create a radiation level of 5 Gy (500 rad) or more in 1 hour at 1 meter in an area that is accessible to any individual.

(2) Each area in which there may exist radiation levels in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

(i) Each entrance or access point shall be equipped with entry control devices which:

(*a*) function automatically to prevent any individual from inadvertently entering a very high radiation area; and

(*b*) permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below the level at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

(*c*) prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 1 mSv (0.1 rem) in 1 hour.

(ii) Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by subparagraph (2)(i) of this subdivision:

(*a*) the radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

(*b*) conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

(iii) The licensee or registrant shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

(*a*) the radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

(*b*) conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

(iv) When the shield for stored sealed sources is a liquid, the licensee or registrant shall provide means to monitor the integrity of the shield and to signal, automatically, loss of shielding to a level at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour.

(v) Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of subparagraphs (iii) and (iv) of this paragraph.

(vi) Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.

(vii) Each area shall be controlled by use of such procedures and devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

(viii) Prior to the first individual's entry into each very high radiation area after any use of the source of radiation, the area shall be checked by a radiation measurement. The area may not be used unless the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour.

(ix) The entry control devices required in subparagraph (i) of paragraph (2) of this subdivision shall have been tested for proper functioning. (*See* section 16.14(f) of this Part for recordkeeping requirements).

(*a*) Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and

(b) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

(c) The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

(x) The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

(xi) Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such procedures and devices as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and to automatically prevent loose radioactive material from being carried out of the area.

(3) Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of paragraph (2) of this subdivision which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of paragraph (2) of this subdivision, such as those for the automatic control of radiation levels, may apply to the department for approval of alternative safety measures.

Alternative safety measures shall provide personnel protection at least equivalent to those specified in paragraph (2) of this subdivision. At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

(4) The entry control devices required by paragraphs (2) and (3) of this subdivision shall be established in such a way that no individual will be prevented from leaving the area.

(g) Unnecessary use of signs and labels. Cautionary signs and labels shall not be used except as required by subdivisions (b) and (c) of this section.

16.13 Notices, instructions and reports to workers; inspections.

(a) Purpose and scope. This section establishes requirements for notices, instructions and reports by radioactive materials licensees or radiation-producing equipment registrants to individuals engaged in work under a license or registration, and options available to such individuals in connection with inspections of the activities and facilities of licensees or registrants by the department or health officer having jurisdiction to ascertain compliance with the provisions of this Part, orders and licenses issued thereunder regarding radiological working conditions.

(b) Posting of notices to workers.

(1) Each licensee or registrant shall post current copies of the following documents:

(i) the regulations of this Part;

(ii) the radioactive materials license and conditions or documents incorporated into the license by reference and amendments thereto, or the certificate of registration;

(iii) the operating procedures (including emergency procedures) applicable to work under the license or registration; and

(iv) any notice of violation involving radiological working conditions, proposed imposition of civil penalty or order issued pursuant to the provisions of the Public Health Law, and any response from the licensee or registrant.

(2) If posting of a document specified in paragraph (1) of this subdivision is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(3) A current copy of "Notice to Employees" shall be posted by each licensee or registrant wherever individuals work in or frequent any portion of a restricted area.

(4) Documents, notices or forms posted pursuant to this section shall be conspicuous, be replaced if defaced or altered, and appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from assigned work locations to which the document applies.

(5) Department documents shall be posted within two working days after receipt of the documents from the department; the licensee's or registrant's response, if any, shall be posted within two working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting violations, if any, has been completed, whichever is later.

(c) Instructions. All individuals likely to receive an occupational dose or frequenting any portion of a restricted area shall be provided instruction as specified in this subdivision. In determining those individuals subject to the requirements of this subdivision, licensees and registrants must take into consideration assigned activities during normal and abnormal

situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed and/or registered facility. The extent of these instructions must be commensurate with potential radiological health protection problems present in the workplace. Individuals described under this Part shall be:

(1) kept informed of the storage, transfer or use of radioactive material, of radiation-producing equipment or of radiation in such portions of the restricted area;

(2) instructed in the operating procedures applicable to work under the license or registration and the health protection problems associated with exposure to such radioactive material, radiation equipment, or radiation, in precautions or procedures to minimize exposure, in the purposes and functions of protective devices employed, and required to demonstrate familiarity with such precautions, procedures and devices;

(3) instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of this Part and licenses and/or registrations for the protection of personnel from exposures to radiation, radiation equipment, or radioactive material occurring in such areas;

(4) instructed of their responsibility to report promptly to the licensee or registrant any condition which may lead to or cause a violation of department regulations and license terms, or unnecessary exposure to radiation or radioactive material;

(5) instructed in the appropriate response to warnings made in the event of any unusual occurrence of malfunction that may involve exposure to radiation or radioactive material; and

(6) advised as to the radiation exposure reports which workers must be given or may request pursuant to subdivision (d) of this section.

(7) The extent of these instructions required under this subdivision shall be commensurate with the nature and level of the likely exposure and with potential radiological health problems in the

restricted area. Instruction shall be given before an individual begins work likely to result in receiving an occupational dose or before an individual begins work in a restricted area and at least annually thereafter. Records documenting individual worker instruction shall be maintained for inspection by the department for a period of three years.

(d) Notification and reports to individuals.

(1) Radiation exposure data for an individual and the results of any measurements, analyses and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this subdivision. The information reported shall include data and results as shown in records maintained by the licensee or registrant pursuant to subparagraphs (i) through (vi) of paragraph (1) of subdivision (d) of section 16.14 of this Part. Each notification and report shall be in writing and include appropriate data, such as the name of the licensee or registrant, the name of the individual, the individual's identifying information together with the individual's exposure information and contain the following statement: "This report is furnished to you under the provisions of Part 16, New York State Sanitary Code, and should be preserved for further reference."

(2) Each licensee or registrant shall advise each worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to subparagraphs (i) through (vi) of paragraph (1) of subdivision (d) of section 16.14 of this Part.

(3) At the request of a worker formerly engaged in work controlled by the licensee or the registrant, each licensee or registrant shall furnish to the worker a report of the worker's exposure to radiation or radioactive material. Such report shall:

(i) be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later;

(ii) cover, within the period of time specified in the request, each calendar year in which the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation producing equipment registered with the department;

(iii) contain the results of any dose to the embryo/fetus and include any calculations and analysis of radioactive material deposited in such individual's body, including any bioassay or other medical evaluation services of which records are required by subparagraphs (ii) through (vi) of paragraph (1) of subdivision (d) of section 16.14 of this Part; and

(iv) include the dates and locations of work under the license or registration in which the worker participated during this period.

(4) When a licensee or registrant is required pursuant to section 16.15 of this Part to report to the department any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide to the individual a report on his exposure data included therein. Such reports shall be transmitted at a time not later than the report transmittal to the department.

(5) At the request of any worker who has been engaged in a work assignment in an area restricted by a licensee or registrant for purposes of radiation protection, and who is terminating employment in such work assignment in the current year, the licensee or registrant shall provide a written report of the radiation dose received by that worker from operations of the licensee or registrant during that specifically identified current year. The report shall be provided to the worker or the worker's designee at termination, and if the final determined personnel monitoring results are not available at that time, a written estimate of that dose shall be provided in the interim. Estimated doses shall be clearly indicated as such.

(e) Inspections; presence of representatives of licensees or registrants and workers during inspection.

(1) Each licensee or applicant for a license or registrant, shall afford the department or health officer having jurisdiction during hours of operation the opportunity to inspect:

(i) the radiation source and the installation, institution, establishment, premises or facilities at which such source is located, possessed, stored or used;

(ii) each record required to be maintained by this Part.

(2) During an inspection, the licensee or registrant shall conduct, or permit the department or health officer having jurisdiction to conduct, such tests as the department or health officer may require, including but not limited to tests of:

(i) any radiation source and the installation, institution, establishment, premises or facilities at which such radiation source is located, possessed, stored or used; and

(ii) the personnel monitoring equipment referred to in section 16.11 of this Part and any other equipment, instrument or devices used in connection with the location, possession, storage or use of such radiation source.

(3) During an inspection, the department or health officer having jurisdiction may consult privately with workers as specified in subdivision (f) of this section. The licensee or registrant may accompany department inspectors or health officer having jurisdiction during other phases of an inspection.

(4) If, at the time of inspection, an individual has been authorized by the workers to represent them during inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the worker's representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(5) Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in subdivision (c) of this section.

(6) Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(7) With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant--for example, a consultant to the licensee or registrant or to the workers' representative--shall be afforded the opportunity to accompany inspectors during the inspection of physical working conditions.

(8) Notwithstanding the other provisions of this section, inspectors are authorized to refuse accompaniment by any individual who deliberately interferes with a fair and orderly inspection. Such determination shall be made at the sole discretion of the inspector and shall not be subject to administrative review. With regard to any area containing proprietary information or radioactive materials in quantities of concern, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

(f) Consultation with workers during inspections.

(1) Inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of department regulations, registrations and licenses to the extent the inspectors deem such consultation necessary for the conduct of an effective and thorough inspection.

(2) During the course of an inspection any worker may privately bring to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason

to believe may have contributed to or caused any violations of this Part, or license condition, or an unnecessary exposure of an individual to radiation from licensed radioactive material or registered radiation equipment under the licensee's or registrant's control. Any such notices in writing shall comply with the requirements of paragraph (1) of subdivision (g) of this section.

(3) The provisions of paragraph (2) of this subdivision shall not be interpreted as authorization to disregard instructions provided pursuant to subdivision (c) of this section.

(g) Requests by workers for inspections.

(1) Any worker or representative of workers who believes that a violation of this Part or of license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the department. Any such notice shall:

(i) be in writing;

(ii) set forth the specific grounds for the notice; and

(iii) be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the department no later than at the time of inspection, except that, upon the request of the worker giving such notice, their name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the department, except for good cause shown.

(2) If, upon receipt of such notice, the department determines that the complaint meets the requirements set forth in paragraph (1) of this subdivision and that there are reasonable grounds to believe that the alleged violation exists or has occurred, the licensee or registrant shall afford the department or health officer having jurisdiction, during routine hours of operation or at other

reasonable times, opportunity to conduct an inspection. Inspection pursuant to this section need not be limited to matters referred to in the complaint or allegation.

(3) No licensee or registrant shall discharge, or in any manner discriminate against, any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under this Part or has testified or is about to testify in any such proceeding, or because of the exercise by such worker on behalf of themself or others of any option afforded by this Part.

(h) Inspections not warranted; informal review.

(1) If the department determines, with respect to a complaint under subdivision (g) of this section, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the department shall notify the complainant in writing of such determination. The complainant may obtain an informal review of such a determination by submitting a written statement of position with the department, which will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the department, which will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the department may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written or oral views presented, the department shall affirm, modify or reverse the initial determination of

the department and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefore.

(2) If the department determines that an inspection is not warranted because the requirements of paragraph (1) of subdivision (g) of this section have not been met, it shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of paragraph (1) of subdivision (g) of this section.

(i) Each person who possesses any radiation source shall, when necessary or desirable in order to aid in determining the extent of any individual's occupational exposure to a radiation source, comply with orders from the department directing such person to make available to such individual bioassay services or other appropriate medical evaluations and to furnish to the department and the health officer having jurisdiction a copy of the reports of such services.

16.14 Records

(a) General provisions.

(1) Each licensee or registrant shall use the SI units: becquerel, gray, sievert and coulomb per kilogram, or the special units: curie, rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this Part, with the exception that information on shipment manifests as required by 10 CFR20.2006(b), as revised and implemented on October 1, 2007, shall be recorded in the SI units.

(2) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this Part, such as, total effective dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

(3) Form of records. Each record required by this Part shall be legible throughout the specified retention period. The record shall either be the original or the record may be stored as electronic media with the capability for producing retrievable, legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications shall include pertinent information, such as stamps, initials, and signatures.

(4) The discontinuance of or curtailment of activities does not relieve any person who possesses any radiation source of responsibility for retaining all records required by this Part.

(b) Records of radiation protection programs. Unless otherwise specified in license conditions or regulation, records shall be maintained for a minimum of three years.

(1) Each licensee or registrant shall maintain records of the radiation protection program, including:

(i) the provisions of the program; and

(ii) audits and other reviews of program content and implementation.

(2) The licensee or registrant shall retain the records required by subparagraph (i) of paragraph (1) of subdivision (b) of this section until the department terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by subparagraph (ii) of paragraph (1) of subdivision (b) of this section for three years after the record is made.

(3) The licensee or registrant shall maintain safeguards sufficient to prevent tampering with and loss of records and shall have adequate procedures or systems in place to ensure the security and integrity of all data and records, and shall have plans to recover from events of data tampering and ensure continuity of care.

(c) Records of surveys.

(1) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by sections 16.10(a) and 16.16(b) and (c) of this Part. The licensee or registrant shall retain these records for three years after the record is made.

(2) The licensee or registrant shall retain each of the following records until the department authorizes the disposition of these records:

(i) records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

(ii) records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

(iii) records showing the results of air sampling, surveys, and bioassays required pursuant to section 16.26(c)(1)(iii)(a) and (b) of this Part; and

(iv) records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

(3) Upon termination of the license or registration, the licensee or registrant shall ensure that all occupationally monitored employees are provided their most recent and final exposure reports.

(4) Records of tests for leakage or contamination of sealed sources. Records of tests for leakage or contamination of sealed sources required by section 16.10(a)(4) of this Part shall be kept in units of becquerel or microcuries and maintained for inspection by the department.

(d) Records of individual monitoring results.

(1) Recordkeeping requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to section 16.11 of this Part, and records of doses received during accidents and emergency conditions. Assessments of

dose equivalent and records made using units in effect before the effective date of this Part need not be changed. These records shall include, when applicable:

(i) the deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and

(ii) the estimated intake or body burden of radionuclides, see section 16.6(b) of this Part; and

(iii) the committed effective dose equivalent assigned to the intake or body burden of radionuclides; and

(iv) the specific information used to assess the committed effective dose equivalent pursuant to section 16.6(d) of this Part; and

(v) the total effective dose equivalent when required by section 16.6(b) of this Part; and

(vi) the total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

(2) Recordkeeping frequency. The licensee or registrant shall make entries of the records specified in this subdivision at least annually.

(3) Recordkeeping format. The licensee or registrant shall maintain the records specified in this subdivision on US NRC's "Occupational Radiation Exposure Record for a Monitoring Period", or in clear and legible records containing all the information required by such form.

(4) The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant worker. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

(5) The licensee or registrant shall retain each required form or record until disposition is authorized by the department.

(6) Upon termination of the license or registration, the licensee or registrant shall provide dosimetry records and/or bioassay data to the individuals who are currently monitored.

(e) Records of dose to individual members of the public:

(1) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. (*See* section 16.7(a) of this Part).

(2) The licensee or registrant shall retain the records required by this subdivision until disposition is authorized by the department.

(f) Records of testing entry control devices for very high radiation areas.

(1) Each licensee or registrant shall maintain records of tests made pursuant to section 16.12(f)(2)(ix) of this Part on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

(2) The licensee or registrant shall retain the records required by this subdivision for three years after the record is made.

(g) Records of transfer, or receipt of radioactive materials.

(1) Each licensee shall maintain accurate and complete written records for each transfer or receipt of radioactive materials including radioactive waste.

(i) The licensee shall retain each record of receipt of radioactive material as long as the material is possessed and for three years or as directed by the department, following transfer or disposal of the material.

(ii) The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a provision of this Part, or other applicable regulations, dictates otherwise.

(iii) The licensee who disposed of the material shall retain each record of disposal of radioactive material until the department terminates each license that authorizes disposal of the material.

(2) The licensee shall retain each record that is required by this or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record must be retained until the department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(3) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward records of disposal of licensed material made under section 16.8 of this Part to the department.

(4) If licensed activities are transferred each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer disposal records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated.

(5) Prior to license termination, each licensee shall forward the records required by the Part for decommissioning to the department.

(h) Records of Patient Fluoroscopy Doses

(1) Skin dose for the purpose of this subdivision shall be determined using information available from the fluoroscopy equipment.

(2) When a patient's skin dose from a fluoroscopic procedure exceeds 2 Gy (200 rad), the facility will record the dose in the patient's medical record along with an unambiguous identification of those areas of the patient's skin that received the dose. Such identification may be documented through diagram or narrative description.

(3) When a patient skin dose from a fluoroscopic procedure is equal to or greater than 3 Gy (300 rad):

(i) The patient's referring physician will be notified and provided information regarding management of skin reactions.

(ii) The patient will receive written follow-up instructions that informs them how to identify skin reactions, how to notify the facility, how to arrange for follow-up.

16.15 Reports.

(a) Reports of stolen, lost, or missing licensed or registered sources of radiation.

(1) Telephone reports. Each licensee or registrant shall report to the department by telephone as follows:

(i) Immediately after an occurrence of stolen, lost, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in 10 CFR 20, appendix C, as revised and implemented in full on March 14, 2023, becomes known to a licensee or registrant.

(ii) Within seven calendar days after an occurrence of lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than 10 times the quantity specified in 10 CFR 20, appendix C, as revised and implemented in full on March 14, 2023, that is still missing becomes known to a licensee.

(iii) Immediately after an occurrence of stolen, lost, or missing radiation equipment becomes known to a registrant.

(iv) Immediately after the discovery of an event that prevents immediate protective action necessary to avoid exposures to radiation or radioactive materials which could exceed the

regulatory limits, or releases of radioactive material which could exceed regulatory limits; due to an event such as an explosion, or toxic gas release.

(2) Written reports. Each licensee or registrant required to make a report pursuant to this subdivision shall, within 30 days after making the telephone report, make a written report to the department setting forth the following information:

(i) A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form, manufacturer, model and serial number for the device and/or source, and the estimated current activity of the source; and, for radiation equipment, the manufacturer, model and serial number, type and maximum energy of radiation emitted; and other pertinent information as requested by the department.

(ii) A description of the circumstances under which the loss or theft occurred.

(iii) A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved.

(iv) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas.

(v) Actions that have been taken, or will be taken, to recover the source of radiation.

(vi) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

(3) After filing the written report, the licensee or registrant shall also report any additional substantive information on the loss or theft within 30 days of the discovery of such information.

(4) The names of individuals who may have received exposure to radiation must be stated only in a separate and detachable portion of the report.

(b) Notification of incidents.

(1) Immediate notification. Notwithstanding other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

(i) an individual to receive:

(a) a total effective dose equivalent of 0.25 Sv (25 rem) or more; or

(b) a lens dose equivalent of 0.75 Sv (75 rem) or more; or

(c) a shallow dose equivalent to the skin or extremities of 2.5 Gy (250 rad) or more; or

(ii) the release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(2) Twenty-four hour notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

(i) an individual to receive, in a period of 24 hours:

(a) a total effective dose equivalent exceeding 0.05 Sv (5 rem); or

(b) a lens dose equivalent exceeding 0.15 Sv (15 rem); or

(c) a shallow dose equivalent to the skin or extremities exceeding 0.5 Sv (50 rem); or

(ii) the release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(3) The licensee or registrant shall prepare each report filed with the department pursuant to this subdivision so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

(4) Licensees or registrants shall make the reports required by paragraphs (1) and (2) of this subdivision by means indicated in section 16.1(c) of this Part.

(c) Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits.

(1) Reportable events. In addition to the notification required by subdivision (b) of this section, each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

(i) incidents for which notification is required by section 16.15(b) of this Part;

(ii) doses in excess of any of the following:

(*a*) the occupational dose limits for adults in section 16.6(a) of this Part;

(*b*) the occupational dose limits for a minor in section 16.6(e) of this Part;

(*c*) the limits for an embryo/fetus of a declared pregnant worker in section 16.6(f) of this Part;

(*d*) the limits for an individual member of the public in section 16.7(a) of this Part;

(*e*) any applicable limit in the license or registration; and

(iii) Levels of radiation or concentrations of radioactive material in:

(*a*) a restricted area in excess of applicable limits in the license or registration;

(*b*) an unrestricted area in excess of 10 times the applicable limit set forth in this Part or in the license or registration, whether or not involving exposure of any individual in excess of the limits in section 16.7(a) of this Part.

(2) Contents of reports.

(i) Each report required by this subdivision shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(*a*) estimates of each individual's dose; and

(*b*) the levels of radiation and concentrations of radioactive material involved; and

(*c*) the cause of the elevated exposures, dose rates, or concentrations; and

(*d*) corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, and associated license or registration conditions.

(ii) Each report filed pursuant to paragraph (1) of this subdivision shall include for each individual exposed: the name and status as minor or adult. With respect to the limit for the embryo/fetus in section 16.6(f) of this Part, the identifiers should be those of the declared pregnant worker. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

(3) All licensees or registrants who make reports pursuant to this subdivision shall submit the report in writing to the department.

(d) Notifications and reports to individuals.

(1) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in section 16.13 of this Part.

(2) When a licensee or registrant is required pursuant to section 16.15(c) of this Part to report to the department any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the department and shall comply with the provisions of section 16.13 of this Part.

(e) Reports of leaking or contaminated sealed sources. If a sealed source is determined to be leaking or contaminated, a report shall be filed within five days with the department describing the equipment involved, the test results and the corrective action taken. The information must include device make and model, source make, model, serial number, isotope, and the activity and date for which the activity was determined and other information as requested by the department.

(f) Each professional practitioner who treats or diagnoses any suspected radiation illness shall report in writing to the department within seven days after such treatment or diagnosis, the fact thereof and the full name, address and age of the individual. Included in this reporting requirement are patients who have developed clinical symptoms as a result of contact with radioactive jewelry or other consumer products.

(g) Radioactive materials licensees and general license registrants shall report events described in 10 CFR 30.50(a), (b), (c)(1) and (c)(2), as revised and implemented on October 16, 2020; 10 CFR40.60(a), (b), (c)(1) and (c)(2), as revised and implemented on October 16, 2020; and 10 CFR70.50(a) and (b), as revised and implemented on October 16, 2020, to the department instead of to the NRC.

(h) Licensees and registrants authorized for medical use shall furnish reports of medical events as required by sections 16.25 and 16.123 of this Part.

(i) Reports of transactions involving nationally tracked sources.

(1) Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall comply with 10 CFR 20.2207, as revised and implemented in full on August 9, 2021.

(j) Immediately report to the department any exceedance of external radiation standards for packages, as specified in section 16.16(d) of this Part.

16.16 Procedures for picking up, receiving, and opening packages.

(a) Each licensee who expects to receive a package containing quantities of radioactive material in excess of the Type A(2) quantities specified in 10 CFR71.4 as revised and implemented on November 30, 2021, and appendix A of 10 CFR 71 as revised and implemented in full on November 30, 2021, shall make arrangements:

(1) to receive the package when the carrier offers it for delivery; or

(2) to receive notification of the arrival of the package at the carrier's terminal and to pick up the package expeditiously.

(b) Each licensee shall:

(1) Monitor the external surfaces of a package Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 as revised and implemented on July 11, 2014, and 172.436-440 as revised and implemented on December 20, 1991, for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR71.4 as revised and implemented on November 30, 2021.

(2) Monitor the external surfaces of a package Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 as revised and implemented on July 11, 2014, and 172.436-440 as revised and implemented on December 20, 1991, for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR71.4 as revised and implemented on November 30, 2021, and appendix A to 10 CFR 71 as revised and implemented on November 30, 2021.

(c) Each licensee, upon receipt of a package containing radioactive material in quantities described in subdivision (a) of this section, or any package that shows evidence of damage or leaking shall monitor the external surfaces of the package for radioactive contamination, shall survey all packages for radiation levels and shall make other surveys as may be required by section 16.10 of this Part. The licensee shall perform the monitoring as soon as practical after receipt of the package, but not later than three hours after the package is received during the licensee's normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.

(d) The licensee shall immediately notify the final delivery carrier and the department by telephone if packages other than those transported by exclusive use vehicle are found to have any of the following conditions:

(1) removable radioactive contamination in excess of the limits specified in 49 CFR173.443 as revised and implemented on July 11, 2014; or

(2) external radiation levels in excess of the limits in 10 CFR 71.47 as revised and implemented on September 28, 1995.

(e) Each licensee shall:

(1) Establish and maintain written procedures for the safe opening of packages in which radioactive material is received that include consideration given to special instructions for the type of package being opened.

(2) Ensure that the procedures are followed.

16.17 Packaging and Transportation of Radioactive Material.

(a) Any person performing packaging, preparation for shipment, and transportation of radioactive material shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 71, Packaging and Transportation of Radioactive Material, as revised and implemented in full on November 30, 2021, except as follows:

(1) Sections 71.0, 71.1, 71.2, 71.6, 71.7, 71.9, 71.10, 71.11, 71.12, 71.14(b), 71.19, 71.31, 71.33 through 71.36, 71.38, 71.39, 71.41, 71.51 -71.81, 71.85(a)-(c), 71.91(b), 71.93, 71.95, 71.99, 71.100, 71.101(c)(2), 71.101(d)-(f), and 71.107-71.125 are excluded.

(2) Any reference to the "Commission", "NRC", "NRC Regional Office" or any other organizational unit thereof shall be deemed to be a reference to the New York State Department of Health, except for when used in 71.5(b), 71.17(b), (c)(3), and (e), 71.85(c), 71.88(a)(4), 71.93(c), 71.95, 71.97(c)(1)(iii), (c)(3)(ii) and (iii), and (f), and 71.101(c)(1).

(3) In section 71.89 "10 CFR 20.1906(e)" is replaced with "10 NYCRR 16.16".

16.18 Surrender of radioactive material; sealing of radiation equipment.

Notwithstanding any exemption set forth in this Part:

(a) The department may, by rule, regulation, license condition or order, impose upon any person possessing a radiation source such requirements, in addition to those set forth in this Part, as it deems appropriate or necessary to protect public health and safety and to minimize danger to life and property from radiation hazards.

(b) The department may by order require the removal through an authorized transferee or surrender to the department of any radioactive material by any person who is not able or equipped, or who fails, to observe radiation protection standards established by the department,

or who uses such radioactive material in violation of law or this Part or order of the department or in a manner other than as set forth in a license issued therefor by the department. Such person shall decontaminate any premises which may have been contaminated with radioactive material as a result of his activities to such radiation levels as the department may specify. The expenses incidental to such transfer, surrender, and/or decontamination shall be borne exclusively by such person responsible for the source.

(c) The department may by order require radiation equipment sealed, with an official New York State Department of Health seal or other suitable method, when such equipment is used by any person who is not able or equipped, or fails to observe with regard to such radiation equipment such radiation protection standards as are established by the department, or who uses such radiation equipment in violation of law or this Part or order of the department. Radiation equipment sealed by the department pursuant to this subdivision shall not be unsealed without prior authorization by the department.

16.19 Limitations on application of radiation to humans.

(a) Diagnostic x-ray equipment. No individual other than a professional practitioner, as defined in section 16.2(a) of this Part; a physician's assistant working under the authority of a physician in accordance with article 37 of the Public Health Law; or, a certified nurse practitioner working in accordance with article 139 of the Education Law, or under the authority of a Medical Director or Medical Board in an article 28 facility, shall direct or order the application of radiation from radiation equipment to a human being. No individual other than a professional practitioner, an individual licensed and registered or exempted under article 35 of the Public Health Law and operating within their scope of practice, or a student currently enrolled in an

approved program of study in radiologic technology and operating under direct supervision of a professional practitioner or licensed and registered radiographer shall position patients, set techniques or apply such radiation to a human being. Such direction or order to apply, or the application of, radiation shall be in the course of the practitioner's professional practice and shall comply with the applicable provisions of Part 89 of this Title and article 35 of the Public Health Law.

(1) Dental assistants may operate dental radiographic equipment for dental x-ray procedures only under the supervision of a licensed dentist pursuant to the applicable provisions of section 89.30 of this Title and of section 3516 of the Public Health Law.

(b) Radiation therapy (external beam and brachytherapy) equipment. No individual other than a qualified physician shall direct or order the application of radiation from therapy equipment to a human being. No individual other than an Authorized User, named on a radioactive materials license for uses specified in 10 CFR sections 35.400, 35.600 and 35.1000, as revised and implemented in full on November 14, 2022, shall direct or order the application of radioactive material or radiation from radioactive material for therapeutic purposes to a human being. Nor shall any individual other than a qualified physician, or a licensed and registered radiation therapist or a student currently enrolled in an approved program of study in radiation therapy technology, and operating under direct supervision of a qualified physician or licensed radiation therapist position patients, set techniques or apply radiation therapy to a human being. Such direction or order to apply, or application of, radiation shall be in compliance with the applicable provisions of Part 89 of this Title and article 35 of the Public Health Law.

(c) Radioactive materials. No individual other than a physician who is an Authorized User, named in a radioactive materials license issued pursuant to section 16.100 of this Part, or a

physician under the Authorized User's supervision shall direct or order the use of radioactive materials specified in 10 CFR sections 35.100, 35.200, 35.300 or 35.1000 or sealed sources for diagnosis specified in 10 CFR 35.500 to a human being, as revised and implemented in full on November 14, 2022. Nor shall anyone other than these individuals, or an individual working under their direction or order, or a licensed and registered nuclear medicine technologist, as defined in article 35 of the Public Health Law, or student currently enrolled in an approved program of study in nuclear medicine technology operating under direct supervision of a professional practitioner or licensed and registered nuclear medicine technologist administer radioactive materials to a human being. Such direction or order, or administration of radioactive materials or radiation shall be in the course of the physician's practice and shall comply with the practitioner's professional practice and shall comply with the applicable provisions of Part 89 of this Title and article 35 of the Public Health Law.

(d) The use of body scanning equipment for security screening. No individual, except as described in article 35 of the Public Health Law and section 16.70 of this Part, shall apply radiation to humans for purposes of security screening.

16.20 Hearings.

(a) On disapproval of applications. If the department disapproves any application for license filed pursuant to section 16.102 of this Part:

(1) The department will conduct a hearing if the applicant files with the department a written petition within 30 days after receipt of such notice of disapproval, and the petition:

(i) asserts that such disapproval was, and the respect in which it was, improper; and

(ii) requests a hearing.

(2) Having determined to conduct a hearing on the issues raised in an applicant's petition, the department will give written notice by personal delivery, or by certified or registered mail, to the applicant at least 20 days prior to the date of such hearing, informing that person of the date and time of hearing and that they may be present and heard at said hearing.

(b) On amendment, suspension or revocation of licenses; imposition of additional requirements; transfer or surrender of radioactive material. Except in any case of willfulness or in which public health or safety requires otherwise, or in which an administrative correction is required, the department shall not amend, suspend or revoke any license pursuant to section 16.107 of this Part, or impose additional requirements on the possessor of a radiation source or require the transfer or surrender of radioactive material pursuant to section 16.18 of this Part without first:

(1) notifying in writing such licensee or person in possession of a radiation source of the facts or conduct which may warrant such amendment, suspension, revocation, additional requirement, transfer or surrender, and giving such licensee or person a reasonable opportunity to demonstrate or achieve compliance with all lawful requirements; and

(2) conducting a hearing if the licensee or person files with the department a written petition within 30 days after receipt of such notice, and the petition:

(i) asserts that such amendment, suspension, revocation, additional requirement, transfer or surrender would be, and the respects in which it would be, improper; and

(ii) requests a hearing.

(3) giving written notice by personal delivery or by certified or registered mail to the licensee or person at least 20 days prior to the date of any hearing ordered pursuant to paragraph (2) of this subdivision. Such notice will inform the licensee or person of the date and time of hearing and that they may be present and heard at said hearing.

The requirements in subdivision (b) of this section may be waived upon consent of the licensee or their authorized representative.

16.21 RESERVED.

16.22 X-ray screening; general requirements; mammography.

(a) General requirements. This applies to each person or operator that provides x-ray screening to a target population when there is no individual order for each procedure.

(1) All screening shall be performed under the supervision of a licensed practitioner pursuant to section 89.2(a) of this Title.

(2) The screening program operator shall establish and maintain a referral system for communicating findings to the patient's primary care provider in a timely fashion.

(3) The screening program operator shall establish and maintain a referral system for patients with suspicious findings or disease when the patient does not report having a primary care provider.

(4) The screening program operator shall annually review the program to determine the appropriateness of continuing screening and report the findings of that review to the department.

(5) A prospective screening program operator shall apply to the department and submit information prior to operation indicating how the operator will comply with paragraphs (1) through (4) of this subdivision.

(6) The screening program operator shall prepare and submit to the department within 15 days of a request, a report that includes the following information for a requested time period:

(i) the total number of patients screened by diagnosis;

(ii) the total number of suspicious findings or disease;

(iii) the total number of patients referred for follow-up for each suspicious finding or disease diagnosed.

(b) Mammography. The following requirements for mammography screening are in addition to those in paragraphs (1) through (5) of subdivision (a) of this section.

(1) All mammographic images shall be interpreted by a qualified physician.

(2) Baseline mammography images shall be maintained for ten years.

(3) The screening program operator shall perform an annual analysis of false positive and false negative findings for cases where the data can be obtained.

(4) The facility shall prepare and submit to the department an annual report including:

(i) total number of individuals screened by age group;

(ii) total number of patients referred for follow-up by age group; and

(iii) results of the analysis of false-positive findings.

16.23 Quality assurance programs for diagnostic facilities.

(a) A quality assurance program is a system of plans, actions, reviews, reports and records whose purpose is to ensure that diagnostic facilities achieve consistent high-quality imaging and other diagnostic results, while maintaining radiation output and personnel doses within limits prescribed by the department.

(1) Each radiation facility conducting diagnostic x-ray, fluoroscopy, cone beam CT, CT and/or radioactive materials procedures, excepting intraoral dental, panoramic dental, podiatric x-ray, and veterinary facilities, shall implement a quality assurance program including at a minimum:

(i) the adoption of a manual containing written policies and procedures for radiation protection and describing the facility's quality assurance program. Policies and procedures must be consistent with the types of equipment and services provided, including but not limited to, use of gonad or scoliosis shielding; personnel monitoring; protection of pregnant workers and patients; and holding of patients. The quality assurance manual must describe the various processing, generator and systems quality control tests appropriate for the types of equipment and services provided in sufficient detail to ensure that they will be performed properly;

(ii) the performance of quality control tests and the correction of deficiencies as specified in the quality assurance manual;

(iii) the maintenance of equipment records for each diagnostic imaging system, containing test results, records of equipment repairs and other pertinent information;

(iv) the provision of a formalized in-service training program for employees, including, but not limited to, quality assurance and radiation safety procedures;

(v) the measurement of radiation output at the point of skin entry for common X-ray examinations;

(vi) the measurement of the amount of activity of each dose of a radiopharmaceutical administered to a patient;

(vii) the calculated absorbed dose for diagnostic procedures involving radioactive materials;

(viii) the recording of patient doses from fluoroscopy as allowed by the equipment;

(ix) patient dose management in fluoroscopically guided procedures in conformance with the ACR-AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (ACR Resolution 44 – 2013), NCRP Report 168, or equivalent standard.

(x) the provision of the information described in subparagraphs (v), (vi), and (vii) of this paragraph to any patient upon request; and

(xi) the conduct of an ongoing analysis of repeated, rejected or misadministered diagnostic studies which is designed to identify and correct problems and to optimize quality.

(xii) Each radiation facility conducting medical imaging studies and storing the imaging data electronically, shall implement a quality assurance program that includes written policies and procedures to ensure continuity of care for electronic images that is consistent with that provided for hardcopy imaging studies including assessment of backup of images and at least an annual testing of the system.

(2) Quality Assurance for Digital Imaging Acquisition Systems. Each radiation facility using digital imaging systems, excepting dental, podiatric and veterinary facilities, shall follow quality assurance (QA) and quality control (QC) protocols for image processing in addition to section 16.23(a)(1) of this Part. Acceptance testing and the radiation safety survey shall be completed and documented before first human use.

(i) Equipment Test Records shall be maintained for each unit in operation. Exposure indicator numbers for typical exams and image retakes shall be trended and kept for three years. If the manufacturer does not provide target numbers and tolerances, QC test results shall be trended to establish control limits.

(ii) Quality Control Records for Equipment. Test Records shall be maintained and available for review for quality control test equipment that requires calibration. Quality Control Records may be maintained in either hardcopy or softcopy format but shall be available for review during inspections.

(iii) Equipment Monitoring.

(*a*) All automated tests recommended by the manufacturer shall be run at the recommended frequency.

(*b*) The following tests shall be performed and documented on non-cassette based (also referred to as direct read or DR) systems using the manufacturer's phantom or a phantom acceptable to the department:

(*1*) Characterization of the beam (kVp, thickness and type of attenuation, mAs, other necessary information).

(*2*) Exposure index number calibration verification.

(*3*) Establish exposure index target values (for anatomic regions or exam type).

(*4*) Low contrast test.

(*5*) Contrast scale test.

(*6*) Spatial resolution test.

(7) Uniformity test.

(*8*) Geometric accuracy test.

(*9*) Artifact test.

(*10*) Number of bad pixels test (if the system is capable).

(*11*) Automatic Exposure Control (AEC) verification.

(*c*) The following tests shall be performed and documented on cassette based (also referred to as computed radiography or CR) systems using the manufacturer's phantom or a phantom acceptable to the department:

(*1*) Characterization of the beam (kVp, thickness and type of attenuation, mAs, other necessary information).

(*2*) Establish exposure index target values (for anatomic regions or exam type).

(*3*) Low contrast test.

(*4*) Contrast scale test.

(*5*) Spatial resolution test.

(*6*) Uniformity test.

(*7*) Geometric accuracy test.

(*8*) Image plate (IP) artifact test.

(9) IP dark noise test.

(10) Laser jitter.

(11) Primary erasure.

(*12*) Automatic Exposure Control (AEC) verification.

(*13*) System Linearity & Sensitivity.

(iv) Primary Diagnostic Monitors (PDM). Each primary diagnostic monitor shall be tested per the manufacturer's quality control requirements. At a minimum the following tests shall be performed and documented:

(*a*) Visual test pattern evaluation (TG-18QC, SMPTE, or equivalent).

(*b*) DICOM calibration of the Grayscale Standard Display Function (GSDF).

(*c*) Maximum luminance output.

(*d*) Minimum luminance output.

(*e*) Luminance ratio of maximum to minimum.

(*f*) Evaluation of viewing conditions.

(v) Laser Printers. Each printer, if used for primary interpretation or for patient records or referral, shall be tested per the manufacturer's quality control requirements and shall be of diagnostic quality. At a minimum the following tests shall be performed and documented.

(*a*) Download and print the SMPTE pattern.

(*b*) Measure the density of the 10%, 40%, and 90% patches.

(*c*) Determine and plot the Mid-density using the density at the 40% patch (MD) and Lower-density (LD) using the density at the 90% patch.

(*d*) Determine and plot Density Difference (DD) subtract the density at the 40% patch from the density of the 10% patch.

(vi) Neonatal imaging. Neonatal intensive care units must develop a QA program which includes the following protocols:

(*a*) establishing a technique chart for neonatal imaging including, at a minimum, specific techniques for chest and abdomen, along with corresponding direct or indirect determination of entrance skin dose; and

(*b*) an annual training program for Licensed Radiographic Technologists (LRTs) for conducting neonatal imaging; and

(*c*) a protocol for the proper use of neonatal collimation; and

(*d*) each facility must produce an annual report on the compliance with the facility's neonatal QA program and forward such report to the facility radiation safety committee for review.

(vii) Imaging of children. Each registrant that conducts x-ray imaging of children must establish specific techniques at least for 1-year old, 5-year-old and 10-year-old children, specific to PA chest and abdomen x-ray studies. Additionally, the entrance skin exposure must be directly or indirectly determined for the latter studies and posted in the facility along with the technique chart wherever it is reasonable to expect that children of such an age group can be x-rayed.

(b) Breast imaging quality assurance. Each facility performing breast imaging examinations that are not regulated by the U.S. Food and Drug Administration's Mammography Quality Standards

Act, shall ensure that the breast imaging system is optimized to provide consistent, high-quality imaging. A breast imaging system includes the x-ray control, x-ray generator, x-ray tube, image receptor and all components of the imaging process. The facility shall use a breast equivalent phantom approved by the department to monitor image resolution. The breast phantom contains test objects which represent low density areas and microcalcifications which are related to the imaging of breast lesions. A test object is either a mass, fiber, or speck set.

(1) No breast imaging shall be performed unless the minimum manufacturer specifications and or the minimum criteria established by the American College of Radiology (ACR) for breast phantom imaging are met.

(2) All facilities shall optimize the breast imaging systems used and determine the breast phantom test object resolution of the system prior to performing breast imaging. The number of test objects resolved is the reference image the facility shall use for comparison during periodic testing. Under any conditions, if during the testing required under subdivision (a) of this section, the system is found to have lost the ability to resolve two test objects previously visible in the reference image, the facility shall investigate the reason and optimize the system.

(3) Diminished phantom test object resolution and facility follow-up.

(i) Whenever the phantom image indicates that the breast imaging system fails to meet the minimum test object resolution defined in paragraph two of this subdivision the facility shall investigate the reason. Correction to achieve the minimum level shall be completed prior to performance of breast imaging.

(ii) In addition, if it is found that breast imaging has been performed while minimum requirements were not met the investigation shall include:

(*a*) a review of phantom images to determine at which point the image resolution fell below the minimum; and

(*b*) a review, by a panel of physicians selected by the department for this review, of breast images performed since the last phantom image that was identified as meeting the minimum level. Physicians selected for the panel must be certified in diagnostic radiology by the American Board of Radiology or the American Osteopathic Board of Radiology or have equivalent qualifications and will be selected for addition to this panel in consultation with the New York State Radiological Society. Members of the panel are deemed volunteers in service to the department within the meaning of paragraph (a) of subdivision one of section 17 of the Public Officers Law and, in lieu of expenses, shall be compensated by the department at the prevailing departmental per diem rate. The cases chosen for review shall include images from the range of studies performed by the facility which the panel ascertains to be sufficient to determine that the clinical images are of diagnostic quality. A record of the review and findings shall be maintained for inspection.

(iii) If images are identified by the physician conducting the review as nondiagnostic, the facility shall, within 5 business days, notify:

(*a*) the referring physician, or other authorized referring practitioner as defined in subdivision (a) of section 16.19 of this Part, or the patient, if not referred by a practitioner, of the need for follow-up; and

(*b*) the department of the results of the investigation and follow-up contacts.

(iv) A record of the results of the investigation and actions taken to correct any deficiency shall be maintained for review by the department for a period of three years.

16.24 Quality assurance programs for the use of radiation for therapy in humans.

(a) External beam therapy and brachytherapy. Each licensee or registrant authorized to administer external beam therapy or brachytherapy to human beings shall implement and maintain a quality assurance program. This program shall systematically monitor, evaluate, and document radiation therapy services to ensure consistent and safe fulfillment of the patient's dose prescription. This program shall also have written policies and procedures to minimize radiation exposure to personnel and adequately monitor the patient's progress and follow-up care. Each such licensee or registrant shall meet or exceed all quality assurance criteria described in this subdivision.

(1) Each licensee or registrant shall adopt, maintain, and implement a quality assurance manual that includes policies and procedures that ensure quality of patient care and safety of patients and other personnel. The manual must include procedures to ensure the following:

(i) Each patient's medical record shall be clear, complete, accurate, legible, and shall include the patient's initial clinical evaluation, simulation data, treatment planning data, patient specific quality assurance checks, treatment delivery data, clinical assessments during treatment, a treatment summary, and plan for subsequent care. Treatment related data shall be recorded in the patient's medical record at the time of each treatment.

(ii) A written and dated order or prescription for the medical use of radiation or radioactive material shall be made for each patient in accordance with subdivisions (b) and (c) of section 16.19 of this Part. The order or prescription shall be signed or approved electronically by a board-certified radiation oncologist or qualified physician who restricts their practice to radiation oncology. Changes to the initial prescription or written directive shall be signed and dated clearly.

(iii) Radiation treatment plans and related calculations shall be checked, as per the facility’s written policy and/or the conditions of the license, by a licensed medical physicist or authorized medical physicist for accuracy before 25 percent of the prescribed dose for external beam therapy or 50 percent of the prescribed dose for brachytherapy is administered, except the check shall be performed prior to treatment for any single fraction treatment and any fractional dose that exceeds 300 cGy.

(*a*) If a treatment plan and related calculations were originally prepared by a licensed medical physicist or authorized medical physicist, it may be rechecked by the same individual using a different calculation method.

(*b*) Treatment plans and related calculations prepared by other qualified personnel must be checked by a licensed medical physicist or authorized medical physicist using procedures specified in the registrant's or licensee's treatment planning procedures manual required pursuant to paragraph (2) of this subdivision, and who has received training in use of the manual pursuant to paragraph (2) of this subdivision.

(iv) The accuracy of treatment plan data and any modifications to treatment plan data transferred to a radiation treatment delivery system shall be verified by qualified clinical staff prior to patient treatment.

(v) The treatment plan shall be reviewed and approved prior to the start of treatment and after any change ordered by a board-certified radiation oncologist or qualified physician who restricts their practice to radiation oncology.

(vi) Set up shall be verified and documented by a radiation therapy technologist prior to every treatment session and set up shall be verified and approved by the radiation oncologist prior to:

(*a*) the first treatment and;

(*b*) prior to treatment for any changes to the initial treatment plan and;

(*c*) during the course of the treatment at frequencies consistent with the written directive and treatment protocol.

(vii) A radiation therapy technologist or board-certified radiation oncologist or qualified physician who restricts their practice to radiation oncology shall obtain clarification before beginning a patient's treatment if any element of the order or other record is confusing, ambiguous, erroneous, or suspected of being erroneous.

(viii) Each patient's identification shall be verified by at least two different means and matched to the treatment plan at the console, by a radiation therapy technologist or physician prior to each treatment.

(ix) Each patient's response to treatment shall be assessed by a board-certified radiation oncologist or other qualified physician in the active practice of external beam therapy and/or brachytherapy at least weekly. Unusual responses shall be evaluated as possible indications of treatment errors and recorded in the patient's medical record, investigated, and resolved.

(x) The medical records of patients undergoing fractionated treatment shall be checked for completeness and accuracy by the licensed medical physicist or their designee at intervals not to exceed six fractions, and the completion of the course of radiation therapy.

(xi) A board-certified radiation oncologist or other qualified physician shall assess patient’s response to treatment during the course of treatment and at the completion of radiation therapy. Unusual responses shall be evaluated as possible indications of treatment errors and recorded in the patient's medical record, investigated, and resolved. Plans for and evidence of follow-up care shall be documented in the medical record.

(xii) All equipment and other technology used in planning, guiding or simulation, and administering radiation therapy shall function properly and safely, and shall be calibrated properly and repaired and maintained in accordance with the written policy and the manufacturer's instructions. The equipment and technology that is subject to such quality assurance includes but is not limited to: computer software and hardware including upgrades and new releases; equipment used to perform simulation and treatment planning; dosimetry equipment; equipment used to guide treatment delivery, including but not limited to ultrasound units, kV and MV imaging equipment and monitors that are used to view patient imaging studies; and personnel radiation safety equipment. Data communication between various systems, including but not limited to treatment planning systems, treatment delivery systems, and data networks/storage media, shall be evaluated and tested to ensure accurate and complete data transfer.

(xiii) Quality assurance tests performed on equipment and technology used in planning and implementing radiation treatment shall be documented, including:

(*a*) detailed procedures for performing each test;

(*b*) the frequency of each test;

(*c*) acceptable results for each test;

(*d*) corrective actions taken;

(*e*) record keeping and reporting procedures for test results including the tester’s name, signature, and date of the test; and

(*f*) the qualifications are specified for the individual(s) conducting the test and for the person who reviews test data.

(xiv) Test results that exceed tolerances/limits shall be immediately reported to the licensed medical physicist or authorized medical physicist.

(xv) Records for all maintenance, repairs, and upgrades of equipment and technology shall be maintained for at least five years.

(xvi) Errors or defects in technology or equipment, including computer hardware and software, shall be reported to the technology or equipment manufacturer and to the United States Food and Drug Administration (MedWatch) as soon as possible and in no event more than 30 days of discovery, and records of equipment errors and reports required by this clause shall be maintained for review by the department for at least three years.

(xvii) External beam therapy equipment calibration/output required by section 16.60(c)(1) or 16.61(b)(1) of this Part shall be verified by an independent means and records of such measurements shall be retained for review by the department for at least three years.

(xviii) Patients with permanent brachytherapy implants shall be provided with instructions to take radiation safety precautions, as required by section 16.123(e)(4) of this Part (incorporating 10 CFR 35.75, as revised and implemented on August 13, 2007) and the licensee's radioactive materials license, after being released from the licensee’s facility.

(xix) All personnel involved in planning or administering radiation therapy shall be credentialed. Credentialing shall include verifying that all professional staff are appropriately licensed, including medical physicists and radiation therapy technologists. Records of credentialing shall be maintained during the period in which the credentialed person provides services to the licensee or registrant, and for three years thereafter. When new treatment types or complex high fractional dose therapies are implemented, all staff involved should be clearly identified in a

written policy, properly trained and records of training maintained in accordance with this section.

(xx) Any unintended deviation from the treatment plan shall be evaluated and corrective action taken to prevent recurrence. Records of unintended deviations and corrective action shall be maintained for audits required by paragraph (3) of this subdivision and for review by the department.

(xxi) There shall be a process to ensure quick and effective response to any radiation therapy related recalls, notices, safety alerts, and hazards.

(xxii) A registrant providing mobile therapeutic radiation machine services shall, at each location of service, comply with all requirements specified in section 16.24 of this Part, as applicable. The registrant shall have policies and procedures to assure proper operation of the device on each day of clinical use, consistent with the registrant's written policy, manufacturer's guidelines, and established professional body guidelines.

(2) Each licensee or registrant shall adopt and maintain a radiation treatment manual that describes how radiation therapy treatment planning is to be performed at the licensee's or registrant's facility. This manual should include the calculation methods and formulas to be used at the facility (including the methods for performing the checks of treatment plans and related calculations as required in paragraph (1) of this subdivision). The treatment planning manual may be part of the quality assurance manual required by paragraph (1) of this subdivision. The radiation treatment manual shall be included in training given pursuant to subdivision (c) of section 16.13 of this Part to facility staff who will participate in treatment planning. Each licensee or registrant shall ensure that a licensed medical physicist or authorized medical physicist prepares or reviews and approves the procedures in this manual and reviews the

treatment planning manual at least annually. This review must include all parts of the treatment planning system including both software and physical components and any new modality or protocols.

(3) Each licensee or registrant shall implement written procedures for auditing the effectiveness of the radiation therapy quality assurance program that include the following:

(i) Audits shall be conducted at intervals not to exceed 12 months by a licensed medical physicist or authorized medical physicist, and also by a physician, both of whom are in the active practice of the type of radiation therapy conducted by the licensee or registrant.

(ii) The licensee or registrant shall ensure that the individuals who conduct the audit prepare and deliver to the licensee or registrant a report which contains an assessment of the effectiveness of the quality assurance program and recommendations for any needed modifications or improvements.

(iii) The licensee or registrant shall promptly review the audit findings, address the need for modifications or improvements, and document actions taken. If recommendations are not acted on, the licensee or registrant shall document the reasons therefor and detail alternative actions taken to address the audit findings.

(iv) Each licensee or registrant shall maintain for review and inspection by the department complete written records relating to quality assurance and audit activities. Audit records shall be maintained for at least six years.

(v) The findings of the audit shall be presented to the RSC or in facilities exempt from having an RSC, the RSO or administrator shall review and document.

(4) Accreditation in Radiation Oncology. Each registrant or licensee providing radiation therapy using radioactive material authorized under 10 CFR sections 35.400, 35.600 or 35.1000 (other

than radiopharmaceuticals), as revised and implemented in full on November 14, 2022, or radiation equipment under sections 16.60 or 16.61 of this Part shall:

(i) maintain accreditation in radiation oncology by an accrediting organization that is approved by the department;

(ii) for a newly licensed or registered practice, submit an application for accreditation to an organization listed in subparagraph (i) of this paragraph no later than six months after patient treatments begin. Within 18 months after start of patient treatments, the licensed or registered practice shall earn and maintain accreditation in radiation oncology by such organization;

(iii) upon addition of a radiation oncology modality that did not fall under an existing accreditation, the registrant or licensee shall notify the department within 30 days and follow the requirements to obtain accreditation by the accrediting organization and as directed by the department;

(iv) notify the department within 30 days upon notice of the outcome of the accreditation survey;

(v) registrants, licensees, and practices where service is provided by physicians and surgeons who are not radiation oncologists, and whose practices do not qualify for an accreditation survey by an organization specified in subparagraph (i) of this paragraph, shall have an annual audit specified in paragraph (3) of this subdivision performed by a physician and a licensed medical physicist or authorized medical physicist, both in active practice of such modalities and who have not provided clinical services at the practice during the period for which they perform the audit.

(b) Radiopharmaceutical therapy. A quality assurance program for radiopharmaceutical therapy is a system of plans, actions, reviews, reports and records whose purpose is to ensure a consistent and safe fulfillment of the written directive or dose prescription by the authorized user.

(1) Each licensee who uses radiopharmaceuticals for therapy in humans shall implement a quality assurance program which includes at a minimum:

(i) the adoption of a manual containing written policies and procedures designed to assure effective supervision, safety, proper performance of equipment, effective communication, and quality control. These must include procedures to assure that:

(*a*) each patient's evaluation and intended treatment by an authorized user is documented in the patient's record;

(*b*) a written, signed and dated order for medical use of radioactive material is made in accordance with subdivision (c) of section 16.19 of this Part;

(*c*) all orders and other treatment records are clear and legible;

(*d*) staff will be instructed to obtain clarification before treating a patient if any element of the order or other record is confusing, ambiguous or suspected of being erroneous;

(*e*) each patient's response to treatment is assessed by a physician knowledgeable in radiopharmaceutical therapy, and unusual responses are evaluated as possible indications of treatment errors; and

(*f*) complete treatment records containing data recorded at the time of each treatment are maintained.

(2) Each licensee shall ensure that all equipment used in planning and administering radiopharmaceutical therapy is designed for the intended purpose and is properly calibrated, functioning properly and maintained in accordance with the manufacturer's instructions and the quality assurance program described in the licensee or registrant's quality assurance manual.

(3) Each licensee shall audit the radiopharmaceutical quality assurance program at intervals not to exceed 12 months to assess the effectiveness of the program; document the audit and any

modifications or improvements found to be needed; institute corrective actions and improvements as indicated by the audit findings; and present the finding of audit to the RSC or in facilities exempt from having an RSC to the RSO for review and approval.

16.25 Misadministration or Medical Event.

(a) A medical event or a misadministration are equivalent terms for purposes of this Part. A medical event shall be the administration of:

(1) A radiopharmaceutical or radiation from a source other than the one ordered.

(2) A radiopharmaceutical or radiation to the wrong person.

(3) A radiopharmaceutical or radiation by a route of administration or to a part of the body other than that intended by the ordering physician.

(4) An activity of a radiopharmaceutical for diagnostic purposes that differs from the activity ordered by more than 50 percent.

(5) An activity of a radiopharmaceutical for therapeutic purposes that differs from the activity ordered by more than 10 percent.

(6) A therapeutic radiation dose from any source other than a radiopharmaceutical or brachytherapy source such that errors in computation, calibration, time of exposure, treatment geometry or equipment malfunction result in a calculated total treatment dose differing from the final total treatment dose ordered by more than 10 percent.

(7) A therapeutic radiation dose from a brachytherapy source such that errors in computation, calibration, treatment time, source activity, source placement or equipment malfunction result in a calculated total treatment dose differing from the final total treatment dose ordered by more than 10 percent.

(8) In a therapeutic radiation course, other than from a brachytherapy source, consisting of more than 5 fractions, the administered dose in an individual treatment or fraction that differs from the dose ordered for that individual treatment or fraction by 50 percent or more, or a dose deviation of 20 percent or more in 5 consecutive fractions. In a treatment course of 5 or fewer fractions, dose deviations of 20 percent or more in any one fraction.

(i) Instances when the administered dose is less than the prescribed dose due to machine interruption or patient decision or inability to complete the treatment are not deemed medical events. However, machine performances resulting in incorrect dose administration shall be investigated and reported to the manufacturer if warranted and corrective actions documented pursuant to section 16.24(a)(1)(xvi) of this Part.

(9) A CT scan is performed on the wrong person.

(10) A CT scan is performed on the wrong body part.

(11) A CT scan that results in damage to an organ, organ system or results in hair loss or erythema as determined by a physician.

(b) Records and Reports of medical events or misadministrations.

(1) Diagnostic medical events or misadministrations.

(i) Records of medical events as defined in subdivision (a) of this section which involve diagnostic procedures, and the corrective actions taken pursuant to subparagraph (ix) of paragraph (1) of subdivision (a) of section 16.23 of this Part, shall be retained for three (3) years.

(ii) If such a medical event results in a dose to the patient exceeding 5 rem (0.05 Sv) to the whole body or 50 rem (0.5 Sv) to any individual organ, or the administration of iodine-131 or iodine-125 in the form of iodide, and in a quantity greater than 30 microcuries, the licensee or

registrant shall notify the department in writing within 15 days and make and retain a record pursuant to paragraph (3) of this subdivision.

(iii) All other diagnostic events may be entered into NYPORTS or otherwise documented for facilities not subject to article 28 requirements.

(2) Therapy medical events or misadministrations.

(i) When a medical event described in paragraphs (5), (6) or (7) of subdivision (a) of this section, in which the percentage of error is less than 20 percent is discovered the licensee or registrant shall immediately investigate the cause and take corrective action.

(*a*) The licensee or registrant shall make and retain a record of all therapy medical events or misadministrations described in this subparagraph. The record shall contain all the information called for in paragraph (3) of this subdivision and shall be retained for six years.

(ii) When a therapy medical event described in paragraphs (a)(1), (2), (3) or (8) of this section is discovered; or when a medical event described in paragraphs (a)(5), (6) or (7) of this section in which the percentage of error is equal to or greater than 20 percent is discovered; the licensee or registrant shall notify the department by telephone. The licensee or registrant shall also notify the referring physician of the affected patient and the patient, of any therapy medical event described in this subparagraph, with the exception of medical events described in paragraphs (a)(1) and (8) of this section. When it is not medically advisable to give such information to the patient, the information shall be made available to the patient's responsible relative or guardian on the patient's behalf. These notifications must be made within 24 hours after the medical event is discovered. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee or registrant shall notify them as soon as

practicable. It is not required that the patient be notified without first consulting the referring physician; however, medical care for the patient shall not be delayed.

(iii) Within 7 days after an initial therapy medical event report, the licensee or registrant shall send a written report to the bureau. The written report must contain the name of the licensee or registrant; the information called for in paragraph (3) of this subdivision; and whether the licensee or registrant notified the patient or the patient's responsible relative or guardian.

(3) Each licensee or registrant shall maintain a record of each reportable medical event for six years. The record must contain the names of all individuals involved in the event (including the treating physician, allied health personnel, the patient, and the patient's referring physician), the medical record number or identification number if one has been assigned, a brief description of the event, the effect on the patient, and actions taken to prevent recurrence.

(4) Within seven days after an initial therapy medical event report made pursuant to subparagraph (ii) of paragraph (2) of this subdivision, the licensee or registrant shall provide the patient a written report with a copy delivered to the patient's referring physician. The report shall contain a brief description of the event, the effect on the patient including any change in the patient's health status which resulted or could result from the medical event, and recommendations for the appropriate course of treatment or follow-up. If it is not medically advisable to give such information to the patient, the report shall be made available to the patient's responsible relative or guardian on the patient's behalf and documented in the patient's treatment record.

16.26 Respiratory protection and controls to restrict internal exposure in restricted areas.

(a) Any person using respiratory protection and controls to restrict internal exposure in restricted areas shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 20, subpart H, "Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas," as revised and implemented in full on December 19, 2002, except as follows:

(1) Any reference to the "Commission" or "NRC" shall be deemed to be a reference to the New York State Department of Health.

16.40 Fees.

(a) General requirement. Unless exempt under subdivision (b) of this section, no person shall establish, maintain or operate a radiation installation with radiation equipment subject to the registration requirements of section 16.50 of this Part, or hold a radioactive materials license as required pursuant to the licensing requirements of section 16.100 of this Part, except upon payment of the applicable fees prescribed in this section and section 16.41 of this Part.

(b) Exemptions.

(1) Agencies of the State of New York and its political subdivisions, except for hospitals and higher education academic institutions operated by such agencies, are exempt from the payment of any fees prescribed in this section and section 16.41 of this Part.

(2) Any operator of a radiation installation that is registered with the New York City Department of Health and Mental Hygiene or any person that holds a radioactive material license issued by the New York City Department of Health and Mental Hygiene, pursuant to sections 16.50(j) and 16.1(b)(2) of this Part, is exempt from paying the fees prescribed in this section and section 16.41 of this Part, unless they also hold a registration certificate or a radioactive material license

issued by the department for which fees are applicable. In the latter case, the applicable fees for the activities registered or licensed by the department shall be assessed.

(c) Payment of fees.

(1) Each application for a radiation installation registration or for a new radioactive material license, shall be accompanied by a remittance of the full amount of the applicable annual fees prescribed in section 16.41 of this Part. Annual fees for each subsequent year shall become due on each anniversary date thereafter, determined by the date of original registration or license issued.

(2) Any operator of a radiation installation who holds a current radiation installation registration certificate issued pursuant to this Part or any person who holds a current radioactive material license issued pursuant to this Part, shall pay the prescribed annual fee as billed by the department. Payment of fees shall be made within the 30-day period immediately following the billing date.

(3) The payment of all fees prescribed by this Part shall be by check or money order made payable to the New York State Department of Health.

(d) Prorating fees. For administrative purposes, the department may alter the fee due date and charge a fee for a period greater or less than one year. In such cases the amount of the fee due will be prorated to correspond to the length of the period covered by the bill.

(e) No refund policy. Except in those cases where the department has determined that a payment of fees is not required, no fees, or portions thereof, paid to the department pursuant to this Part shall be refundable.

(f) Failure to pay prescribed fee. If an applicant for a license or registration fails to remit with such application the full amount of the fees as prescribed by this Part, the department will not

process the application and will notify the applicant that the application will not be processed unless fees are first paid. The department may revoke, suspend or amend a registration or radioactive material license in whole or in part for failure to pay all prescribed annual fees due.

(g) Registration fees charged by New York City Department of Health and Mental Hygiene. Provided that a written schedule of the registration fees to be charged by the New York City Department of Health and Mental Hygiene has been submitted in a manner prescribed by the State Commissioner of Health and so approved, the New York City Department of Health and Mental Hygiene is authorized to charge within its jurisdiction such approved registration fees. The State of New York or any political subdivision thereof or any agency or instrumentality of either are exempt from the payment of such fees.

(h) Fees charged by local health departments. Provided that a written schedule of fees to be charged, together with a written analysis of the estimated costs of its radiation protection regulatory program, has been submitted to and approved by the State Commissioner of Health, the New York City Department of Health and Mental Hygiene or, as the department shall direct, the appropriate county or part-county health officer having jurisdiction that inspects installations with radiation equipment under a program of inspection certified by the State Department of Health, or any county, part-county or city health district that licenses and inspects radioactive materials in accordance with section 16.1(b)(2) of this Part, is authorized to charge adequate and reasonable fees for inspection, licensing and/or other radiation protection services rendered. Such fees shall not exceed the estimated costs of such services, except that, with the approval of the State Commissioner of Health, one or more of such services may be rendered without charge. The State of New York or any political subdivision thereof or any agency or instrumentality of either are exempt from the payment of such fees.

(i) Fees charged by certified radiation equipment safety officers. A certified radiation equipment safety officer shall not charge, or propose to charge, a fee for an inspection in excess of a fair and reasonable amount as determined by the department. Such officer shall furnish to the department, upon request, information as to fees charged or proposed to be charged by the officer. Such fees shall not exceed the estimated cost of services.

(j) Fees paid prior to the effective date of this section. Facilities that had paid fees which cover a period that extends beyond the effective date of this section, shall be responsible for the difference between the prorated amount of any fee previously paid for such period and the full sum due under this section for such period.

16.41 Fee schedule.

Effective upon adoption, the annual fees assessable shall be as prescribed in this section.

(a) Registration fees. Except for entities exempt from fees under section 16.40(b)(1) of this Part, the annual registration fee for radiation installations required to be registered shall be as listed in this section.

(b) Fee categories for radiation installations required to be registered with the department. For the purpose of assessing annual fees, all radiation installations required to be registered with the department pursuant to section 16.50(a) of this Part are categorized in one of the following six categories:

Category I: Radiation installations with any five or more of the modalities listed below.

Category II: Radiation installations with three or four of the modalities listed below.

Category III: Radiation installations with two of the medical modalities listed below.

Category IV: Radiation installations with one of the medical modalities listed below and annual patient workload of 750 examinations or more.

Category V: Radiation installations with one of the medical modalities listed below and annual patient workload of less than 750 examinations, and all other radiation installations with one or two of the non-medical modalities listed below except as listed under Category VI.

Category VI: Dental, podiatric, bone densitometry or veterinary installations.

The modalities to be used in determining the fee category for radiation installations required to be registered with the department pursuant to section 16.50(a) of this Part are:

Medical Modalities: radiography, fluoroscopy, computed tomography, angiography, stereotactic breast biopsy systems, and Grenz/orthovoltage therapy, utilized in humans.

Non-medical Modalities: radiography, fluoroscopy, analytical equipment (including electron microscopes, fluorescence analysis and x-ray diffraction equipment), gauges and other commercial devices not otherwise listed here, and computed tomography and particle accelerators that are not utilized on humans.

(c) Fee schedule for radiation installations routinely inspected by the department. All radiation installations required to be registered with the department pursuant to section 16.50(a) of this Part that are not exempt from fees under section 16.40(b) of this Part and that are routinely inspected by the department shall, in addition to the registration fee prescribed in subdivision (a) of this section, be assessed annual fees according to the following schedule:

Category I radiation installations: $ 2600

Category II radiation installations: $ 1800

Category III radiation installations: $ 1250

Category IV radiation installations: $ 550

Category V radiation installations: $ 325

Category VI radiation installations: $ 100

(d) Fee schedule for radiation installations routinely inspected by a county or part-county health officer or by a certified radiation equipment safety officer. All radiation installations required to be registered with the department pursuant to section 16.50(a) of this Part that are not exempt from fees under section 16.40(b) of this Part and that are routinely inspected by a county or part-county health officer having jurisdiction, as the department shall direct, under a program certified by the department, or by a certified radiation equipment safety officer as directed by the department shall, in addition to the registration fee prescribed in subdivision (a) of this section, be assessed an annual fee according to the following schedule:

Category I radiation installations: $ 600

Category II radiation installations: $ 450

Category III radiation installations: $ 300

Category IV radiation installations: $ 125

Category V radiation installations: $ 65

Category VI radiation installations: $ 25

(e) Fee categories for non-commercial, radioactive material licensees and radiation installations that use accelerators in medical therapy. For the purpose of assessing annual fees, all persons holding radioactive material licenses issued by the department and all radiation installations that are required to be registered with the department, pursuant to section 16.50(a) of this Part and

that use accelerators in medical therapy are categorized in one or more of the following six categories:

Category I: Persons issued a broad scope medical license.

Category II: Persons issued a broad scope academic or broad scope research and development license.

Category III: Persons issued a specific license which allows the use of radioactive materials for both nuclear medicine and brachytherapy, or a license which authorizes the operation of a nuclear pharmacy at an institution or a pharmaceutical production cyclotron.

Category IV: Radiation installations operating a medical therapy accelerator and/or persons issued a specific license which authorizes the use of radioactive materials in nuclear medicine, brachytherapy, mobile nuclear medicine service, teletherapy (including Co-60 teletherapy and gamma knife), research and development, academic uses, veterinary medicine or large irradiators.

Category V: Persons issued a specific license which authorizes the use of radioactive materials in a clinical laboratory, lead paint analyzers, mobile nuclear medicine sites, leak tests, equipment calibration, self-shielded irradiators, diagnostic sealed sources, and any other use not included in categories I through VI as listed in this subdivision.

Category VI: Persons issued a specific license for use of radioactive materials in gas chromatographs.

(f) Radioactive materials/medical therapy accelerator fee schedule.

(1) Except for entities exempt from fees under section 16.40(b) of this Part, all persons that hold radioactive material licenses issued by the department and all radiation installations that are required to be registered with the department and that use accelerators in medical therapy shall be assessed annual fees according to the following schedule:

Category I: $ 9600

Category II: $ 6200

Category III: $ 2400

Category IV: $ 1500

Category V: $ 600

Category VI: $ 120

(2) When more than one fee category as described in section 16.41(e) of this Part applies, the fee which corresponds to the highest applicable category will be assessed, provided, however, that separate Category III fees will be assessed to any person that holds a license to operate a nuclear pharmacy or a pharmaceutical production cyclotron for each type of these uses that applies, in addition to any other categories of fees that apply; and radiation installations or licensees that provide teletherapy (Co-60, gamma knife or a medical therapy accelerator) services or veterinary medicine services, or use radioactive materials in large irradiators, or, except for Category I or II licensees, use radioactive materials in research and development, will be assessed Category IV fees for each type of these uses that applies, in addition to any other categories of fees that apply. If a person that holds a radioactive material license is also the operator of a radiation installation that uses an accelerator in medical therapy and the licensed activities are conducted at such installation, the licensed radiation installation shall be considered as one and the same entity for purposes of assessing fees described under section 16.41(e) of this Part.

(g) Fee categories for commercial radioactive material licensees. For the purpose of assessing annual fees, all persons holding radioactive material licenses issued by the department shall be categorized in one or more of the following six categories:

Category I: Persons issued a specific license which authorizes the use of radioactive material for cyclotron operations, industrial radiography - fixed facility only, industrial radiography - temporary job sites (may include fixed), licenses of broad scope not otherwise specified (NOS), manufacturing NOS, manufacturing of radioactive products - broad scope, nuclear laundry, nuclear pharmacy operations, open irradiator (> 1MCi), research and development - broad scope, waste broker, waste disposal facility (active), or waste services NOS.

Category II Persons issued a specific license which authorizes the use of radioactive material for commercial distribution of radioactive products, decontamination and decommissioning service, distribution of radioactive medical products, distribution of radioactive products NOS, manufacturing of radioactive medical products – limited scope, manufacturing of radioactive products – limited scope, open irradiator (>10,000 Ci <1MCi), research and development – limited scope (>1 Ci), waste disposal facility (inactive), waste processing or repackaging, or well logging and tracer studies

Category III Persons issued a specific license which authorizes the use of radioactive material for device installation, maintenance and repair service, full health physics consulting service, leak test and calibration service, medical system service, moisture/density gauge, open irradiator (<= 10,000 Ci), redistribution of

radioactive products, research and development – limited scope (<1 Ci), sealed or unsealed sources NOS, services NOS, and well logging (sealed sources only).

Category IV Persons issued a specific license which authorizes the use of radioactive material for analytical laboratory (radioactive sample analysis), calibration service, fixed gauges, gauges NOS, leak test service, portable X-ray fluorescence analyzer, possession incident to exempt distribution (NRC E-license), and self-shielded irradiators.

Category V Persons issued a specific license which authorizes the use of radioactive material for Analytical instruments NOS, demonstration and sales of radioactive products, gas chromatograph, or storage only pending disposal.

(h) Annual fee schedule for commercial radioactive materials licenses.

Category I $3600

Category II $3000

Category III $2400

Category IV $1800

Category V $ 600

(i) Generally licensed devices. A non-refundable fee in the amount of $120, payable to the department, shall be submitted with each registration of a generally licensed device.

(j) Additional fees.

A non-refundable fee for commercial licenses shall be submitted to the department according to the following schedule:

(1) Fee for the review of decommissioning plan submitted in accordance with section 16.113 of this Part shall be $2,500.

(2) Fee for sealed source and device certificate application review shall be $1,500.

(3) Fee for reciprocity shall be 50% of the commercial license fee by category (i.e., category 1 reciprocity will be $1800 for 6 months).

RADIATION EQUIPMENT

Introductory note: Sections under this heading contain the registration and transfer notification provisions for radiation equipment and general and additional radiation protection requirements applicable only to specific radiation equipment.

16.50 Registration of installations with radiation equipment; notification of transfer of radiation equipment.

(a) No person shall establish, maintain or operate any radiation installation at which is located or used any radiation equipment in operable condition or intended to be used, unless such installation has been registered as evidenced by a current certificate of registration issued to the operator thereof by the department or has been registered in an alternate manner accepted by the department in accordance with subdivision (j) of this section. Radiation equipment exempted from the requirements of this Part under section 16.4 is exempt from the registration requirement.

(b) Radiation installation application for registration, as described in subdivision (a) of this section shall be made by the operator thereof, to the department on a written form and in a manner prescribed by the department. This must be done 30 to 60 days prior to: a new installation of equipment, an existing installation certificate expiration date (renewal), and any changes in ownership, operation status, or location.

(c) The department may withhold, suspend, or revoke a certificate of registration if it finds that:

(1) the information submitted in the application is incorrect or incomplete; or

(2) the fees for registration and/or the certificate have not been paid as required; or

(3) the installation is, has been or will be established, maintained or operated in violation of the State Public Health Law, the State Sanitary Code (Chapter I of this Title) or any other applicable law, rule, regulation or order; or

(4) the certificate has not been issued correctly.

(d) A certificate of registration shall be issued for a limited period of time extending from the date of issuance to the date of expiration as specified on the certificate.

(e) The certificate of registration issued for a radiation installation to the operator thereof shall expire upon:

(1) the expiration date specified on the certificate; or

(2) revocation by the department; or

(3) a change of the operator; or

(4) a change in location of the radiation installation if it is not a mobile unit; or

(5) a change in the name of the installation; or

(6) the discontinuance of the installation.

(7) failure to pay the required fee by the specified date.

(f) A certificate of registration shall not be transferable or assignable except as approved by the department.

(g) An unexpired certificate of registration issued for a radiation installation shall be conspicuously posted at the installation and made available by the operator, upon request, to the department, the health officer having jurisdiction, or other person or agency making a survey of the installation pursuant to paragraph (1) of subdivision (a) of section 16.10 of this Part.

(h) The certificate of registration does not imply any endorsement or approval of business practices by the department, and shall not be used to advertise or promote business.

(i) The operator of a radiation installation shall keep correct and complete the information submitted in his application for registration by reporting to the department in writing within 10 days any change affecting such information.

(j) The department may accept, in lieu of registration with the department, registration with the New York City Department of Health and Mental Hygiene. Acceptance of registration may be done only for radiation installations surveyed under an inspection program conducted by the New York City Department of Health and Mental Hygiene as described in paragraph (1) of subdivision (a) of section 16.10 of this Part. As a condition of the department's acceptance of registration pursuant to this section, the registering agency shall furnish to the department in writing, at such times and in such form as the commissioner may prescribe, pertinent information concerning the registration of each and every radiation installation registered by the agency. The information furnished to the department shall cover at least those items contained in the department's application form for registration of a radiation installation.

(k) The distributor, retailer or other agent who sells, leases, transfers, loans or installs X-ray or fluoroscopic equipment or other radiation equipment subject to the registration requirements of this section shall notify the department in writing within 10 days after making such sale, lease, transfer, loan, or installation on, and in accordance with the instructions of, a form prescribed by the department.

(l) No person shall make, sell, lease, transfer, loan, or install radiation equipment subject to the registration requirement of this section or the supplies used in connection with such equipment unless such supplies and equipment, when placed in operation and used, will meet the requirements of this Part.

(m) Every distributor or retailer of radiation equipment, or agent thereof, or radiation consultant, who installs, tests, or otherwise services radiation equipment shall be registered with the commissioner on a form prescribed by them. Registration shall be made prior to undertaking such installation, testing, or servicing. Such distributors, retailers, agents or consultants shall, while engaged in installation, testing, or other servicing of radiation equipment, comply with the requirements of this Part.

16.51 General requirements for and prohibited uses of radiation equipment.

(a) General requirements. All radiation equipment shall meet any applicable specific provision of the sections of this Part set forth under the heading "Radiation Equipment" (section 16.50 to 16.70), and all possession or use thereof shall comply with the requirements of sections of this Part set forth under the heading "General Provisions" (section 16.1 through 16.20), and any other requirement imposed by the department. Radiation equipment which is not intended to be used must be made inoperable to the satisfaction of the department by dismantling or sealing with an official New York State Department of Health seal or other suitable method; and shall not be unsealed or restored to operable condition without prior authorization by the department.

(b) Prohibited uses and activities include the following:

(1) non-image intensified fluoroscopic equipment which has not been certified in accordance with 21 CFR 1020 as revised and implemented in full on January 20, 2023. (*See* section 16.200 of this Part);

(2) shoe-fitting fluoroscopic devices;

(3) intra-oral fluoroscopy used in dental examinations;

(4) photofluorographic equipment;

(5) the sale of gold jewelry which is known by the owner to be contaminated with radioactive materials, except for sale to the department;

(6) body composition assessment or analysis not under the direction and order of an authorized individual pursuant to section 16.19 of this Part;

(7) exposure of human beings for demonstration purposes;

(8) hand-held fluoroscopic devices.

(c) Beam Quality *Half-value layer (HVL)*. The HVL of the useful beam for a given x-ray tube potential shall not be less than the appropriate value shown in Table 1 in paragraph (c)(1) of this section under the heading "Specified Dental Systems," for any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980; under the heading "I--Other X-Ray Systems," for any dental x-ray system designed for use with intraoral image receptors and manufactured before December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006; and under the heading "II--Other X-Ray Systems," for all x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006. If it is necessary to determine such HVL at an x-ray tube potential which is not listed in Table 1 in paragraph (c)(1) of this section, linear interpolation or extrapolation may be made. Positive means shall be provided to ensure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure. Table 1 follows:

Table 1

X-Ray Tube Voltage (kilovolt peak)	Measured Operating	Minimum HVL (mm of aluminum)		
Designed Operating Range	Potential	Specified Dental Systems[1]	I--Other X-Ray Systems[2]	II--Other X-Ray Systems[3]
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

[1]Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.

[2]Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006.

[3]All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

16.52 Electrical hazards.

(a) All radiation equipment, except equipment used solely in research and development, installed in a radiation installation shall, where applicable, be listed by the Underwriters Laboratories Inc., or shall comply with The National Electrical Code of the National Fire Protection Association (NFPA), as implemented by NFPA70: National Electric Code 2023, which is hereby incorporated by reference, or an equivalent safety standard.

(b) Existing equipment employing uninsulated or bare overhead conductors moved to a new location or registered as a new installation under section 16.50 of this Part shall be certified as being free of electrical hazards.

(c) Certification by a duly authorized local authority that the installation is free of electrical hazards shall be acceptable.

16.53 Dental radiographic installations.

(a) Intraoral Equipment.

(1) The protective tube housing shall be of diagnostic type.

(2) Diaphragms or cones shall be used for restricting the useful beam to the area of clinical interest and shall provide at least the same degree of protection as is required of the tube housing.

(3) The diameter of the useful beam at the face of the patient shall not exceed three inches.

(4) A cone or spacer frame shall provide a source-skin distance of not less than seven inches with equipment operating above 50 kVp or four inches with equipment operating at 50 kVp or below for intra-oral radiography.

(5) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(6) A device shall be provided to terminate the exposure after a preset time interval or exposure. The exposure switch shall be of the dead-man type and, where protective barriers are required, shall be so arranged that it cannot be operated outside the shielded area.

(7) Each installation shall be so arranged that the operator can stand at least six feet from the patient, the X-ray tube, and the useful beam during exposure. A protective barrier shall be provided where the operator cannot stand at least six feet away from the patient, the X-ray tube and the useful beam during exposures.

(8) The tube head shall remain stationary when placed in the exposure position.

(b) Conditions for operation of equipment.

(1) The film or image receptor shall not be held by the dentist or technician during the exposure.

(2) Only the patient shall be in the useful beam.

(3) Neither the tube housing, pointer nor cone shall be handheld during the exposure.

(4) Only persons required for the radiographic procedure shall be in the radiographic room during the exposure.

(5) For extra-oral radiography, the x-ray film used as the recording medium during the x-ray examination shall show substantial evidence of cut-off (beam delineation).

(c) Special installations.

(1) Panoramic installations are dental installations which consist of a tube head with a collimator providing a narrow (1-2mm) useful beam and an extra-oral film carrier which are interlocked in their motion about the patient.

(i) Equipment.

(*a*) The protective tube housing shall be of diagnostic-type.

(*b*) Diaphragms or cones shall be used for restricting the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the tube housing.

(*c*) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(*d*) A device shall be provided to terminate the exposure after a preset time interval or exposure. The exposure switch shall be of the dead-man type.

(*e*) Each installation shall be provided with a protective barrier for the operator or shall be so arranged that the operator can stand at least six feet from the patient, the X-ray tube, and the useful beam.

(ii) Conditions for operation of equipment. Only the patient shall be in the useful beam.

(2) Handheld X-ray devices - portable dental X-ray devices which are used in dentistry for taking intraoral radiographs. The devices are battery-powered, portable and designed to be used when held in the hands of the operator during exposure. Only units that are FDA approved and have been reviewed and approved by the department may be used in New York State.

(i) Equipment.

(*a*) The protective tube housing shall be of diagnostic type.

(*b*) Diaphragms or cones shall be used for restricting the useful beam to the area of clinical interest and shall provide at least the same degree of protection as is required of the tube housing.

(*c*) For intra-oral radiography the diameter of the useful beam at the face of the patient shall not exceed three inches.

(*d*) A cone or spacer frame shall provide a source-skin distance of not less than seven inches with equipment operating above 50 kVp or four inches with equipment operating at 50 kVp or below for intra-oral radiography.

(*e*) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(*f*) A device shall be provided to terminate the exposure after a preset time interval or exposure. The exposure switch shall be of the dead-man type, the handheld unit shall be operated with the scatter shield in place.

(*g*) Each installation shall be so arranged that the operator can stand behind the X-ray tube, and the useful beam during exposure.

(*h*) The unit shall only be operated by authorized personnel who have been trained in the operation of the device.

(*i*) When not in use the handheld unit must be secured to prevent inadvertent exposures or use by unauthorized personnel.

(*j*) The backscatter shield shall be in place.

(3) Cone Beam CT (CBCT) – the requirements of section 16.65 of this Part shall apply.

16.54 Veterinary radiographic and fluoroscopic installations.

(a) Fixed radiographic, CT, CBCT installations.

(1) Equipment.

(i) The protective tube housing shall be of diagnostic type.

(ii) Collimating devices capable of restricting the useful beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required of the tube housing.

(iii) The images shall show substantial evidence of cut-off (beam delineation).

(iv) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown below:

Operating kVp	Minimum total filter (Inherent plus added)
Below 50 kVp	0.5 mm aluminum
50-70 kVp	1.5 mm aluminum
Above 70 kVp	2.5 mm aluminum

(v) A device shall be provided which terminates the exposure after a preset time interval or exposure. The exposure switch shall be of the dead-man type and shall be so arranged that it cannot be operated outside a shielded area.

(2) Structural shielding.

(i) Control apparatus for the radiographic equipment shall be located in an adjacent room or in a fixed booth within the same room, provided such booth is composed of radiation shielding material to a minimum height of seven feet. The control booth either shall be so arranged that

the radiation has to be scattered at least twice before entering the booth, or shall be provided with a protective door that is interlocked in such a way that the X-ray tube(s) cannot be energized unless the door is in the closed position.

(ii) The operator shall be able to see the animal patient by means of a mirror or through a window of lead equivalent sufficient for the required protection and so placed that the operator is always in a shielded position.

(3) Conditions for operation of equipment.

(i) Only persons required for the X-ray procedure shall be in the X-ray room during the exposures.

(ii) When an animal patient must be held in position during exposures, mechanical supporting or restraining devices shall be used. Animal patients or image receptors shall be held only under extreme conditions when clinically necessary. Individuals holding animal patients or image receptors shall wear protective gloves having at least 0.5 mm lead equivalent, a protective apron of at least 0.25 mm lead equivalent, and shall keep all parts of their body out of the useful beam. The exposure of any individual used for holding animals shall be monitored. Pregnant women and persons under 18 years of age shall not hold animal patients or films under any conditions.

(b) Portable or mobile radiographic installations.

(1) Equipment.

(i) The protective tube housing shall be of diagnostic type.

(ii) Collimating devices capable of restricting the useful beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required of the tube housing.

(iii) The X-ray images shall show evidence of cut-off (beam delineation).

(iv) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown below:

Operating kVp	Minimum total filter (Inherent plus added)
Below 50 kVp	0.5 mm aluminum
50-70 kVp	1.5 mm aluminum
Above 70 kVp	2.5 mm aluminum

(v) A device shall be provided which terminates the exposure after a preset time interval or exposure.

(vi) A dead-man type of exposure switch shall be provided with a cord sufficiently long so that the operator can stand at least six feet from the animal patient, the X-ray tube, and the useful beam.

(2) Conditions for operation of equipment.

(i) No person shall be regularly employed to support or hold animals or film during X-ray exposures.

(ii) When an animal must be held in position during exposures, mechanical supporting or restraining devices shall be used. Individuals should hold animals only when clinically necessary under extreme conditions. Such individuals shall wear protective gloves having at least 0.5 mm lead equivalent, a protective apron of at least 0.25 mm lead equivalent, and shall keep all parts of his body out of the useful beam. The exposure of any individual used for holding animals shall be monitored. Pregnant women and individuals under 18 years of age shall not hold animals under any conditions,

(c) Fluoroscopic installations.

(1) Equipment.

(i) The protective tube housing shall be of diagnostic type.

(ii) Equipment shall be so constructed that the entire cross section of the useful beam is always intercepted by a primary protective barrier (usually a lead glass screen or image intensifier assembly) irrespective of the panel screen distance. For conventional fluoroscopes, this requirement may be assumed to have been met if, when the collimating system is opened to its fullest extent, an unilluminated margin is left on all edges of the fluorescent screen regardless of the position of the screen during use.

(*a*) Collimators, and adjustable diaphragms, or shutters used to restrict the size of the useful beam shall provide the same degree of protection as is required of the tube housing.

(*b*) The exposure shall automatically terminate when the barrier is removed from the useful beam.

(*c*) With the fluorescent screen 14 inches from the panel of the tabletop, the exposure rate two inches beyond the viewing surface of the screen shall not exceed 30 mR/hr for each roentgen per

minute at the tabletop with the screen in the useful beam without a patient and with the fluoroscope operating at the highest potential employed.

(iii) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown below:

Operating kVp	Minimum total filter (Inherent plus added)
Below 50 kVp	0.5 mm aluminum
50-70 kVp	1.5 mm aluminum
Above 70 kVp	2.5 mm aluminum

(iv) The fluoroscopic exposure switch shall be of the dead-man type.

(v) Mobile fluoroscopic equipment is subject to the following additional requirements:

(*a*) in the absence of a tabletop, a cone or spacer frame shall limit the source-to-skin distance to not less than 12 inches;

(*b*) image intensification shall always be provided;

(*c*) it shall be impossible to operate a machine unless the useful beam is intercepted by the image intensifier.

(2) Conditions for operation of equipment.

(i) Protective gloves and aprons of at least 0.25 mm lead equivalent each shall be made available and shall be worn by the fluoroscopist during every examination.

(ii) Unless measurements indicate that they are not needed protective gloves and protective aprons of at least 0.25 mm lead equivalent each shall be worn by the physician, nurse, technician and all other persons within the fluoroscopic room.

(iii) Only persons needed in the fluoroscopic room shall be present during the exposure.

(iv) The fluoroscopic room shall be free of extraneous light that interferes with the examination.

(d) Special installations.

(1) Handheld X-ray devices. The requirements of paragraph 16.53(c)(2) of this Part shall apply, except that "Animal" shall replace any reference to "human being" or "patient."

16.55 Podiatric radiographic installations.

(a) Equipment.

(1) The protective tube housing shall be of diagnostic type.

(2) Collimating devices capable of restricting the useful beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required of the tube housing.

(3) The X-ray images shall show substantial evidence of cut-off (beam delineation).

(4) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(5) A device shall be provided which terminates the exposure after a preset time interval or exposure. The exposure switch shall be of the dead-man type and where protective barriers are required shall be so arranged that it cannot be operated outside the shielded area.

(6) Each installation shall be arranged so that the operator can stand at least six feet from the patients, the X-ray tube and the useful beam during exposure. A protective barrier shall be provided when the operator cannot stand at least six feet away from the patient, the X-ray tube and useful beam during exposures.

(b) Conditions for operation of equipment.

(1) No person shall hold film during the exposure.

(2) Only persons required for the radiographic procedure shall be in the radiographic room during exposure.

(c) Special Installations.

(1) Handheld X-ray devices,

(i) The requirements of paragraph 16.53(c)(2) of this Part shall apply for patient anatomy limited to the foot.

(ii) The handheld unit is operated with the manufacturer's stand.

(2) Cone Beam CT – the requirements of section 16.65 of this Part shall apply.

16.56 Radiographic installations excluding dental, veterinary, and podiatric installations.

(a) Equipment.

(1) The protective tube housing shall be of diagnostic type.

(2) Collimating devices capable of restricting the useful beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required of the tube housing.

(3) The X-ray images shall show substantial evidence of cut-off (beam delineation).

(4) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(5) A device shall be provided which terminates the exposure after a preset time interval or exposure.

(6) A dead-man type of exposure switch shall be used and so arranged that it cannot be operated outside a shielded area. Exposure switches for "spot-film" devices used in conjunction with fluoroscopic equipment are excepted from this shielding requirement.

(7) The tube head shall remain stationary when placed in the exposure position.

(b) Structural shielding.

(1) Except for mammography systems, control apparatus for the radiographic equipment shall be located in an adjacent room or in a fixed booth within the same room provided such booth is composed of radiation shielding material to a minimum height of seven feet. The control booth either shall be so arranged that the radiation has to be scattered at least twice before entering the booth, or shall be provided with a protective door that is interlocked in such a way that the X-ray tube(s) cannot be energized unless the door is in the closed position.

(2) The operator shall be able to see the patient by means of a mirror, through a window of lead equivalent material sufficient for the required protection, closed-circuit television, or an equivalent and so placed that the operator is always in a shielded position.

(3) Provision shall be made for the operator to communicate with the patient from a shielded position.

(c) Conditions for operation of equipment.

(1) No person shall be regularly employed to hold patients or image receptors during exposures, nor shall such duty be performed by any individual occupationally exposed to radiation during the course of their other duties. When it is necessary to restrain the patient, mechanical supporting or restraining devices shall be used whenever possible. If patients or image receptors must be held by an individual, that individual shall be provided with appropriate shielding devices such as protective gloves and a protective apron of at least 0.25 mm lead equivalent. No part of the attendant's body shall be in the useful beam. The exposure of any individual used for holding patients shall be determined. Pregnant women and persons under 18 years of age shall not hold patients under any conditions.

(2) Only persons required for the radiographic procedure shall be in the radiographic room during exposure; and, except for the patient, all such persons shall be equipped with appropriate shielding devices such as protective gloves and a protective apron of at least 0.25 mm lead equivalent.

16.57 Portable, bedside or mobile X-ray equipment excluding dental, veterinary and podiatric equipment.

(a) Equipment.

(1) The protective tube housing shall be of diagnostic type.

(2) Collimating devices capable of restricting the useful beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required of the tube housing.

(3) The X-ray images shall show substantial evidence of cut-off (beam delineation).

(4) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(5) A device shall be provided which terminates the exposure after a preset time interval or exposure.

(6) All mobile, portable or beside equipment shall be provided with cones or metal frames so that the minimum source to skin distance is at least 12 inches.

(7) The exposure switch shall be of the dead-man type and shall be provided with a cord of sufficient length that the operator can stand at least six feet from the patient, the X-ray tube and the useful beam.

(b) Use. If a mobile unit is used routinely in any location, it shall be considered a fixed installation, and shall meet the requirements of section 16.56 of this Part.

(c) Conditions for operation of equipment.

(1) No person shall be regularly employed to hold patients or image receptors during exposures, nor shall such duty be performed by any individual occupationally exposed to radiation during the course of their other duties. When it is necessary to restrain the patient, mechanical supporting or restraining devices shall be used. If patient or image receptors must be held by an individual, that individual shall be protected with appropriate shielding devices such as protective gloves and a protective apron of at least 0.25 mm lead equivalent. No part of the attendant's body shall be in the useful beam. The exposure of any individual used for holding patients shall be monitored. Pregnant women and persons under 18 years of age shall not hold patients under any conditions.

16.58 Fluoroscopic installations excluding veterinary installations.

(a) Equipment.

(1) The protective tube housing shall be of diagnostic type.

(2) Equipment shall be so constructed that the entire cross section of the useful beam is always intercepted by the primary protective barrier irrespective of the position.

(i) Collimators and adjustable diaphragms or shutters used to restrict the size of the useful beam shall provide the same degree of protection as is required of the tube housing.

(ii) The exposure shall automatically terminate when the barrier is removed from the useful beam.

(3) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in Table 1 of section 16.51(c) of this Part.

(4) Fluoroscopic exposure switch shall be of the dead-man type.

(5) Source-skin distance.

(i) Means shall be provided to limit the source-skin distance to not less than 38 cm on stationary fluoroscopes and to not less than 30 cm on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 20 cm. When provided, the manufacturer must set forth precautions with respect to the optional means of spacing.

(ii) For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than 45 cm, means shall be provided to limit the source-skin distance to not less than 19 cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 10 cm. When

provided, the manufacturer must set forth precautions with respect to the optional means of spacing.

(6) Fluoroscopy equipment shall not be operated for human use unless a cumulative timing device, activated by the fluoroscope exposure switch, is functioning. It shall indicate the passage of a period of irradiation, not exceeding five minutes, either by an audible signal or by temporary interruption of the irradiation.

(7) The exposure rate as measured, at no less than 70 kVp, if the machine is capable of this, otherwise the max kVp, in the mode of least magnification with the image intensifier at 30 cm above the tabletop or over table fluoroscopy tube at a source to image distance normally used for an average patient, with a patient phantom composed of 1 and 1/2 inches of Type 1100 aluminum plus 0.5 mm of copper, in a 7 inch square or an equivalent device in the fluoroscopic beam shall not exceed 5 roentgens per minute except during recording of fluoroscopic images or during activation of optional high level control. The maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 88 mGy per minute (10 roentgens per minute) except as follows:

(i) Equipment manufactured before May 19, 1995 and certified in accordance with 21 CFR 1020 as revised and implemented in full on January 20, 2023, (see section 16.200 of this Part) and having an optional high level control is limited to a maximum output of 44 mGy per minute (5 roentgens per minute) unless the high level control is activated and an audible signal to that effect is provided. When the high level control is activated, the maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 176 mGy per minute (20 roentgens per minute).

(ii) Certified equipment manufactured after May 19, 1995 with automatic exposure rate and having an optional high level control is limited to a maximum output of 88 mGy per minute (10 roentgens per minute) unless the high level control is activated and an audible signal to that effect is provided. When the high level control is activated, the maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 20 roentgens per minute.

(iii) Certified equipment manufactured after May 19, 1995 without automatic exposure rate is limited to 44 mGy per minute (5 roentgens per minute) unless the high level control is activated and an audible signal to that effect is provided. When the high level control is activated, the maximum exposure rate measured in air at a point where the center of the useful beam enters the patient shall not exceed 176 mGy per minute (20 roentgens per minute).

(8) Primary protective barriers shall provide the following protection:

(i) For uncertified equipment, with the image intensifier 36 cm (14 inches) from the tabletop, the exposure rate two inches beyond the image intensifier shall not exceed 5uGy/hr (30 mR/hr) for each roentgen per minute at the tabletop with the intensifier in the useful beam without a patient and with the fluoroscope operating at the highest potential available for use.

(ii) For certified equipment, the exposure rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the image intensifier, if provided, shall not exceed 0.33 uGy per hour (two milliroentgens per hour) at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each 0.01 Gy per hour (roentgen per minute) or entrance exposure rate.

(9) The spatial resolution of the fluoroscopic system shall be measured using a test tool composed of a line pair (lp) plate with discreet line pair groups and a maximum lead foil

thickness of 0.1 mm or an equivalent device. The test tool shall be placed on a 0.75 inch (19 mm) thickness of type 1100 aluminum, large enough to completely intercept the useful beam, with the test tool 12 inches (30 cm) from the entrance surface of the image receptor assembly. If the system has variable source-to-image distance (SID), the measurement SID shall not exceed 40 inches (100 cm). The image receptor of the fluoroscopic system shall be operated in the largest available field of view (FOV) that does not exceed six inches (15 cm). If all the fluoroscopic system's FOVs exceed six inches (15 cm), the system shall be operated in the smallest FOV. The minimum spatial resolution at center of the beam for all FOVs shall be determined by the following equation: 2 lp/mm x (6 inches (15cm)/size of FOV used) = minimum number of lp/mm.

(10) The low contrast performance of the fluoroscopic system shall be capable of resolving a minimum hole size of 3 mm using a test tool composed of a 1.0 mm aluminum sheet with two sets of four holes of dimension 1.0, 3.0, 5.0 and 7.0 mm and a patient equivalent phantom or an equivalent device.

(11) Radiation therapy simulation systems shall be exempt from the requirements of paragraphs (2), (6), (7) and (8) of this subdivision provided that:

(i) the systems are designed and used in a manner such that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and

(ii) systems which do not meet the requirements of paragraph (6) of this subdivision are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

(b) Conditions for operation of equipment.

(1) The operator of the installation shall make and record the outputs made pursuant to paragraph (7) of subdivision (a) of this section, where the center of the useful beam enters the patient during routine fluoroscopy and cinefluoroscopy, at annual intervals or more frequently if outputs are found to exceed the limits defined in this section.

(2) Other than tabletop mini C-arms, protective garments of at least 0.25 mm lead equivalent material each shall be worn by the physician, nurse, radiologic technologist and all other persons within the fluoroscopic room. In lieu of wearing protective garments, the use of a method of dose reduction equivalent to protective garments is acceptable, provided that measurements are made demonstrating its effectiveness.

(3) Only persons needed in the fluoroscopic room shall be present during the exposure.

(4) The cumulative fluoroscopic time must be reset for each new patient.

(5) Displays of values of AKR and cumulative air kerma. Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the AKR and cumulative air kerma. The following requirements apply for each x-ray tube used during an examination or procedure:

(i) When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in mGy/min shall be continuously displayed and updated at least once every second.

(ii) The cumulative air kerma in units of mGy shall be displayed either within 5 seconds of termination of an exposure or displayed continuously and updated at least once every 5 seconds.

(iii) The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma.

(iv) The AKR and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope. The reference location shall be identified and described specifically in the information provided to users according to 21 CFR 1020.30(h)(6)(iii) as revised and implemented on January 20, 2023.

16.59 Computed Tomography (CT) equipment.

(a) Definitions

(1) “Computed tomography (CT)” scan and “computerized axial tomography (CAT)” scan refer to an imaging procedure that uses x-rays to create cross-sectional images of the human body.

(2) “Computed tomography dose index” (CTDI) means the integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan where the dose profile is centered around z = 0 and for a multiple tomogram system, the scan increment between adjacent scans is nT;

z = position along a line perpendicular to the tomographic plane;

D (z) = Dose at position z;

T = Nominal tomographic section thickness;

n = Number of tomograms produced in a single scan

(3) “CT x-ray system” is technology that is used to perform CT scans and includes but is not limited to, a control panel, image display device, gantry, x-ray tube, collimating device with filters, high voltage transformer and a data acquisition system.

(4) “CT scanner” refers to technology used to perform and interpret CT scans and includes, but is not limited to, a control panel, gantry, high voltage generator, x-ray tube, table and display devices that are used for image interpretation.

(5) “CTDI100” is the dose measurement made with a 16 cm diameter (head/pediatric body) or a 32 cm diameter (body) acrylic phantom. The measurements are made utilizing a 100 mm long pencil ionization chamber. Readings are made with the ion chamber in both the center (axial or central dose) position and near surface slots of the phantom (the peripheral dose).

(6) “CTDIW”, the weighted or blended dose, is calculated by adding together two-thirds of the CTDI100 peripheral dose with one-third of the CTDI100 axial or center dose. (CTDIW = 2/3 CTDI100 peripheral + 1/3 CTDI100 axial or center). CTDIW represents an average dose in the x and y planes.

(7) “CTDIVOL” represents the integrated dose over the total volume that is irradiated, CTDIVOL = (1/PITCH) x (CTDIW), where “Pitch” is defined as the table travel per rotation divided by the collimation of the x-ray beam. CTDIVOL represents the average dose in the x, y and z planes.

(8) "CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including nominal tomographic section thickness, filtration, and the technique factors.

(9) "CT dosimetry phantom" means the phantom used for determination of the dose delivered by a CT x-ray system. The phantom shall be a right circular cylinder of polymethyl-methacrylate of density 1.19±0.01 grams per cubic centimeter. The phantom shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing any CT system designed to image any section of the body (whole body scanners) and 16.0 centimeters for any system designed to

image the head (head scanners) or for any whole-body scanner operated in the head scanning mode. The phantom shall provide means for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom.

(10) “Dose length product” (DLP) is defined as the CTDIvol times the irradiated length of the body for the whole series of images that are taken during a CT scan.

(11) “Picture Archiving and Communication System (PACS)” is a medical imaging technology that provides access to and storage for medical images from multiple modalities. It is comprised of an image acquisition system, display, network and data storage or archiving system.

(12) "Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

(13) "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram or a series of tomograms.

(14) "Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

(15) “Technique” means the settings selected on the control panel of the equipment and may include the position of the x-ray tube, image intensifier and patient.

(16) “Technique chart” means a chart that lists the standard settings and positions for a given technique.

(17) “Tomogram” is an image of a tissue plane or section of tissue.

(18) "Tomographic plane" means that geometric plane which the manufacturer identified as corresponding to the output tomogram.

(19) "Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

(b) CT X-Ray System Equipment Requirements.

(1) Each control panel and gantry of a CT x-ray system shall include visual signals that indicate to the operator of the CT x-ray system whenever x-rays are being produced and when x-ray production is terminated, and, if applicable, whether the shutter is open or closed.

(2) Each CT x-ray system shall be equipped with a control that allows the operator of the CT x-ray system to terminate the x-ray exposure at any time during a scan, or series of scans, when the exposure time is greater than one-half second duration.

(3) Each CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence are indicated prior to the initiation of a scan or a scan sequence.

(4) Each CT x-ray system shall include a clearly and conspicuously labeled emergency shutoff button or switch.

(5) Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation by the operator prior to the initiation of another scan.

(c) Patient communication and viewing requirements.

(1) Each CT x-ray system shall be equipped to allow two-way aural communication between the patient and the operator at the control panel.

(2) Each CT x-ray system shall be equipped with windows, mirrors, closed-circuit television, or an equivalent to permit continuous visual observation of the patient during CT scanning by the CT operator from the control panel.

(3) When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

(d) Calibration.

(1) Each registrant shall ensure that the calibration of the radiation output of each CT x-ray system that it operates is performed by, or under the direction of, a licensed medical physicist.

(2) Each registrant shall maintain and make available for review by the department, on the premises of its radiation installation where a CT x-ray system is located written procedures for the appropriate calibration of the CT x-ray system.

(3) After initial installation, the CT x-ray system shall be calibrated prior to its use on human beings and recalibrated at least within every 14 months thereafter. Any change or replacement of components of a CT x-ray system which could cause a change in the radiation output will require a recalibration within 30 days of component installation by, or under the direction of, a licensed medical physicist operating within their scope of practice.

(4) The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. This system shall have been calibrated either by the National Institute of Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL) and traceable to NIST. The calibration shall have been performed within the previous 24 months and after any servicing that might have affected system calibration.

(5) CT dosimetry phantom(s) shall be used in determining the radiation output of each CT x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

(i) Any effects on the doses measured because of the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

(ii) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(iii) The requirements of subparagraphs (i) and (ii) of this paragraph can also be met by using an alternative method of radiation measurement and calculation published in the peer-reviewed scientific literature and acceptable to the department.

(6) Records of calibrations performed shall be maintained for a period of three (3) years at the radiation installation where the CT is located.

(e) Quality Assurance Testing

(1) Each registrant shall maintain a Quality Assurance (QA) manual that shall contain written procedures for all testing and shall meet the requirements specified in this section and section 16.23(a)(1) of this Part. The CT Quality Assurance procedures shall have been developed under the direction of a licensed medical physicist or radiologist.

(2) The QA procedures shall incorporate the use of one or more image quality dosimetry phantoms, or the phantom supplied by the original equipment manufacturer which have the capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CT Number for water or other reference material. All these image quality parameters shall be evaluated at least annually by a licensed medical physicist.

(3) Written records of the QA checks performed by the registrant shall be maintained for review by the department for a period of at least three (3) years.

(4) QA checks shall include the following:

(i) Images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations. The images shall be retained as photographic copies or as electronic copies stored within the CT x-ray system or stored on the PACS.

(ii) Dose assessment for the most common CT examinations that are performed on the system for which reference levels have been published by the American College of Radiology (ACR), the American Association of Physicists in Medicine (AAPM) or the National Council on Radiation Protection and Measurements (NCRP) for pediatric heads, pediatric abdomens, adult heads and adult abdomens.

(iii) An evaluation of image quality.

(f) Operating Procedures and Policies

(1) The CT x-ray system shall not be operated on a human being except by a physician or by a radiologic technologist licensed pursuant to article 35 of the Public Health Law who has been specifically trained in its operation.

(2) The registrant shall ensure that each CT x-ray system has a radiation protection survey or other measurement and assessment of exposure to persons in controlled and non-controlled areas made at the time of installation. Additional radiation protection surveys shall be done after any change in the radiation installation or equipment which might cause a significant increase in radiation hazard.

(3) Each CT x-ray system shall have available at the control panel or nearby within the CT control room written information regarding the operation and calibration of the CT x-ray system. Such information shall include:

(i) dates of the latest calibration and QC checks and the location within the facility where the results of those tests may be obtained;

(ii) instructions on the use of the CT dosimetry phantom(s) including a schedule of QC tests that are appropriate for the system as determined by the manufacturer, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;

(iii) a current set of default protocols are available at the control panel (either electronically or as a document) which specifies for each routine examination the CT conditions of operation and the slice thickness, spacing between slices and/or pitch;

(iv) a list of techniques optimized for the body part being imaged to obtain a quality image and to ensure that the lowest amount of radiation is used as consistent with good medical practice.

(4) If the QC testing on the CT x-ray system identifies that a system operating parameter has exceeded a tolerance as specified in the Quality Assurance manual, use of the CT x-ray system on patients shall be limited to those exceptions permitted by established written instructions of the licensed medical physicist or radiologist. Upon completion of corrective action, the QC testing shall be repeated to verify that the system is back within tolerance.

(5) Each registrant performing CT scans on human beings shall ensure that for each scan, the radiation dose delivered by the scanner to a reference phantom or the dose received by the patient is saved and recorded. The dose delivered shall be recorded as Computed Tomography Dose Index volume (CTDIvol), dose length product (DLP) or other dosimetry metric published

in the peer reviewed scientific literature and acceptable to the department. The dose received by a patient shall be recorded as organ dose or other dosimetry metric published in the peer reviewed scientific literature and acceptable to the department.

(6) The displayed dose shall be verified on an annual basis by or under the supervision of a licensed medical physicist to ensure that the equipment manufacturer's displayed dose is within 20% of the measured dose.

(7) Each current registrant that performs diagnostic CT scans on human beings shall be accredited by a nationally recognized accreditation program that is acceptable to the department. A facility performing CT that loses their existing accreditation or a registrant or licensee that fails to obtain accreditation must report this fact within 30 days to the department. New licensees or registrants will have 18 months to become accredited, but must demonstrate that they have initiated the accreditation process within 90 days of the start of operations. New units at existing registrations and replacement units will begin the accreditation process as soon as possible but no later than 90 days following installation.

(8) Each registrant that performs CT scans on human beings shall establish and implement a policy and a procedure to ensure that:

(i) a request for a CT scan originates from a physician or other authorized health care practitioner familiar with the patient's clinical condition; and

(ii) the request includes sufficient information to demonstrate the medical indication for the CT examination and allow for the proper performance and interpretation of the CT scan.

(g) Exemptions – CT equipment used exclusively for non-diagnostic purposes does not need to meet the accreditation requirements of this section. This includes but is not limited to the

following: attenuation correction, biopsy, guiding or delivering treatment planning and post operative units.

16.60 Therapy equipment operated at potentials over 60 kVp.

(a) Equipment.

(1) The protective tube housing shall be of therapeutic type.

(2) Fixed diaphragms or cones used to restrict the useful beam shall be constructed so as to provide the same degree of protection as is required of the tube housing.

(3) Adjustable or removable beam limiting diaphragms or cones shall not transmit more than five percent of the useful beam at the maximum kilovoltage and with the maximum treatment filter.

(4) The filter system shall be so arranged as to minimize the possibility of error in filter selection and alignment. The filter slot shall be so constructed that the radiation escaping through it does not produce an exposure exceeding one roentgen per hour at one meter, or if the patient is likely to be exposed to radiation escaping from the slot, 30 roentgens per hour at two inches (five centimeters) from the external opening. Each removable filter shall be marked with its thickness and material.

(5) It shall be possible for the person operating the controls of the therapeutic equipment to determine from the operating position what filters are in place in the equipment. Filters shall be so mounted as to prevent their movement during treatment.

(6) The X-ray tube shall be secured so that it cannot move in respect to the housing aperture. A mark on the exterior of the tube housing is recommended to indicate the focal spot.

(7) Adequate devices shall be provided to secure the tube housing during stationary portal treatment.

(8) An easily discernible indicator which shows whether or not X-rays are being produced shall be on the control panel.

(9) A suitable exposure control device (e.g. an automatic timer, exposure meter or dose meter) shall be provided to terminate the exposure automatically after a preset time interval or preset exposure or dose limit. Means shall be provided for the operator to terminate the exposure at any time.

(10) Equipment utilizing shutters to control the useful beam shall have a shutter position indicator on the control panel.

(b) Structural shielding.

(1) The protective barriers for all therapy equipment operating at voltages above 60 kVp shall not be removable.

(2) The control panel for all therapy equipment operating at voltages above 150 kVp shall be located outside the treatment room.

(c) Conditions for operation of equipment.

(1) The beam output shall be calibrated prior to the use of the apparatus for treating humans. Calibration shall be performed by an individual who is currently licensed by the New York State Department of Education as a Medical Physicist – Therapeutic Radiology. The method of calibration used shall be in accordance with procedures recommended by the American Association of Physicists in Medicine for the energy and type of radiation employed. Calibration shall be made at least annually. Recalibration, however, shall be made after each tube replacement and after any changes or replacements in the generating apparatus, or changes or

updates in computer programs which govern or interact with the functions of the machine, and which could change the X-ray output.

(2) No person other than the patient, shall be permitted to remain within the therapy room while the generator is in operation at voltages above 150 kVp. At voltages less than or equal to 150 kVp, any individual in the treatment room, other than the patient, must be protected by a protective barrier required by this Part.

(3) Every entrance to a therapy room in which equipment is capable of operating above 150 kV shall be protected by interlocks to insure that during the production of ionizing radiation no person can enter the therapy room without turning off the radiation equipment. Interlocks shall be so arranged that irradiation equipment cannot be started again without manually resetting the controls.

(4) Windows, mirror systems, or closed-circuit television viewing screens shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may see the patient and the control panel from the same position.

(5) Provision shall be made for oral communication with the patient.

(6) In addition to the interlocking controls, there shall be installed alerts which are readily observable or discernible near the outside of all access doors to indicate the production of ionizing radiation.

(7) No therapy vault shall be able to be closed from inside the therapy vault.

(8) Instructions for emergency response, contact information for manufacturer's technical assistance, radiation oncologist, medical physicist and the RSO should be posted at the control console.

16.61 Therapy equipment operating at potentials of 60 kVp and below.

(a) Equipment. All provisions of subdivision (a) of section 16.60 shall apply except that the leakage five centimeters from the surface of the tube housing shall not exceed 0.1 roentgen per hour.

(b) Conditions for operation of equipment.

(1) The output of the X-ray generator shall be calibrated prior to the use of the apparatus for treating humans. Calibration shall be performed by an individual who is currently licensed by the New York State Department of Education as a Medical Physicist – Therapeutic Radiology. The method of calibration used shall ensure accurate delivery of the prescribed dose under all conditions of use. Calibrations shall be made at least annually. Recalibration, however, shall be made after each tube replacement and after any changes or replacements in the generating apparatus which could change the x-ray output.

(2) If the tube must be hand-held during irradiation, the operator shall wear protective gloves and a protective apron of no less than 0.5 mm lead equivalent material.

(3) The operator shall be able to observe and communicate with the patient during irradiation.

(4) Equipment having an output of more than 1,000 roentgens per minute at any accessible place shall not be left unattended without the power being shut off at the main disconnect switch in addition to the control panel switch.

(5) When operating equipment constructed with beryllium or other low filtration windows, the operator shall insure that the useful beam is blocked at all times except when actually being used.

(6) Instructions for emergency response, contact information for manufacturer's technical assistance, radiation oncologist, medical physicist and the RSO should be readily available. at the location of use of the device

16.62 Industrial Radiography.

Use of x-ray based Industrial Radiography equipment shall follow the requirements of section 16.119 of this Part, as applicable.

16.63 Miscellaneous and special types of radiation producing equipment. Types or uses of radiation producing equipment not specifically covered by this Part and not exempted in section 16.4 of this Part, and such other types or uses of radiation producing equipment as may be designated by the department, shall be subject to special inspection or surveys by the department. Such special inspections or surveys by the department shall, with respect to the radiation producing equipment so inspected or surveyed, substitute for the inspections required by paragraph (1) of subdivision (a) of section 16.10 of this Part.

16.64 RESERVED.

16.65 Diagnostic Cone Beam Computed Tomography (CBCT).

Cone Beam Computed Tomography – Cone beam computed tomography (or CBCT, also referred to as C-arm CT, Cone beam volume CT, or flat panel CT) is a medical imaging technique consisting of x-ray computed tomography where the x-rays are divergent, forming a cone.

(a) Equipment

(1) The protective housing shall be of diagnostic type.

(2) X-ray activation controls shall be mounted in a protected area and situated so that the operator is required to remain in the protected area during the entire exposure.

(3) Each control panel and CBCT system shall include visual signals that indicate to the operator of a system whenever x-rays are being produced and when x-ray production is terminated.

(4) Each CBCT x-ray system shall be equipped with a control that allows the operator of the CBCT system to terminate the x-ray exposure at any time during a scan, or series of scans.

(5) Each CBCT system shall include a clearly and conspicuously labeled emergency shutoff button or switch.

(6) Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CBCT conditions of operation by the operator prior to the initiation of another scan or series of scans.

(7) Each CBCT system shall be equipped to allow the operator at the control panel to maintain view of the patient by means of a window or mirror and two-way aural communication.

(b) Quality Assurance Program shall include:

(1) Identification of the facility New York State registration identification number.

(2) Identification of the make and model of the unit.

(3) Identification of the staff trained to perform QC testing and patient care.

(4) Identification of the licensed medical physicist.

(5) The most recent licensed medical physicist survey.

(i) Copies of the licensed medical physicist surveys shall be kept on file electronically or on paper for a period of three years.

(6) Documentation of preventive maintenance and service records, including any corrective actions.

(7) The provision of a formalized in-service training program for employees, provided prior to use on patients and thereafter annually, including:

(i) Basic radiation principles and safety.

(ii) Machine model specific training.

(iii) Displays and systems used for viewing.

(iv) Documentation of initial and annual training completion shall be maintained for a period of three years and available upon request.

(v) The practitioner shall attest in writing to employee completion of initial and annual training for each qualified employee allowed to operate the CBCT.

(vi) Examinations shall be performed only when clinically indicated and by written order of the practitioner.

(vii) No person shall be regularly employed for the purpose of imaging training demonstrations. This means no person shall be imaged for the express purpose of testing or demonstrating the equipment.

(8) Eighteen months after the effective date of this Part, each current registrant that performs diagnostic CBCT scans on human beings shall be accredited by a nationally recognized accreditation program that is acceptable to the department. A facility performing CBCT scans that loses their existing accreditation or a registrant or licensee that fails to obtain accreditation must report this fact within 30 days to the department. After the effective date of this Part new licensees or registrants will have 18 months to become accredited and must demonstrate that they have initiated the accreditation process within 90 days of the start of operations.

(c) Cone Beam CT Quality Control program.

(1) Test requirements may vary from manufacturer to manufacturer. Each cone beam CT unit shall be tested to the manufacturer's requirements, or a QC test program shall be developed in

consultation with the New York State licensed medical physicist if not provided by the manufacturer. Requirements include:

(i) Phantom test device from the manufacturer (FDA 21 CFR subchapter J section 1020.33 as revised and implemented in full on January 20, 2023) capable of QA/QC test completion as directed by the manufacturer or licensed medical physicist.

(ii) Documentation of QC test results and completion, including any system used for image viewing.

(2) Quality Control testing performed by a New York State licensed medical physicist or other individual authorized by law or regulation:

(i) Initial acceptance testing, testing after a major repair, software upgrade, or change to any part of the system affecting unit output and patient dose, and annual testing thereafter shall be performed by a New York State licensed medical physicist or other individual authorized by law or regulation, consistent with currently accepted professional standards. Physicist testing shall include but not be limited to:

(*a*) Calibration of the CBCT unit. The radiation output calibration of a CBCT x-ray system shall be performed with a calibrated dosimetry system. This system shall have been calibrated either by the National Institute of Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL) traceable to NIST. The calibration shall have been performed within the previous 24 months and after any servicing that may affect system calibration.

(*b*) Dose area product (DAP) or (KAP).

(*c*) Dose to pediatric and adult patients for the most common exam techniques.

(*d*) CT number for water or other reference material.

(*e*) Low and high contrast resolution.

(*f*) Noise.

(*g*) Scan localization accuracy.

(*i*) Artifacts.

(*j*) Field of View.

(*k*) Scatter measurements performed within 30 days of installation.

(3) Registrant QC testing responsibilities shall include:

(i) Daily or days of CBCT patient imaging:

(*a*) Equipment function indicators, mechanical, and other safety checks.

(*b*) Film processing or digital system QC, if applicable.

(*c*) CT number for water and bone.

(*d*) Field uniformity.

(*e*) Artifacts.

(*f*) Repeat or rejected patient images shall be monitored and include the reason for patient image repeat or reject.

(ii) Weekly:

(*a*) Image viewing system software and hardware – as applicable.

(iii) Ongoing:

(*a*) Repeat reject analysis as determined by section 16.23(a)(1)(xi) of this Part.

(4) Each registrant shall maintain and make available for review by the department, on the premises of its radiation installation where the CBCT system is located, written procedures for appropriate calibration of the CBCT x-ray system.

(d) Additional Requirements.

(1) Each patient record shall document exposure or dose area product (DAP) or air kerma (AK) (DAP or AK where indicated, system may display DAP or AK for each examination).

(2) Pediatric and adult patients' most common exam technique and the resulting dose, as determined annually by the licensed medical physicist, shall be displayed at the operator console.

(3) The CBCT system shall not be operated except by an individual who has been specifically trained in its operation.

(e) Exemptions. CBCT equipment used exclusively for non-diagnostic purposes, including but not limited to the following, does not need to meet the accreditation requirements of this section: attenuation correction, biopsy, guiding or delivering treatment planning and post operative units.

16.66 RESERVED.

16.67 RESERVED.

16.68 RESERVED.

16.69 RESERVED.

16.70 Use of Body Scanning.

(a) This section shall not apply in cities having a population of two million or more.

(b) Practitioners licensed under article 35 of the Public Health Law and unlicensed personnel employed at a local correctional facility may utilize body imaging scanning equipment that applies ionizing radiation to humans for purposes of screening inmates committed to such facility, solely in connection with the implementation of such facility's security program and in accordance with the provisions of this Part.

(c) Definitions.

(1) "Body imaging scanning equipment" or "equipment" means equipment that is specifically manufactured for security screening purposes and utilizes a low dose of ionizing radiation, with a

maximum exposure per scan equal to or less than 10 uSv (1 mrem), to produce an anatomical image capable of detecting objects placed on, attached to or secreted within a person's body. The utilization of body imaging scanning equipment is for purposes of screening inmates committed to such facility, in connection with the implementation of such facility's security program.

(2) "Local correctional facility" shall mean a local correctional facility as defined in Correction Law section 2(16).

(3) "Equipment operator" or "operator" means personnel employed at the local correctional facilities that have successfully completed a training course approved by the department.

(4)"Screening" means the sum of radiation exposures or scans necessary to image objects concealed on all sides of the body as intended by the system design under normal conditions.

(d) Equipment use and installation requirements.

(1) Prior to the equipment's first use on humans at a specific physical location or following any major repairs that could influence image quality or exposure:

(i) body imaging scanning equipment purchased or installed at a local correctional facility must be registered with the department, in accordance with section 16.50 of this Part; and

(ii) a radiation protection survey, shielding evaluation and verification of image usefulness for detecting foreign objects must be completed by a licensed medical physicist.

(2) Equipment must have a clearly marked restricted area and one or more indicators when a scan is in process that is clearly visible to all security screening system operators and anyone approaching the restricted area.

(3) Equipment must be periodically inspected by the department as described in section 16.10 of this Part.

(4) Equipment must be tested annually by a licensed medical physicist or other individual authorized by law or regulation, to verify the equipment is operating as designed.

(5) The facility must maintain a policy and procedure manual describing equipment operations and body scanning procedures. Records and associated facility policies shall be maintained and available upon request by the department. The policy and procedure manual must include the following items:

(i) operating procedures appropriate for the specific equipment and intended scan types;

(ii) policy prohibiting the use of the equipment on individuals who are not inmates;

(iii) policy regarding the determination of pregnancy that has been approved by the jail physician;

(iv) emergency contact information in the event the equipment overexposes any individual or there is equipment related failure that potentially requires service prior to scanning other inmates;

(v) requirements for exposure records to be provided to an inmate upon release or transfer to another facility; and

(vi) exposure per scan for each scan protocol used.

(6) Records and documentation of the program operation shall be maintained in accordance with section 16.14 of this Part and shall include, at a minimum, the following:

(i) the number of times the equipment was used on inmates upon intake, after visits, and upon the suspicion of contraband, as well as any other event that triggers the use of such equipment;

(ii) the average, median, and highest number of times the equipment was used on any inmate, with corresponding exposure levels;

(iii) the number of times the use of the equipment detected the presence of drug contraband, weapon contraband, and any other illegal or impermissible object or substance; and

(iv) the number of times an inmate has been scanned.

(e) Exposure limits and reporting requirements

(1) No person other than an inmate of a local correctional facility shall be exposed to the useful beam and then only by an individual that has met the provisions of subdivision (f) of this section.

(2) Limits on the use of equipment exposure to inmates are:

(i) no more than fifty percent of the annual exposure limits for non-radiation workers as specified by applicable regulations, not to exceed 0.5 mSv (50 mrem);

(ii) inmates under the age of eighteen shall not be subject to more than five percent of such annual exposure limits, not to exceed 0.05 mSv (5 mrem); and

(iii) pregnant women shall not be subject to scanning at any time.

(3) The following events shall be reported to the department in writing within 30 days:

(i) incidents or any injuries or illness resulting from the use of such equipment or reported by persons scanned by such equipment; and

(ii) exposure that exceeds the limits set forth in this Part.

(f) Training Requirements.

(1) Every equipment operator shall receive initial operator training, to be provided by the equipment manufacturer or their approved representative, or another source approved by the department.

(2) The contents of the initial operator training must include radiation safety, equipment operations, exposure and exposure limits for occupational exposed staff and inmates; applicable regulations; and facility policies and procedures.

(3) Initial operator training must be documented and available for review by the department upon request. Such documentation must include the names of the presenter or sources, attendees, dates and contents of the training.

(4) Every equipment operator shall receive annual refresher training, to be provided by the equipment manufacturer or their approved representative, or another source approved by the department. Such training shall meet the requirements listed in paragraphs (1), (2) and (3) of this subdivision and include any changes to the policies and procedures manual or updates to the regulations.

LICENSING OF RADIOACTIVE MATERIALS

Introductory note: The sections under this heading contain the licensing provisions for radioactive material, i.e., byproduct material, source material, special nuclear material in quantities not sufficient to form a critical mass naturally occurring radioactive material, and accelerator produced radioactive material.

16.100 Overall licensing requirements for radioactive material.

(a) A person may manufacture, produce, acquire, receive, possess, prepare, use or transfer any radioactive materials only in accordance with a specific license issued by the department or as allowed in subdivisions (b) or (c) of this section.

(b) A specific license is not required for persons who comply with all applicable requirements for a general license as set forth in section 16.101 of this Part.

(c) A specific license is not required for persons who comply with all applicable requirements to qualify for an exemption as set forth in section 16.4 of this Part or other exemptions provided for in this Part or for the removal of source material from its place of deposit in nature.

16.101 General licenses

(a) This section establishes:

(1) general licenses for the possession and use of radioactive material;

(2) a general license for ownership of radioactive material;

(3) registration requirements for certain devices;

(4) a limit of no more than one millicurie of gamma-emitting radioactive material in a sealed source, where gamma radiation is the emission of interest, and no more than one millicurie of strontium 90 or any transuranic radionuclide per device that may be possessed or used under a general license, and;

(5) terms, conditions and limitations.

(b) Any person who possesses or uses radioactive material under a general license shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 31, General Domestic Licenses for Byproduct Material, as revised and implemented in full on July 23, 2008, except as follows:

(1) Sections 31.1-31.4, 31.11, 31.5(c)(13)(i), (ii) and (iv), and 31.21-31.23 are excluded.

(2) Any reference to the “Commission,” “NRC,” “Director,” “Office of Nuclear Material Safety and Safeguards,” “NRC Regional Office” or any other office thereof shall be deemed to be a

reference to the New York State Department of Health, except when used in sections 31.8(c)(2) and 31.11(d)(2).

(3) Reporting required in 10 CFR 31.5, as revised and implemented in full on July 23, 2008, other than reports of import or export, shall be submitted to the department by means specified in section 16.1(c) of this Part, instead of to the NRC by method listed in 10 CFR30.6(a) as revised and implemented in full on October 16, 2020.

(4) Upon receipt of any fixed measuring, gauging or controlling devices that contain radioactive material not exceeding the limits specified in subdivision (a) of this section, each person shall register the device with the department on a form prescribed by the department and accompanied by the required fee. Each address for a location of use represents a separate general licensee and requires a separate registration and fee. Portable or mobile measuring, gauging or controlling devices containing radioactive material are not applicable under this paragraph and thereby require a specific license under 16.100 of this Part.

(5) Any reference in 10 CFR 31 as revised and implemented in full on July 23, 2008, to the import or export of radioactive material is under the direct and exclusive jurisdiction of the NRC.

(c) Any person who is licensed pursuant to section 16.123 of this Part for medical use is also authorized to use radioactive material described in 10 CFR31.11(a) as revised and implemented in full on November 14, 1968, under the conditions of such specific license without filing for a general license registration.

16.102 Applications for specific licenses.

(a) An application for a specific license for any radioactive material shall be filed on a form prescribed by the department. Such application shall be complete and include all requested

information. The application may incorporate by clear and specific reference information contained in any previous application, supplementary statement, notification or report filed with the department.

(b) At any time subsequent to the filing of an application for a license and before the termination of a license issued in response thereto, the department may require the applicant to submit one or more supplementary statements containing additional information to enable the department to determine whether such application should be approved or denied, or whether a previously issued license should be amended, suspended or revoked.

(c) Each application or supplementary statement shall be signed by either the applicant personally or a person duly authorized by the applicant to sign for and on the applicant's behalf.

(d) A single application may apply for more than one license or for a license covering more than one radioactive material.

(e) The applicant shall permit the department to perform an onsite inspection or inspections prior to issuance of a license to verify information provided in the license application and any supplemental application information.

(f) Applications submitted without the fee specified in section 16.41 of this Part will not be processed until the department receives payment in full.

(g) As provided by section 16.114 of this Part, certain applications for specific licenses filed under this Part must contain a proposed decommissioning funding plan or a certification that financial assurance for decommissioning has been provided.

(h) Emergency plans for responding to a release of radioactive material.

(1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 10 CFR 30.72, schedule C, "Quantities of

Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," as revised and implemented in full on October 1, 2007, must contain either:

(i) an evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem (10 mSv) effective dose equivalent or 5 rems (50 mSv) to the thyroid; or

(ii) an emergency plan for responding to a release of radioactive material.

(2) One or more of the following factors may be used to support an evaluation submitted under subparagraph (1)(i) of this subdivision:

(i) the radioactive material is physically separated so that only a portion could be involved in an accident;

(ii) all or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(iii) the release fraction in the respirable size range would be lower than the release fraction shown 10 CFR 30.72 as revised and implemented in full on October 1, 2007, due to the chemical or physical form of the material;

(iv) the solubility of the radioactive material would reduce the dose received;

(v) facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in 10 CFR 30.72 as revised and implemented in full on October 1, 2007;

(vi) operating restrictions or procedures would prevent a release fraction as large as that shown in 10 CFR 30.72 as revised and implemented in full on October 1, 2007; or

(vii) other factors appropriate for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted under subparagraph (1)(ii) of this subdivision must include the following information:

(i) Facility description. A brief description of the licensee's facility and area near the site.

(ii) Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

(iii) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

(iv) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

(v) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(vi) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

(vii) Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the commissioner, and responsibilities for developing, maintaining, and updating the plan.

(viii) Notification and coordination. An express commitment and brief description of the means by which the licensee will promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established and the notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment

will not prevent the notification and coordination. The licensee shall also commit to notify the commissioner immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

(ix) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the commissioner.

(x) Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide to workers on how to respond to an emergency; including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(xi) Safe shutdown. A brief description of the means by which the facility may be restored to a safe condition after an accident.

(xii) Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises, although recommended, is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct

implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected

(xiii) Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the commissioner. The licensee shall provide any comments received within 60 days to the commissioner with the emergency plan.

(5) Prior to the commencement of the on-site biennial emergency exercises required by paragraph (3) of this subdivision, at least 72 hours’ notice must be provided to the New York State Department of Health, Bureau of Environmental Radiation Protection.

(i) An application from a medical facility, educational institution, or federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licenses in its consortium authorized for medical use under section 16.123 of this Part shall include:

(*a*) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under this part for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(*b*) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 10 CFR 32.72(a)(2) as revised and implemented on August 24, 2023.

(*c*) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in 10 CFR 32.72(b)(2) as revised and implemented in full on August 24, 2023.

(*d*) Information identified in 10 CFR 32.72(a)(3) as revised and implemented in full on August 24, 2023, on the PET drugs to be noncommercially transferred to members of its consortium.

16.103 Licensing requirements for radioactive materials.

(a) The department may approve an application for, and issue in response thereto, a specific license to transfer, receive, possess and use any radioactive material, if the department determines that the following requirements have been met:

(1) the applicant's proposed use, equipment, facilities and procedures will protect public health and safety and minimize danger to life and property from radiation hazards;

(2) the applicant's radiation detection and measuring instrumentation is appropriate for the uses of radioactive materials requested in the application;

(3) the applicant, (or the applicant's personnel if the applicant is not an individual), is qualified by training and experience to use such radioactive material for each purpose covered by the application so as to protect public health and safety and to minimize danger to life and property from radiation hazards; and

(4) the applicant submits sufficient information to support a determination that the requirements of this section are satisfied.

(b) Any person issued a specific license to manufacture, transfer, receive, possess or use any radioactive material shall comply with the provisions of the following federal regulations, which

are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 30, Rules of General Applicability to Domestic Licensing of Byproduct Material as revised and implemented in full on October 16, 2020; Part 40, Domestic Licensing of Source Material as revised and implemented in full on August 24, 2023: and Part 70, Domestic licensing of Special Nuclear Material, as revised and implemented in full on August 24, 2023, except as follows:

(1) Sections 30.2, 30.3, 30.4 definitions of "Utilization facility", "Commencement of construction" and "construction", 30.5, 30.7, 30.8, 30.9, 30.21(c), 30.31, 30.32(a)-(f), 30.32(h), 30.33, 30.34(d), 30.34(e)(1)-(4), 30.37, 30.38, 30.39, 30.41 (b)(6), 30.50(c)(3), 30.51(c), 30.52, 30.53, 30.55, 30.61, 30.62, 30.63, 30.64, 40.2a, 40.4 definitions of "Commencement of Construction", "Construction", "Foreign obligations", "Reconciliation", "Residual radioactive material", and "Uranium milling", 40.5 – 40.9, 40.12(b), 40.13(c)(5)(iv), 40.14, 40.20 40.23, 40.26, 40.27, 40.28, 40.31(a)-h) and (j)-(m), 40.32 (d) with respect to "common defense and security", 40.32, (e) and (g), 40.33, 40.35 (d)-(f), 40.38, 40.41(d), (e), (g) and (h), 40.43, 40.44, 40.45, 40.51(b)(6), 40.52, 40.53, 40.56, 40.64 – 40.82, criterion 11A. through F of appendix A to Part 40, 70.1, 70.2, 70.10(b), 70.13, 70.14, 70.17, 70.20a, 70.20b, 70.21, 70.22, 70.24, 70.25(a)(1), (c), (d), f), and (h), 70.31 are excluded.

(2) Any reference to the "commission," "NRC," "US NRC," "NRC regional office," "United States nuclear regulatory commission," "administrator of the appropriate regional office," "Director of the Office of Nuclear Material Safety and Safeguards," "NRC Operations Center" or any other office or person thereof, shall be deemed to be a reference to the New York State Department of Health, except for when used in: sections 30.12, 30.21(c), 30.34(h)(1), 30.50(c)(1), 40.11. 70.11, 70.19(a)(1) and (2), 70.39(b), 70.40(b)-(d).

(3) Any reference to “Department” in 10 CFR40.11 means the United States Department of Energy.

(4) Any reference to “Parts 19, 20, and 21 of this Chapter” shall be deemed to be a reference to Title 10 of the CFR.

(5) Any reference to “an appropriate method listed in 10 CFR 30.6(a), 40.5(a) and 70.5(a)” shall be deemed to be a reference to “a means specified in section 16.1(c) of this Part”.

(6) Any reference to an “NRC Form” shall been deemed to reference “a form prescribed by the Department.”

16.104 Conditions of specific licenses.

(a) It is hereby made a condition of each specific license:

(1) that the licensee thereunder shall comply with all applicable provisions of the Public Health Law, of all other laws now or hereafter in effect, and with all applicable rules, regulations, codes and orders now or hereafter in effect of the department and of all appropriate regulatory agencies;

(2) that neither such license, nor any right, title or interest in, of or to such license, shall be disposed of by assignment, transfer or otherwise, either voluntarily or involuntarily, either directly or indirectly, unless the department shall, after securing complete and accurate pertinent information, have approved in writing of such disposal;

(3) that the licensee shall confine their possession and use of licensed radioactive material to such location or locations and for such purpose or purposes as the license may authorize; provided, however, that except as otherwise provided in such license or this Part, such license shall be deemed to authorize the licensee to transfer the material covered by such license to any

other person authorized to receive it by the department, the New York City Department of Health and Mental Hygiene, the United States Nuclear Regulatory Commission or any Agreement State; and

(4) that the licensee shall notify the department by letter within 30 days if an authorized user, radiation safety officer or radiation therapy physicist permanently discontinues performance of duties under the license; and

(5)(i) that each licensee shall notify the department in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(*a*) the licensee;

(*b*) an entity (as that term is defined in 11 U.S.C. 101(15) (see section 16.200 of this Part) controlling the licensee or listing the license or licensee as property of the estate; or

(*c*) an affiliate (as that term is defined in 11 U.S.C. 101(2)) (see section 16.200 of this Part) of the licensee.

(ii) This notification must indicate:

(*a*) the bankruptcy court in which the petition for bankruptcy was filed; and

(*b*) the date of the filing of the petition.

(6) that any license covering the use of special nuclear material in the course of which licensed use additional special nuclear material is produced, shall be deemed to cover any such special nuclear material so produced; provided, however, that the total quantity of special nuclear material possessed by the licensee is not sufficient to form a critical mass.

(7) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall

test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with 10 CFR35.204, as revised and implemented in full on July 16, 2018. The licensee shall record the results of each test and retain each record for three years after the record is made.

(8) Security requirements for portable gauges, excluding X-ray Fluorescence devices.

Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(9) Manufacture, preparation, or transfer for distribution of radioactive drugs containing byproduct material for medical use under 10 CFR 35.

(i) Authorization under 10 CFR 30.32(j) as revised and implemented in full on September 30, 2014, to produce Positron Emission Tomography (PET) radioactive drugs for transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other federal and State requirements governing radioactive drugs.

(ii) Each licensee authorized under 10 CFR 30.32(j) as revised and implemented in full on September 30, 2014, to produce PET radioactive drugs for transfer to medical use licensees in its consortium shall:

(*a*) Satisfy the labeling requirements in 10 CFR 32.72(a)(4), as revised and implemented in full on August 24, 2023, for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for distribution to members of its consortium.

(*b*) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for distribution to members of its consortium and meet the procedural, radioactivity

measurement, instrument test, instrument check, and instrument adjustment requirements in 10 CFR 30.32(j) as revised and implemented on September 30, 2014, to produce PET radioactive drugs for transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(*1*) an authorized nuclear pharmacist that meets the requirements in 10 CFR 32.72(b)(2) as revised and implemented on August 24, 2023, or

(*2*) an individual under the supervision of an authorized nuclear pharmacist as specified in 10 CFR35.27, as revised and implemented in full on November 14, 2022.

(iii) A pharmacy, authorized under 10 CFR 30.32(j) as revised and implemented on September 30, 2014, to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of 10 CFR 32.72(b)(5) as revised and implemented on August 24, 2023.

(b) The department may at any time set forth in any license or incorporate by reference therein, additional conditions, restrictions or requirements applicable to the licensee's transfer, receipt, possession or use of the radioactive material covered by such license in order to protect the public health and safety and to minimize danger to life and property from radiation hazards.

16.105 Duration, expiration and termination of specific licenses.

(a) Except as otherwise provided in this subdivision, each specific license will expire at the end of the expiration date stated in such license. If any licensee duly files with the department not less than 30 days prior to such expiration date, an application in accordance with section 16.102 of this Part for the renewal of his license or for a new and superseding license, such license shall not be deemed to have expired until the department has finally determined such application.

(b) The department may terminate any specific license upon written request of the licensee

(c) Each specific license continues in effort, beyond the expiration date if necessary, with respect to possession of radioactive material until the commissioner notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

(1) limit actions involving radioactive material to those related to decommissioning; and

(2) continue to control entry to restricted areas until they are suitable for release in accordance with department requirements.

16.106 Renewal or amendment of specific licenses.

Any application by a licensee for the renewal or amendment of the license shall be considered as an application for a license and shall be filed in accordance with section 16.102 of this Part; and any such application for amendment shall set forth the reasons for such requested amendment. In considering any such application for renewal or amendment, the department will apply the requirements set forth in section 16.103 of this Part as appropriate. Corrective amendments to a license may be issued by the department at any time upon its initiative.

16.107 Amendment, suspension or revocation of licenses.

(a) Specific and general licenses may be subject to amendment, suspension or revocation by reason of amendment of the Public Health Law, enactment or amendment of any other applicable law, amendment of this Part or amendment or promulgation of any other applicable rule, regulation, or order.

(b) The department may amend, revoke or suspend any license in whole or in part, for:

(1) any material misstatement in the application therefor or in any supplementary statement thereto;

(2) any condition revealed by such application, supplementary statement, report, record, inspection or other means, which would warrant the department to refuse to grant a license on an original application; or

(3) any violation or failure to observe any of the applicable terms or provisions of such license, the Public Health Law, this Part, or any other applicable rule, regulation, code or order now or hereafter in effect.

16.108 Recognition of Agreement State and U.S. NRC Licenses.

(a) The holder of a specific license or permit issued by the State Department of Health, the New York City Department of Health, the United States Nuclear Regulatory Commission, and any Agreement State, or any licensing nonagreement state, may bring, possess or use radioactive material covered by such license or permit within the commissioner's jurisdiction for a period not in excess of 180 days in any calendar year without obtaining a specific license from the commissioner, and is granted a general license to conduct the same activity within areas of exclusive State jurisdiction within New York State, provided that:

(1) such license or permit does not limit the holder's possession or use of such material to a specific installation or installations;

(2) such holder shall, at least 3 days before engaging in each activity for the first time in a calendar year, file a submittal containing a completed form specified by the department, a copy of its U.S. Nuclear Regulatory Commission or Agreement State specific license, and the appropriate fee as prescribed in sections 16.40 and 16.41 of this Part with the New York State

Department of Health. If a submittal cannot be filed 3 days before engaging in activities under reciprocity, because of an emergency or other reason, the department may waive the 3-day time requirement provided the licensee:

(i) informs the department by telephone, facsimile, a completed form specified by the department, or a letter of initial activities or revisions to the information submitted on the initial form specified by the department;

(ii) receives oral or written authorization for the activity from the department; and

(iii) within 3 days after the notification, files a completed form specified by the department, a copy of the U.S. Nuclear Regulatory Commission or Agreement State license, and the fee payment;

(3) such holder, at least three days prior to engaging in such activities within the commissioner's jurisdiction, files with the commissioner a notice indicating the period, type and location of proposed possession and use within the commissioner's jurisdiction and a copy of the license or permit. At the discretion of the commissioner, oral notification of the commissioner or notification of the commissioner less than three days prior to engaging in such activities may be accepted in lieu of the filing requirement under this paragraph;

(4) such holder supplies such additional information as the commissioner may reasonably request;

(5) such holder, during the period of his possession and use of such material within the commissioner's jurisdiction, complies with all relevant provisions of this Part, and any additional requirements which the commissioner may impose, and which are reasonable under the circumstances;

(6) such holder is engaged in licensable activities exclusive to the use, possession, or temporary storage of x-ray fluorescence devices, portable gauges, industrial radiography, well logging, decontamination and decommissioning services, waste brokerage, packaging of radioactive materials for transport, possession of radioactive material for training purposes, installation, manufacture, or service radioactive devices or equipment unless stated otherwise under subdivision (b) of this section, or other uses as deemed applicable by the department.

(b) Any holder of a license or permit issued by the State Department of Health, the New York City Department of Health and Mental Hygiene, the United States Nuclear Regulatory Commission, any Agreement State, or any licensing nonagreement state which authorizes the holder to manufacture, install or service a device of the type which is generally licensed may install or service such device without obtaining a license from the department, provided that:

(1) such person shall file a report with the department within 30 days after the end of each calendar quarter in which any device is transferred to or installed within the department's jurisdiction. Such report shall contain the name and address of each person receiving such a device, shall identify the type of device or devices so transferred, and shall state the quantity and type of radioactive material contained in such device or devices;

(2) any such device is installed and serviced in accordance with the terms of the license or permit issued to such person;

(3) such person shall assure that any labels required to be affixed to any such device shall bear a statement that reads "Removal of this label is prohibited"; and

(4) the person to whom such holder transfers any such device or on whose premises such holder installs or services any such device has a copy of the general license requirements or equivalent requirements outlined in section 16.103 of this Part.

16.109 Licensees and contractors of the United States Nuclear Regulatory Commission and the United States Department of Energy within the State.

(a) Each person who holds a license from the United States Nuclear Regulatory Commission authorizing activities within the State shall be exempt from the requirements of this Part with respect to such activities during the period that such license is valid, provided, however, that such person:

(1) shall afford the department and health officer having jurisdiction access to all records which such person is required to maintain pursuant to the United States Nuclear Regulatory Commission's rules and regulations or pursuant to the provisions of the United States Nuclear Regulatory Commission license,

(2) shall afford the department and health officer having jurisdiction opportunity to sample effluents, and to conduct such measurement or survey of levels of radiation and radioactive contamination as will not substantially interfere with or interrupt any activities licensed by the United States Nuclear Regulatory Commission, and

(3) shall afford the department and health officer having jurisdiction access to the facilities of such person in order to accomplish the foregoing review of records, sampling of effluents and conduct of measurements or surveys.

(b) Each United States Nuclear Regulatory Commission contractor or subcontractor and each United States Department of Energy contractor and subcontractor of the following categories operating within the State shall be exempt from the requirements of this Part to the extent that such contractor or subcontractor under such contract transfers, receives, possesses, or uses sources of radiation:

(1) prime contractors performing work for the United States Department of Energy at United States government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

(2) prime contractors performing research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;

(3) prime contractors using or operating nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel; and

(4) any other prime contractor or subcontractor when the State and the United States Nuclear Regulatory Commission or the United States Department of Energy jointly determine that:

(i) under the terms of the contract or subcontract there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety; and

(ii) the exemption of such contractor or subcontractor is otherwise appropriate.

16.110 Licensure and inspection of radioactive materials; fees authorized. Provided that a written schedule of the licensing and inspection fees to be charged has been submitted to and approved by the State Commissioner of Health, any county, part-county or city health district having a population of more than 2,000,000 which has established substitute licensure requirements acceptable to the State Department of Health pursuant to the provisions of paragraph (2) of subdivision (b) of section 16.1 of this Part is authorized to charge adequate and reasonable fees for the licensing and inspection of radioactive materials not exceeding the estimated cost of such services except that, with the approval of the State Commissioner of Health, one or more of such services may be rendered without charge.

16.111 Transfer of radioactive material.

(a) No licensee shall transfer radioactive material except as authorized pursuant to this section.

(b) Except as otherwise provided in his license and subject to the provisions of subdivisions (c) and (d) of this section, any licensee may transfer radioactive material:

(1) to the department, only after receiving prior approval from the department;

(2) to the United States Nuclear Regulatory Commission;

(3) to any person exempt from the regulations in this Part to the extent permitted under such exemption;

(4) to any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the department, the United States Nuclear Regulatory Commission, or any Agreement State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Department of Energy, or any Agreement State; or

(5) as otherwise authorized by the department in writing.

(c) Before transferring radioactive material to a specific licensee of the department, the United States Nuclear Regulatory Commission or the licensing agency of an Agreement State, or to a general licensee who is required to register with the department, the United States Nuclear Regulatory Commission or the licensing agency of an Agreement State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form and quantity of radioactive material to be transferred.

(d) The following methods for the verification required by subdivision (c) of this section are acceptable:

(1) the transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;

(2) the transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date;

(3) for emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date, provided that the oral certification is confirmed in writing within 10 days;

(4) the transferor may obtain other sources of information compiled by a reporting service from official records of the department, the United States Nuclear Regulatory Commission or the licensing agency of an Agreement State as to the identity of licensees and the scope and expiration dates of licenses and registrations; or

(5) when none of the methods of verification described in paragraphs (1) through (4) of this subdivision are readily available, or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the department, the United States Nuclear Regulatory Commission or the licensing agency of an Agreement State that the transferee is licensed to receive the radioactive material.

(e) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of section 16.17 of this Part.

16.112 Physical protection of category 1 and category 2 quantities of radioactive material, fingerprinting and criminal background check requirements.

(a) This section contains the requirements for the physical protection program for any licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material, which provide reasonable assurance of the security of such material from theft or diversion. Specific requirements for access to material, use of material, transfer of material, and transport of material are included.

(b) The licensee shall comply with 10 CFR 71.97, July 1, 2018, version.

(c)The licensee shall comply with the 10 CFR 37, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material,” August 9, 2021, version, except as follows:

(1) Sections 37.1, 37.3, 37.7, 37.9, 37.11(a-b), 37.13, 37.105, 37.107, and 37.109 are excluded.

(2) Any reference to the Commission or NRC shall be deemed to be a reference to the New York State Department of Health, except:

(i) section 37.5 Definitions: “Agreement State”, “Byproduct material”, “Commission”, “Fingerprint orders”, “Person”;

(ii) section 37.25(b);

(iii) section 37.27(a) and (c);

(iv) section 37.29(a);

(v) section 37.71 referring to NRC’s license verification system.

(3) License required reports of events or notifications in sections 37.41, 37.45, 37.57, 37.77(a)-(d), 37.81, shall be reported to the department by means specified in section 16.1(c) of this Part instead of to the NRC.

16.113 Decommissioning.

(a) Decommissioning Plan.

(1) A licensee must submit a decommissioning plan: if otherwise required by this Part; if required by license condition; or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the department and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii) workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during the operation for which the license was issued;

(iii) procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(iv) procedures could result in significantly greater releases of radioactive material to the environment than those associated with the operation for which the license was issued.

(2) Procedures with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(3) The proposed decommissioning plan for the facility or site (or separate building or outdoor area) must include:

(i) a description of the conditions of the facility or site sufficient to evaluate the acceptability of the plan;

(ii) a description of planned decommissioning activities;

(iii) a description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(iv) a description of the radiation survey planned to demonstrate compliance with paragraphs (f)(4) and (g)(1) of this section; and,

(v) an updated detailed cost estimate for decommissioning, comparison of that estimate with existing funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(4) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay. The proposed decommissioning plan may be approved by the department if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(5) DFP (Decommissioning Funding Plan) Reviewed and Revised at least on a three (3) year basis

(b) Timeliness of Decommissioning.

(1) Each licensee or person in possession of a non-exempt source of radioactive material who decides to terminate all activities involving that source of radiation shall notify the department immediately in writing.

(2) Each licensee or person responsible for a facility or site which includes a non-exempt source of radioactive material or which may be contaminated by residual radioactivity shall, no less than 30 days before vacating or relinquishing possession or control of a restricted area, the facility or site, notify the department in writing of the intent to vacate.

(3) The licensee shall notify the department in writing within 60 days of the occurrence of any of the following:

(i) the licensee has decided to permanently cease principal activities at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with this Part; or,

(ii) no principal activities under the license have been conducted for a period of 24 months; or,

(iii) no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with this Part.

(c) From the date of notification of the department required in subdivision (a) of this section, the licensee shall either:

(1) begin decommissioning activities; or

(2) within 12 months of notification submit a decommissioning plan, if required by subdivision (a) of this section, and begin decommissioning upon department approval of that plan.

(d) Coincident with the notification of the department required in subdivision (b) of this section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee in conjunction with a license issuance or renewal or as required by this Part. The amount of the financial assurance must be increased, or may be decreased with permission of the department, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to section 16.113(a)(3)(v) of this Part.

(e) The department may approve an alternate schedule for the submission of plans and for the completion of decommissioning as required pursuant to subdivisions (a) and (c) of this section if the department determines that the alternate schedule:

(1) is necessary to effectively conduct decommissioning;

(2) presents no undue risks to public health and safety; and

(3) is otherwise in the public interest.

The request must be submitted no later than 30 days before notification pursuant to subdivision (b) of this section. The schedule for decommissioning may not commence until the department has made a determination on the request.

(f) Completion of Decommissioning.

(1) The licensee shall complete decommissioning of the facility or site as soon as practicable but no later than 24 months following the initiation of decommissioning, unless an alternate schedule addressing the factors in paragraph (3) of this subdivision is requested with written justification and approved by the department.

(2) When decommissioning involves the entire site, the licensee shall request license termination upon completion of decommissioning activities.

(3) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the decommissioning schedule warranted by consideration of the following:

(i) whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(ii) whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(iii) whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(iv) whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and,

(v) other site-specific factors which the department may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(4) As the final step in decommissioning, the licensee shall:

(i) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner. The licensee shall, as appropriate:

(*a*) report levels of gamma radiation in units of millisieverts (or microroentgens) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (or disintegrations per minute or microcuries) per 100 square centimeters - removable and fixed - for surfaces, megabecquerels (or microcuries) per milliliter for water, and becquerels (or picocuries) per gram for solids such as soils or concrete; and,

(*b*) specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(ii) Certify the disposition of all licensed material including accumulated wastes, by submitting a form approved by the department.

(g) Termination of a License and Release of a Site Without Restriction.

(1) A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 0.25 millisievert (25 mrem) per year, including that from

groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). When calculating TEDE to the average member of the critical group, the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning. Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

(2) Specific licenses, including expired licenses, will be terminated upon written notice to the licensee when the department determines that:

(i) radioactive material has been properly disposed;

(ii) reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(iii) documentation is provided to the department that:

(*a*) a radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with department requirements; or

(*b*) other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with department requirements.

(iv) The licensee has complied with applicable sections of the New York State Environmental Conservation Law regarding radiological decommissioning.

(h) Applicability of Decommissioning Criteria Following License Termination. After a site has been decommissioned and the license terminated in accordance with the criteria in this Part, the department will require additional cleanup only if, based on new information, it determines that the criteria of this Part were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

16.114 Financial assurance and record keeping for decommissioning.

(a) Any person issued a specific license to possess and use radioactive material shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 30, Rules of General Applicability to Domestic Licensing of Byproduct Material, Section 35, Financial Assurance and Recordkeeping for Decommissioning, December 19, 2014, version. Any reference to the "Commission" or "NRC" shall be deemed to be a reference to the New York State Department of Health.

16.115 RESERVED.

16.116 RESERVED.

16.117 RESERVED.

16.118 RESERVED.

16.119 RESERVED.

16.120 Specific licenses for the use of radioactive materials on human beings.

An application seeking a specific license for use of radioactive materials on human beings shall be approved if all of the following criteria are satisfied:

(a) The application is completed, signed by an appropriate individual, and submitted to the department.

(b) The applicant is an individual, corporation, partnership or other entity that is legally authorized to do business in New York State. If the applicant is seeking a specific license pursuant to section 16.123 of this Part, the applicant shall be legally authorized to practice

medicine in New York State or operate a hospital as defined in section 2801 of the Public Health Law.

(c) The applicant satisfies the requirements set forth in section 16.103 of this Part.

(d) The applicant demonstrates to the satisfaction of the department that it has adequate facilities for clinical care of patients.

(e) The applicant demonstrates to the satisfaction of the department that its facilities will be appropriately equipped and staffed and will be operated as required by this Part.

(f) The applicant provides additional information as requested by the department.

16.121 RESERVED.

16.122 RESERVED.

16.123 Specific licenses for certain medical uses of byproduct materials.

(a) Purpose and scope. This section contains requirements for the medical uses of byproduct materials that are subject to specific licenses. These requirements are in addition to, and not a substitute for, other requirements in this Part. Any license issued prior to the effective date of this section that references subdivisions (b) or (c) shall be deemed to reference the equivalent medical use category in 10 CFR 35 as follows:

Previous designation(s)	10 CFR 35 equivalent
16.123(b)(1) or 16.123(c)(1)	35.100
16.123(b)(2) or 16.123(c)(2)	35.200
16.123(b)(3) or 16.123(c)(3)	35.300
16.123(b)(4) or 16.123(c)(4)	35.400

16.123(b)(5) or 16.123(c)(5)…….35.500

16.123(c)(6)……35.600

16.123(c)(7)……..35.1000

(b) Definitions. Whenever used in this section, or in federal regulations incorporated herein, the following terms shall have the following meanings:

(1) “Associate Radiation Safety Officer”

(i) meets the requirements of 10 CFR 35.50 and 35.59, as revised and implemented in full on November 14, 2022;

(ii) Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:

(*a*) a specific medical use license issued by the Commission or an Agreement State; or

(*b*) a medical use permit issued by a Commission master material license.

(2) "Authorized medical physicist" means an individual who is authorized to practice medical physics pursuant to article 166 of the Education Law and:

(i) meets the requirements for an authorized medical physicist set forth in 10 CFR 35.51, 35.57 and 35.59, as revised and implemented in full on November 14, 2022; or

(ii) is identified as an authorized medical physicist or teletherapy physicist on:

(*a*) a specific medical use license issued by the Nuclear Regulatory Commission or Agreement State;

(*b*) a medical use permit issued by a Nuclear Regulatory Commission master material licensee;

(*c*) a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; or

(*d*) a permit issued by a Nuclear Regulatory Commission master material license broad scope medical use permittee.

(3) "Authorized nuclear pharmacist" means an individual who is authorized to practice pharmacy pursuant to article 137 of the Education Law and:

(i) meets the requirements for an authorized nuclear pharmacist set forth in 10 CFR 35.55 and 35.59, as revised and implemented in full on November 14, 2022; or

(ii) is identified as an authorized nuclear pharmacist on:

(*a*) a specific license issued by the Nuclear Regulatory Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(*b*) a permit issued by a Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(*c*) a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

(*d*) a permit issued by a Nuclear Regulatory Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

(iii) is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(iv) was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and the individual practiced at a pharmacy at a federal government agency or federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the Nuclear Regulatory Commission.

(4) "Authorized user" means an individual who is authorized to practice medicine pursuant to article 131 of the Education Law and:

(i) meets the applicable requirements for an authorized user set forth in 10 CFR 35.59 and 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.590, or 35.690 as revised and implemented in full on November 14, 2022; or

(ii) is identified as an authorized user on:

(*a*) a Nuclear Regulatory Commission or Agreement State license that authorizes the medical use of byproduct material;

(*b*) a permit issued by a Nuclear Regulatory Commission master material licensee that is authorized to permit the medical use of byproduct material;

(*c*) a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or

(*d*) a permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

(5) "Medical use" means the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an authorized user.

(6) “Ophthalmic physicist”

(i) meets the requirements in 10 CFR 35.433(a)(2) and 35.59 as revised and implemented in full on November 14, 2022; and

(ii) is identified as an ophthalmic physicist on a:

(*a*) specific medical use license issued by the Commission or an Agreement State; or

(*b*) permit issued by a Commission or Agreement State broad scope medical use license; or

(*c*) medical use permit issued by a Commission master material licensee; or

(*d*) permit issued by a Commission master material licensee board scope medical use permittee.

(7) "Positron emission tomography facility" is a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

(8) "Prescribed dosage" means the specified activity or range of activity of unsealed byproduct material as documented in a written directive, or in accordance with the directions of the authorized user for procedures performed pursuant to 10 CFR 35.100 and 35.200 as revised and implemented in full on November 14, 2022. Further details concerning this referenced code are contained in subdivision (c) of this section.

(9) "Prescribed dose" means:

(i) for gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(ii) for teletherapy, the total dose and dose per fraction as documented in the written directive;

(iii) for manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(iv) for remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

(10) "Radiation safety officer" means an individual who:

(i) meets the requirements for a radiation safety officer set forth in 10 CFR 35.50 and 35.59 as revised and implemented in full on November 14, 2022; or

(ii) is identified as a radiation safety officer on:

(*a*) a specific medical use license issued by the Nuclear Regulatory Commission or Agreement State; or

(*b*) a medical use permit issued by a Nuclear Regulatory Commission master material licensee.

(11) "Sealed source" means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

(12) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(c) Approved medical uses of byproduct materials. A licensee may use byproduct materials on human beings for the particular uses set forth below, provided that the licensee meets all applicable requirements of this Part:

(1) use of unsealed byproduct material for uptake, dilution and excretion studies;

(2) use of unsealed byproduct material for imaging and localization studies;

(3) use of unsealed byproduct material for which a written directive is required;

(4) use of sources for manual brachytherapy;

(5) use of sealed sources for diagnosis;

(6) use of sealed source in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit; or

(7) other specific medical uses of byproduct material or radiation from byproduct material, as licensed by the department.

(d) Federal Standards. All licensees shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference in paragraphs (e)(1)-(4) and subdivisions (f)-(m) of this section, with the same force and effect as if fully set forth at length. All referenced provisions are found within 10 CFR 35, Medical Use of Byproduct Material, as revised and implemented in full on November 14, 2022. This code is published by the Office of the Federal Register National Archives and Records Administration. Copies may be obtained from the Superintendent of Documents, United States Government Printing Office, Washington D.C. 20402. This code is available for copying and inspection at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, NY 12237.

Notwithstanding any provision herein to the contrary, if a conflict occurs between the above referenced CFR and other provisions in this Part, compliance with the more restrictive regulation is required.

(e) General requirements applicable to all licensees authorized to use byproduct materials for medical purposes.

(1) Record Keeping Requirements. A licensee shall comply with all record keeping requirements set forth in 10 CFR 35 subpart L (Records), as revised and implemented in full on November 14, 2022. Further details concerning this referenced code are contained in subdivision (c) of this section.

(2) Reporting requirements: A licensee shall comply with all reporting requirements set forth in 10 CFR 35 subpart M (Reports), as revised and implemented in full on November 14, 2022 as revised herein as follows: (i) in 35.3045(c), 35.3047(c), and 35.3204(a) replace phrase "NRC Operations Center" with "Department"; (ii) in 35.3045(d), 35.3047(d), 35.3067 and 35.3204(b) replace “By an appropriate method listed in 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in 30.6 of this chapter” with “shall submit a written report to the Department"; (iii) in 35.3045(g)(1) and 35.3047(f)(1), replace the term "NRC" with "Department"; and, (iv) in 35.3067 replace "The report must be filed with the appropriate NRC Regional Office listed in 30.6 of this chapter, by an appropriate method listed in 30.6(a) of this chapter, with a copy to the Director, Office of Federal and State Materials and Environmental Management Programs." with "The report shall be filed with the Department".

(3) Training and experience requirements. A licensee shall ensure that all staff who are involved in the use of byproduct material pursuant to a specific license have the training and experience required by this Part.

(4) Other General Requirements. A licensee shall comply with requirements set forth in 10 CFR 35.5, 35.6, 35.11(a) and 35.11(b), 35.24(b), 35.24(e), 35.24(f) and 35.24(g), 35.27, 35.40, 35.41, 35.49, 35.60, 35.61, 35.63, 35.65, 35.67, 35.69, 35.70, 35.75, 35.80, and 35.92 as modified herein as follows: in 35.27(a)(1) and 35.27(b)(1), replace "19.12 of this chapter" with "16.13(c) of this Part."

(f) Requirements for the use of unsealed byproduct material for uptake, dilution and excretion studies. A licensee shall use unsealed byproduct material for uptake dilution and excretion studies only if authorized to do so by a specific license issued by the department and provided that the licensee complies with 10 CFR 35.100 and 35.190 as revised and implemented in full on November 14, 2022, and other applicable provisions of this Part.

(g) Requirements for the use of unsealed byproduct material for imaging and localization studies. A licensee shall use unsealed byproduct material for imaging and localization studies only if authorized to do so by a specific license issued by the department, and provided that the licensee complies with 10 CFR 35.200, 35.204 and 35.290 as revised and implemented in full on November 14, 2022, and other applicable provisions of this Part.

(h) Requirements for the use of unsealed byproduct material for which a written directive is required. A licensee shall use unsealed byproduct material for which a written directive is required only if authorized to do so by a specific license issued by the department and provided that the licensee complies with 10 CFR 35 subpart E (Unsealed Byproduct Material-Written Directive Required), as revised and implemented in full on November 14, 2022, and other applicable provisions of this Part.

(i) Requirements for the use of sources for manual brachytherapy. A licensee may use sources for manual brachytherapy only if authorized to do so by a specific license issued by the

department and provided that the licensee complies with 10 CFR 35 subpart F (Manual Brachytherapy), as revised and implemented in full on November 14, 2022.

(j) Requirements for the use of sealed sources for diagnosis. A licensee may use sealed sources for diagnosis only if authorized to do so by a specific license issued by the department and provided that the licensee complies with 10 CFR 35 subpart G (Sealed Sources for Diagnosis) , as revised and implemented in full on November 14, 2022, and other applicable provision of this Part.

(k) Requirements for the use of sealed sources in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit. A licensee may use a sealed source in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit only if authorized to so by a specific license issued by the department and provided that the licensee complies with 10 CFR 35 subpart H (Photon Emitting Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units), as revised and implemented in full on November 14, 2022, and other applicable provisions of this Part.

(l) Requirements for the use of other medical uses of byproduct material or radiation from byproduct material. A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subdivisions (f) through (k) of this section if the licensee submits to the department information required by 10 CFR 35.12(b) through (d) as revised and implemented in full on November 14, 2022, the licensee has received written approval from the department in a specific license or license amendment, and the licensee uses the material in accordance with specific conditions that the department deems necessary or desirable for the safest medical use of the material.

(m) Notwithstanding the requirements of this Part, physically present for the use of high dose rate afterloader units, teletherapy units, and gamma stereotactic radiosurgery units means that the authorized medical physicist and physician is located at the console, unobstructed from visually viewing and communicating with the patient and able to provide face-to-face services immediately in the event of an emergency requiring immediate medical intervention.

(n) General Use License. Any licensee who is licensed for one or more of the types of medical uses specified in subdivisions (f) through (k) of this section also is authorized to use radioactive material under the general license in paragraph 16.101(a)(1) of this Part for the specified "in vitro" uses without registering with the department, provided, however, that the licensee is subject to the other provisions of 10 CFR 31.11 as revised and implemented on November 14, 1968.

16.124 Licenses to manufacture or transfer certain items containing radioactive material.

(a)(1) This section contains requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing radioactive material for sale or distribution to:

(i) persons exempted from the licensing requirements of this Part, or equivalent regulations of an Agreement State, the NRC; or

(ii) persons generally licensed under this Part or equivalent regulations of an Agreement State or the NRC; or

(iii) persons licensed under section 16.123 of this Part.

(2) This section prescribes requirements for the issuance of specific licenses to persons who introduce radioactive material into a product or material owned by or in the possession of a licensee or another person, and regulations governing holders of such licenses.

(3) This section prescribes certain requirements governing holders of licenses to manufacture or distribute items containing byproduct material.

(4) This section describes procedures and prescribes requirements for the issuance of certificates of registration (covering radiation safety information about a product) to manufacturers or initial transferors of sealed sources or devices containing sealed sources.

(b) The provisions and requirements of this section are in addition to, and not in substitution for, other requirements of this Part.

(c) Any person who manufactures or transfers items containing radioactive material shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10CFR 32, Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material as revised and implemented in full on August 24, 2023, except as follows:

(1) Sections 32.1, 32.11, 32.12, 32.14 through 32.23, 32.25 through 32.32, 32.301, and 32.303 are excluded.

(2) Any reference to the "Commission," "NRC," or "NRC Regional Office" or any other office thereof shall be deemed to be a reference to the New York State Department of Health, except for when used in 10 CFR 32.51(a)(3)(iii), 32.54(a), 32.58, 32.71(d), 32.72(b)(5), and 32.74(a)(3).

(3) Reporting required in 10 CFR32.56(a) shall be submitted to the department by means specified in section 16.1(c) of this Part, instead of to the NRC.

16.125 Additional Requirements for the Manufacture, preparation, or transfer for commercial distribution of drugs containing radioactive material for medical use under 10 CFR 35 or the equivalent regulations of any state.

(a) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to 10 CFR 35 or the equivalent regulations of any state may be approved if:
(1) the applicant satisfies the general requirements specified in section 16.103 of this Part;
(2) the applicant submits evidence that the applicant is registered or licensed by the New York State Board of Pharmacy as a drug manufacturer or a pharmacy, as appropriate to their practice;
(3) the applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and
(4) the applicant satisfies the following labeling requirements:
(i) a label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words “Caution, Radioactive Material” or “Danger, Radioactive Material”; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted; and
(ii) a label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the

words “Caution, Radioactive Material” or “Danger, Radioactive Material” and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(b) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(1) perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument, and make adjustments when necessary;

(2) check each instrument for constancy and proper operation at the beginning of each day of use; and

(3) use differing activity concentrations in preparing different radiopharmaceuticals, and ensure that any discrepancy between the calculated volume of a dosage and the volume found to be required by measurement to achieve the prescribed activity is resolved before the dosage is dispensed. Records of actions taken to resolve any such discrepancy shall be maintained for three years.

(c) A licensee shall possess and use instrumentation for performing surveys and analyses for radioactive contamination and for making such measurements of radiation levels and radiation dose as may be necessary to demonstrate compliance with all requirements of this Part. In addition, the licensee shall:

(1) provide appropriate instrumentation for each application. This must include but is not limited to: a microrem or microR meter for surveying non-radioactive trash before disposal, and for surveying workers' skin and clothing for contamination; a thyroid uptake system with a reproducible geometry and an adequate lower limit of detection; and analytical instruments for identifying and quantifying radioactive contamination; and

(2) calibrate all instruments in accordance with the manufacturer's specifications and calibrate all meters at least every 12 months.

(d) (1) A licensee shall provide a radiation safety officer who is a health physicist with qualifications listed in paragraph (3) of this subdivision.

(2) a licensee shall only allow persons who are certified by the New York State Board of Pharmacy as nuclear pharmacists to act as pharmacists in a facility licensed pursuant to this section. A licensee may also propose such a certified nuclear pharmacist as radiation safety officer provided that the nuclear pharmacist will be assisted in the administration of the radiation protection program by a health physicist with the qualifications listed in subparagraph (iii) of this paragraph, and who will be present at the licensee's facility for the equivalent of one working day per month at a minimum, and who will provide the following services:

(i) provide classroom instruction to non-professional personnel who will perform work under the license;

(ii) review personnel monitoring reports and recommend methods to reduce exposures exceeding ALARA levels;

(iii) review survey records and make confirmatory measurements;

(iv) review air monitoring and emission levels and ensure compliance with limits;

(v) assist in thyroid bioassays and review absorbed dose calculations;

(vi) observe operations and make recommendations for improvements;

(vii) assist in response to, and in the evaluation of root causes and impacts of, incidents and accidents in order to minimize their impact and prevent their recurrence; and

(vii) consult with the RSO and provide health physics support as needed. The services to be provided must be documented in a contractual agreement between the licensee and the health physicist, and the department must be given a minimum of thirty days advance notice of the licensee's intent to retain a different health physicist.

(3) A health physicist who will act as radiation safety officer, or who will provide the services described in paragraph (2) of this subdivision, must have the following qualifications:

(i) experience in performing radiation protection services or the duties of a radiation safety officer for programs of similar type, size and scope as the licensee's program; and

(ii) a bachelor's degree in health physics or radiological health and four years of experience as described in clause (a) of this subparagraph; or certification by the American Board of Health Physics (Comprehensive), the American Board of Radiology in Medical Nuclear Physics, the American Board of Science in Nuclear Medicine in Radiation Protection or the American Board of Medical Physics in Medical Health Physics, and two years of the experience as described in clause (a) of this subparagraph.

(e) (1) A licensee shall only locate a nuclear pharmacy in a building that is zoned for commercial use, and which is not in a heavy public traffic area such as a large shopping center.

(2) A licensee who proposes to locate within a multi-tenant building must demonstrate that:

(i) there are no areas above or below the proposed facility which are not under the licensee's control, and to which the licensee does not have the authority to restrict access; and

(ii) there are no neighboring tenants on the same level with walls contiguous to the proposed radioactive materials use and storage areas. There must be a buffer zone of unrestricted area within the licensee's proposed facility along any walls that are common walls with a neighboring tenant.

16.126 Sealed source and device registration.

(a) Purpose. The requirements of this section apply to any manufacturer or initial distributor of a sealed source or device containing a sealed source to submit a request to the New York State Department of Health for evaluation of radiation safety information about its product and for its registration.

(b) Specific requirements. Each manufacturer or initial distributor of a sealed source or device shall comply with the provisions of 10 CFR 32, "Subpart D- Sealed Source and Device Information," Sections 32.210 and 32.211, December 19, 2014 edition.

16.127 Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations.

(a) This section contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials for persons using these sealed sources in industrial radiography, and for depleted uranium shielding in a radiographic exposure device. This section also contains radiation safety requirements for industrial radiography. The requirements of this section are in addition to other requirements of this Part.

(b) Any person that possesses or uses sealed sources for industrial radiography shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference,

with the same force and effect as if fully set forth at length herein: 10 CFR 34, Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations as revised and implemented in full on October 16, 2020, except as follows:

(1) Sections 34.1, 34.5, 34.8, 34.11, 34.43(a)(2), 34.45(a)(9), 34.111, 34.121 and 34.123 are excluded.

(2) Any reference to the "Commission," "NRC," "NRC Regional Office" or any office or individual thereof shall be deemed to be a reference to the New York State Department of Health, except for 34.20(a)(1), 34.27 (a)-(c) and (e), 34.41(c) and 34.43(a)(1).

(3) Reports and notifications required by 34.27(d) and 34.101 shall be reported to the Department by a means specified in 16.1(c) of this Part instead of to the NRC Director, Office of Nuclear Material Safety and Safeguards.

(4) In section 34.20 "10 CFR part 71" is replaced with "section 16.17."

(5) In section 34.25 "10 CFR 20" is replaced with "this Part."

(6) In section 34.33 (a)(1) "20.1601(a)(1) of this chapter" is replaced with "16.12(d)(1)(i) of this Part."

(7) In section 34.42 (c)(1) "current 10 CFR part 20 of this chapter" and "10 CFR part 20" are replaced with "this Part."

(8) In section 34.42 (c)(4) "20.2203 of this chapter" is replaced with "16.15(c) of this Part."

(9) In section 34.43 (b)(1) and (c)(1) "10 CFR parts 19 and 20, of this chapter" is replaced with "this Part."

(10) In section 34.43 (g)(4) is replaced to read: "The requirements of pertinent State and Federal regulations; and."

(11) In section 34.45 (a)(1), “10 CFR part 20 of this chapter ‘Standards for Protection Against Radiation’” is replaced with “this Part”, and the word “person” is replaced with “individual.”

(12) In section 34.53, “20.1902 of this chapter” is replaced with “16.12(b)(1) of this Part” and “20.1903 of this chapter” is replaced with “16.12(b)(2) of this Part.”

(13) In section 34.89(a)(2) “10 CFR parts 19 and 20” is replaced with “this Part.”

(14) In section 34.101(b) “10 CFR 20.2203” is replaced with “section 16.15(c) of this Part.”

16.128 Well-Logging.

(a) Any person conducting well-logging operations shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 39, Licenses and Radiation Safety Requirements for Well Logging as revised and implemented in full on March 18, 2020, except as follows:

(1) Sections 39.1, 39.5, 39.8, 39.11, 39.45, 39.91, 39.101, and 37.103 are excluded.

(2) Any reference to the “Commission” or “NRC” shall be deemed to be a reference to the New York State Department of Health, except in sections:

(i) 39.35 (b) and (d);

(ii) 39.41(f);

(iii) 39.43 (c) - (e); and

(iv) 39.51.

(3) Any reference to parts 19 and 20 shall be deemed to be a reference to this Part.

(4) Any reference to section 20.1901(a) shall be deemed to be a reference to section 16.12(a) of this Part.

(5) Section 39.63(h) “20.1906 of this chapter” is replaced with “16.16 of this Part.”

(6) Section 39.71(b) “20.1003 of this chapter” is replaced with “16.2 of this Part.”

(7) Section 39.75(d) “71.5 of this chapter” is replaced with “16.17 of this Part.”

(8) Section 39.77(b) “20.2201-20.2202, 20.2203” is replaced with “16.15 of this Part.”

(9) Reports of events or notifications in sections 39.35(d)(2), 39.63(l), and 39.77 shall be reported to the department by means specified in section 16.1(c) of this Part instead of to the NRC.

(b) The requirements in this section do not relieve any person from the requirements in New York State Department of Environmental Conservation (NYSDEC) regulations (6 NYCRR Part 380) for the use of unsealed radioactive material for tracer studies in the environment.

16.129 Specific requirements for irradiators.

(a) This section contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This section also contains radiation safety requirements for operating irradiators. These requirements are in addition to other requirements of this Part. Nothing in this section relieves the licensee from complying with other applicable federal, State, and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

(b) This section applies to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources, and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads)

per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this Part.

(c) This section does not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

(d) Any person conducting irradiator operations shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: 10 CFR 36, Licenses and Radiation Safety Requirements for Irradiators, as revised and implemented in full on March 18, 2020, except as follows:

(1) Section 36.2 definitions of “commencement of construction” and “construction”, sections 36.5. 36.8. 36.11, 36.15, 36.17, 36.19, 36.91 and 36.93 are excluded.

(2) Section 36.21 (a)(1) is amended to add “or equivalent Agreement State Regulations” following “10 CFR 32.210.”

(3) Section 36.23(g) is amended to replace “10 CFR 20.1902” with “this Part.”

(4) Section 36.51(a)(2) is amended to replace “Parts 19 and 36 of NRC regulations” with “this Part.”

(5) Section 36.83(b) is amended to read: “The report must include a telephone report within 24 hours as described in 10 CFR 30.50(c)(1), and a written report within 30 days as described in 10 CFR 30.50(c)(2), except that such reports shall be made to the Department by means specified in section 16.1(c) of this Part instead of to the NRC Operation Center.”

(6) Any reference to the “Commission,” “NRC” or “NRC Regional Office” shall be deemed to be a reference to the New York State Department of Health, except for 10 CFR 36.59(a) and (c).

16.140 Radon testing and reporting.

(a) Definitions. As used in this Part:

(1) "Radon" means the radioactive noble gas radon-222.

(2) "Radon testing firm" means a commercial business which uses equipment or provides detectors for testing for radon or radon decay products, or analyzes radon measurement devices, including continuous radon monitors, and which provides the results of such tests to customers.

(3) "Radon mitigation firm" means a commercial business which evaluates buildings for the purpose of developing plans for reducing indoor air radon levels, and/or implements measures designed to reduce such levels within existing buildings. This includes contractors who install passive mitigation systems in new construction.

(b) General requirements.

(1) A radon testing firm shall report to the department in writing, within 30 days following the end of a reporting period, a summary of all indoor air radon screening and long-term radon tests performed in the State during that reporting period. Reporting periods shall be from January 1st to June 30th and July 1st to December 31st of each year. The report shall include the dates for which the report is made and the number of such measurements performed for the reporting period in each county or ZIP code area in the State.

(2) When any radon screening or long-term testing result exceeds 20 pCi/l or 0.1 working level as defined in section 16.2 of this Part, the radon testing firm shall advise the customer, if a

resident of this State, in writing to contact the New York State Department of Health, Bureau of Environmental Radiation Protection for further technical advice and assistance.

(3) When any radon screening or long-term testing result exceeds 100 pCi/l or 0.5 working level as defined in section 16.2 of this Part, the radon testing firm shall provide telephone and written notification of measured radon concentrations to the department within two working days.

(4) Pursuant to Public Health Law Section 502 and Subpart 55-2 of this Title, no environmental laboratory may perform any examination on samples collected in the State of New York for which the commissioner issues a certificate of approval for such examination unless the laboratory has been issued such certificate of approval. Approval must be obtained through the department's Environmental Laboratory Approval Program.

(5) A radon mitigation firm shall report to the department in writing, within 30 days following the end of a reporting period, a summary of the number of homes mitigated in the State during that reporting period. Reporting periods shall be from January 1st to June 30th and July 1st to December 31st of each year. The report shall include the dates for which the report is made and the number of buildings for which mitigation was performed for the reporting period in each county or ZIP code area in the State.

16.200 Material incorporated by reference.

(a) Documents. The following documents, referenced in this Part, are available for review and copying through the Records Access Officer, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, NY 12237:

(1) Except as set forth in paragraph (2) of this subdivision, Title 10 of the Code of Federal Regulations, Chapter I (Nuclear Regulatory Commission) Parts 19 (as revised and implemented

in full on October 16, 2020), 20 (as revised and implemented in full on March 14, 2023), 30 (as revised and implemented in full on October 16, 2020), 31 (as revised and implemented in full on July 23, 2008), 33 (as revised and implemented in full on March 19, 2013), 35 (as revised and implemented in full on November 14, 2022), 37 (as revised and implemented in full on November 30, 2021), 71 (as revised and implemented in full on November 30, 2021) and 40.13 (revised as of May 29, 2013), 40.21 (revised as of October 3, 1980) and 40.22 (revised as of November 30, 2021) are hereby incorporated by reference with the same force and effect as if fully set forth in this Part. The CFR provisions incorporated by reference herein may be obtained from the department at the address provided above, or from the following:

(i) The United States Government Publishing Office (GPO), 710 North Capitol Street, N.W., Washington, DC 20401 (866) 512-1800, or GPO online at http://www.gpo.gov/fdsys, or

(ii) The U.S. Nuclear Regulatory Commission online at http://www.nrc.gov/reading-rm/doc-collections/cfr/.

(2) The following sections from Title 10 Chapter I of the CFR are not incorporated:

(i) Part 19: 19.1, 19.2, 19.4, 19.5, 19.8, 19.18, 19.30, 19.31, 19.32, and 19.40.

(ii) Part 20: 20.1001, 20.1002, 20.1006 through 20.1009, 20.1405, 20.1406(b), 20.1905(g), 20.2203(c), 20.2401, 20.2402, part 20 appendix D.

(iii) Part 30: 30.1, 30.2, 30.5 through 30.8, 30.21(c), 30.37 through 30.39, 30.41(b)(6), 30.53, 30.55, 30.62, 30.63, 30.64.

(iv) Part 31: 31.1, 31.2, 31.4, 31.22, and 31.23.

(v) Part 33: 33.1, 33.8, 33.11(b-c), 33.14, 33.15, 33.16, 33.21, 33.23, 33.100 Schedule A.

(vi) Part 35: 35.1, 35.8, 35.4001, and 35.4002.

(vii) Part 37: 37.1, 37.3, 37.7, 37.9, 37.11(a-b), 37.13, 37.105, 37.107, and 37.109.

(viii) Part 71: 71.2, 71.6, 71.11, 71.14(b), 71.19, 71.31 through 71.45, 71.51 through 71.77, 71.99, 71.100, 71.101(c)(2), 71.101(d)-(f), 71.107 through 71.125.

(3) To reconcile differences between this Part and the incorporated sections of the CFR, the following meanings shall be substituted for certain terms in the incorporated language of the CFR:

(i) Any reference to ‘‘NRC’’ or ‘‘Commission’’ in the incorporated CFR regulations means the department, unless the context clearly indicates otherwise. Notifications and correspondence indicated in the incorporated sections of the CFR should be sent to the department, except as required by 10 CFR 37.27 (relating to requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material), which should be sent to the NRC.

(ii) References to forms in the incorporated CFR regulations mean the appropriate forms prescribed by the department.

(iii) Any reference to ‘‘NRC or Agreement State’’ in the incorporated CFR regulations means this department, NRC, or Agreement State.

(iv) Any reference to “Type A specific license of broad scope” in the incorporated CFR regulations means “specific license of broad scope” as defined in this Part

(v) Any reference to “byproduct material” in sections 30.31 through 30.62, and 31.9 of the incorporated CFR regulations means “radioactive material” as defined in this Part.

(4) Title 21 of the Code of Federal Regulations, Food and Drugs Parts 900 (as revised and implemented in full on July 14, 2023) and 1020 (as revised and implemented in full on January 20, 2023) are hereby incorporated by reference with the same force and effect as if fully set forth

in this Part. The CFR provisions incorporated by reference herein may be obtained from the department at the address provided in paragraph (1) of this subdivision, or from the following:

(i) The United States Government Publishing Office (GPO), 710 North Capitol Street, N.W., Washington, DC 20401 (866) 512-1800, or GPO online at http://www.gpo.gov or https://www.ecfr.gov/current/title-10.

(5) The National Fire Protection Association (NFPA) 70, National Electrical Code - International Electrical Code Series, 2023 Edition, as incorporated by reference herein may be obtained from the department at the address provided in paragraph (1) of this subdivision, or online at https://www.nfpa.org/product/nfpa-70-code/p0070code.

(b) All persons subject to the requirements of this Part are required to comply with the specific regulations of Title 10 of the Code of Federal Regulations (CFR) as incorporated into this Part pursuant to subdivision (a) of this section.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Section 7 of Part B of Chapter 58 of the Laws of 2006 sets forth the authority for the Commissioner of Health to modify or abrogate the regulations found in Part 38 of Title 12 (Labor) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) pertaining to the radiation control program.

The Public Health and Health Planning Council is authorized by § 225(4) of the Public Health Law (PHL) to establish, amend, and repeal provisions of the State Sanitary Code (SSC), subject to the approval of the Commissioner of Health. PHL §§ 201(1)(r) and 225(5)(p) & (q) authorize SSC regulations to protect the public from the adverse effects of ionizing radiation. Pursuant to such statutory authority and as set forth in 10 NYCRR Part 16, the Department of Health (Department), licenses or registers health care providers to use radioactive materials or ionizing radiation emitting equipment on patients.

The federal Atomic Energy Act of 1954 (the Act), codified at 42 USC § 2021, et. seq., authorizes the United States Nuclear Regulatory Commission (NRC) to regulate the use of radioactive materials. The Act also authorizes "Agreement States," to regulate the use of radioactive materials in lieu of the NRC, provided that the "Agreement State" promulgates regulations that are comparable to or exceed NRC's regulatory standards. New York State is an "Agreement State" within the meaning of the Act. New York's regulatory standards for the use of radioactive materials in 10 NYCRR Part 16 must therefore meet or exceed comparable NRC regulatory standards. The Act governs only the use of radioactive materials: it does not apply to x-rays or radiation therapy equipment that emit only x-rays.

Legislative Objectives:

Chapter 58 of the Laws of 2006 transferred the radiation control program from the Department of Labor (DOL) to the Department of Health, effective July 1, 2006. The law specifically sets forth that the regulations (12 NYCRR Part 38) would remain in effect until "duly modified or abrogated by the Commissioner of Health." The amendments being made by this regulation to 10 NYCRR Part 16 will incorporate and update the regulatory provisions currently found in 12 NYCRR Part 38. It is therefore appropriate to repeal 12 NYCRR Part 38 in its entirety.

The legislative intents of PHL §§ 201(1)(p) and (q) and 225(5) are to protect the public from the adverse effects of ionizing radiation. Promulgating regulations to ensure safe and effective uses of radioactive material and radiation producing equipment is consistent with this legislative objective. Section 225(5)(q) of the Public Health law also authorizes the Department to recover the cost of the programs by charging adequate and reasonable fees for its regulatory activities. Such fees enable the program to maintain the staffing level required to meet the legislative mandate. By establishing the Special Revenue Operating fund in 1999 the Legislature intended the program to be funded through fees.

Needs and Benefits:

The US Nuclear Regulatory Commission (NRC) has relinquished its authority to regulate the use of radioactive materials in New York State to the State. The Atomic Energy Act of 1954 (the Act) (codified at 42 USC § 2021 et. seq.) requires New York to adopt and enforce regulatory standards for the use of radioactive materials that are comparable to or exceed federal regulatory standards that apply to the use of radioactive materials. The Department regulates approximately 1,100 facilities that use radioactive material and approximately 10,000 facilities that use x-ray

equipment. The proposed regulations incorporate by reference many of the NRC regulatory standards that govern the use of radioactive materials in medical and commercial settings. In recent years the technology and equipment used to deliver radiation therapy to cancer patients, including systems used to plan and execute radiation therapy treatment, have become significantly more complex. Recently developed radiation therapy systems more effectively deliver high-dose rate treatments to precisely defined three-dimensional tumor volumes while sparing doses to healthy tissue. Patients benefit significantly when, as is the case in most of such radiation treatments, the dose is delivered as intended.

Schedules for licensing and registration fees currently being assessed by the Bureau of Environmental Radiation Protection (BERP) are published under two separate Titles of the NYCRR. Title 12 NYCRR section 82.8 contains the fee schedule for radioactive materials licenses and radiation equipment registrations issued to industrial and commercial facilities formerly regulated by DOL under Industrial Code Rule number 38 (12 NYCRR 38). Title 10 NYCRR section 16.41 contains the corresponding schedule for radioactive sources regulated by the Department under 10 NYCRR Part 16. The current proposal combines these into one fee schedule to be published in 10 NYCRR § 16.41. Regulated parties would benefit from having a single fee schedule in one location for all radiation sources regulated by the Department.

The current fee schedules were established in 2001 (for the Department) and 2005 (for DOL). The costs of the Department's program have increased due to increased salary, equipment and travel costs. In addition to these cost increases, increased security measures have been adopted requiring closer tracking and more frequent inspection by the Department of certain radiation sources that are of concern for national security reasons. The increased costs from these additional measures must be recovered through fees.

Finally, the proposed rule establishes an annual fee for reciprocity. Reciprocity is required under federal rules as it allows an entity licensed in another state to operate temporarily in New York based on their radioactive materials license in their home state. New York is currently one of only two states that does not charge a reciprocity fee (the other is Alabama). Other states' fees (including 48 other state programs) range from $100 to $1,400 with an average fee of about $900 per year.

The NRC audited New York State in August 2022 to review the overall status of the agreement state program. A significant finding of the last two such audits was that the New York State program is failing to meet compatibility standards. Since this is the third audit where NYS was deemed not compatible with NRC regulations, NRC placed NYS on heightened oversight. This status will be maintained until these regulations are updated and NRC completes another audit.

Costs:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

This regulation updates the fees charged to facilities that use radioactive materials or x-ray equipment. On average the fee increases are 68% over existing fees. These fees are still significantly less than the corresponding fees charges by the NRC which, depending on facility type range from $12,300 to over $53,800, or two to six times higher than the proposed fees. Geographically adjacent states (PA, NJ, and MA) have different fee structures that are more variable, but in general their fees are slightly higher than what the Department is proposing in this rule.

Fee Category	Current fee	Proposed fee	Count
Radiation Equipment Category I (i.e., Hospital)	$1,420	$2,600	75
Radiation Equipment Category II (i.e., Clinic)	$1,080	$1,800	200
Radiation Equipment Category III (i.e., Large Private practice)	$740	$1,250	200
Radiation Equipment Category IV (i.e., Small Practice)	$325	$550	600
Radiation Equipment Category V (i.e., Small Practice Low Volume)	$190	$325	1,400
Radiation Equipment Category VI (i.e., Dental/Vet/Podiatry)	$65	$100	7,400
Radioactive Materials Category I (i.e., Medical Broadscope)	$5,265	$9,600	6
Radioactive Materials Category II (i.e., Academic Broadscope)	$3,510	$6,200	9
Radioactive Materials Category III (i.e., Nuc Pharm, Brachytherapy)	$1,400	$2,400	37
Radioactive Materials Category IV (i.e., Nuclear Medicine, LINAC)	$880	$1,500	502
Radioactive Materials Category V (i.e., Clinical Labs, XRF)	$350	$600	78
Radioactive Materials Category VI (i.e., Gas Chromatograph)	$50	$120	2
Radioactive Materials Commercial 1 (i.e., Industrial Radiography)	$2,500	$3,600	52
Radioactive Materials Commercial 2 (i.e., Manufacturing)	$1,833	$3,000	23
Radioactive Materials Commercial 3 (i.e., R&D, Irradiators)	$1,333	$2,400	148
Radioactive Materials Commercial 4 (i.e., Gauges)	$1,000	$1,800	182

Radioactive Materials Commercial 5 (i.e., GC, analytic Equipment)	$500	$600	5
Radioactive Materials General (i.e., General License)	$33	$120	146
Totals (count x fee)	$2,555,458	$4,291,760	11,065

Additionally, these regulations will impose new costs on Cone-Beam CT units (CBCTs). These units, like all other CT units, will have to be accredited within 18 months of the adoption of this rule. They will also be subject to annual quality assurance testing. Accreditation costs are approximately $3,000 every three years, and the annual Quality Assurance (QA) testing will be $800 to $1,200 per year.

C**osts to State and Local Governments:**

Government agencies are exempt from the fees in these regulations, except for government operated hospitals and higher education institutions. This will include about 30 hospitals (including Nassau County Medical Center, Westchester County Medical Center, and Erie County Medical Center) and State University of New York (SUNY) colleges which will have an approximately 60% to 75% increase in fees.

The cost increase to the three county run health care facilities are listed below:

County	Current Fees	Proposed Fees	Net increase
Nassau	2300	4100	+1800
Westchester	3635	5875	+2240
Erie	1960	3300	+1340

There are approximately 25 SUNY facilities that have X-ray equipment or a radioactive materials license. The sum of all SUNY fees will increase from approximately $36,000 currently to a total of $63,000 spread over the 25 regulated facilities. These fee increases are incidental costs for programs of this size.

Costs to the Department of Health:

These regulations make numerous technical changes and updates to the radiation safety rules. These changes will require the Department to update guidance, forms, and Standard Operating Procedures. These activities are done periodically and will not incur significant extra costs for the Department.

Local Government Mandates:

These proposed regulations apply to hospitals operated by public benefit corporations including Nassau, Erie and Westchester Medical centers. The increased annual fees will apply to these facilities. Registrants and licensees, including the hospitals operated by State and local governments, are currently required to retain all quality assurance documents for review by the Department. As such, no other additional costs or mandates are associated with implementation of these regulations.

Paperwork:

Department regulations (10 NYCRR Part 16) require registrants and licensees to maintain a variety of records relating to the use of ionizing radiation for review by the Department. The

Department estimates that licensees and registrants may have a small amount of additional documentation to create, maintain, or file these records. These regulations change the content of those records (ex. different quality assurance requirements) but do not significantly increase any required documentation over the current standards.

Duplication:

There is no duplication of the proposed regulatory requirements by any federal, State, or local agency for licensees, registrants, or authorized users subject to 10 NYCRR Part 16. New York State entered into an agreement with the federal government on October 15, 1962, by which the federal government discontinued its direct exercise of regulatory authority over the use of radioactive materials and New York assumed such authority.

Alternatives:

Many of the regulatory changes are required to meet federal standards. The alternative to the present fee proposal is to leave the current fees unchanged. This would require a proportional reduction in the scope of the Department's regulatory program to offset the effects of inflation and increased security measures. Failure to implement these changes would jeopardize New York's "agreement state" status and could also jeopardize public health.

Federal Standards:

New York State's agreement with the NRC requires it to promulgate regulations consistent with the NRC's rules, either by incorporation by reference or by developing state rules that are

nearly identical. These regulations incorporate by reference many federal standards developed by the U.S. NRC.

Compliance Schedule:

Except for the Cone-Beam CT accreditation requirements, there is no compliance schedule imposed by these regulations, which shall be effective upon publication of the Notice of Adoption in the State Register. The Cone-Beam accreditation rule requires that facilities apply to an accrediting body within 90 days of the regulations going into effect and that they complete the process with 18 months.

Contact Person:

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

These regulations will apply to two State University hospitals, one county hospital and three hospitals operating as a public benefit corporation. There are approximately 200 other facilities operated by local government agencies, mostly jails and community clinics that will be affected by these regulations but that are exempt from the fees set forth in regulation.

Of the roughly 11,000 licenses and registrations currently issued under 10 NYCRR Part 16, it is estimated that approximately two-thirds constitute small business, roughly 6,400 throughout the State. This figure does not include any hospitals, educational facilities or government operated entities.

Compliance Requirements:

This rule change will affect small businesses and local government facilities that use ionizing radiation, including healthcare facilities, colleges, and commercial services. This is a repeal and replace of the entire existing regulation. Significant changes and updates include the following:

- Radioactive material licensing is updated to incorporate federal standards by reference and to include NYS Department of Labor regulations that were previously turned over to the Department of Health.
- Radioactive materials license and x-ray equipment registration fees are increased an average of 68%, fees for reciprocity are added, and late fees are removed. Commercial

license fees were converted to annual fees from triannual which will reduce the initial burden on applicants.

- The proposed rules include a requirement for accreditation and quality assurance (QA) testing on Cone-Beam CT units used on people, most of which are used in dentistry.
- QA requirements for diagnostic imaging have been updated to reflect the current technologies, in particular the replacement of film with digital imaging modalities. The regulations have been developed based on American College of Radiology (ACR) and American Association of Physicists in Medicine (AAPM) guidance documents that the Department of Health (Department) has used as a standard for facilities for the past decade.
- Definitions have been added for compatibility and clarity purposes. Other sections of the regulations have had out of date language or unclear phrasing reworded based on discussions with regulated entities and NRC staff.
- Updates require recording of high patient doses from fluoroscopy and notification of referring physician and instructions to patient.

Regulated facilities will need to become familiar with the updated rules and may need to modify their radiation safety program and quality assurance policies and procedures accordingly. Those facilities with Cone Beam CT units that are not accredited will need to do so within 18 months of the effective date of the rule.

Professional Services:

Many large facilities have in-house staff that perform quality assurance testing and operate radiation emitting technology. Smaller offices and private practices employ consultants

to provide QA services and assistance in the development of policies and procedures relating to radiation safety. The QA related changes will not require significant time and the Department will provide updated guidance and references to current professional and national standards as applicable.

The Department does not expect that it will be necessary for licensees to use additional professional services for completion of applications for accreditation or to implement the quality assurance requirements other than the operators of Cone-Beam equipment who will have to develop QA plans and become accredited.

Compliance Costs:

The Cone-Beam CT accreditation will cost the registrant about $3,000 dollars for a three-year period and the Cone Beam CT QA testing will cost approximately $800 to 1,200 per year. In addition, radioactive materials license and x-ray equipment registration fees are increased an average of 68%, fees for reciprocity are added, and late fees are removed. This fee increase is needed to cover program cost as the fees have not increased since 2001. Program used the US Bureau of Labor Statistics Consumer Price Index Calculator to determine average increases from 2002 to 2023. This program is a partial cost recovery program and staff salaries, and other program operation expenses are covered through the fees. Commercial license fees were converted to annual fees from triannual which will reduce the initial burden on applicants.

Economic and Technology Feasibility:

There are no capital costs or new technology required to comply with the proposed rule. Most of the facilities affected will be dental, veterinary, and podiatric facilities and they will

have a $35 increase in registration fee which is still a low cost relative to many other states' annual fees. Large hospitals, universities and other large corporate entities will see larger amounts proportional to the cost to inspect and regulate these facilities. Therefore, the proposal should be economically and technologically feasible for regulated entities.

Minimizing Adverse Impact:

Most facilities will not need a substantial amount of time to comply with these updates. Mitigating the fee increase for commercial licensees will be the fact that they only pay a 1-year fee instead of a 3-year fee. Late fees for all regulated facilities are dropped. Facilities will have 90 days to apply for accreditation and 18 months to become accredited. This will allow a facility adequate time to select the accreditation body of their choice, complete an application, and budget funds for the accreditation fee. Most users of Cone Beam CT equipment already charge patients a fee for the images made by this equipment and will be able to recoup the increased cost associated with the increased QA requirements.

Small Business and Local Government Participation:

The diagnostic quality assurance testing changes were reviewed by NYS medical and health physics societies for technical content during the past several years. The therapy regulation updates have been developed with input from radiation oncology facilities, based on current professional standards and practices. The Department of Health will provide notice of rulemaking to organizations that represent the interested parties including the dental, veterinary, podiatry, medical (MSSNY) and healthcare (HANYS) and other interested parties. In addition, the proposed regulations will be published in the State Register to provide Small Business and

Local Government a review and comment period, which is an opportunity for comment and to participate in the regulatory process. Some sections of the regulations have had out of date language or unclear phrasing reworded based on discussions with regulated entities and NRC staff and many of their suggestions have been included.

For Rules That Either Establish or Modify a Violation or Penalties Associated with a Violation:

Violations that had previously been cited by 12 NCYRR Part 38 may now be cited under 10 NYCRR Part 16 as the NYS Department of Labor regulations are transcribed into Title 10 NYCRR Part 16. There are no changes to any violations or penalties, however late fees have been removed from the fee schedule and will no longer be charged.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the State, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 44 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2020 (https://www.census.gov/quickfacts/). Approximately 17% of small health care facilities are located in rural areas.

Allegany County
Broome County
Cattaraugus County
Cayuga County
Chautauqua County
Chemung County
Chenango County
Clinton County
Columbia County
Cortland County
Delaware County
Essex County
Franklin County
Fulton County
Genesee County
Greene County
Hamilton County
Herkimer County
Jefferson County
Lewis County
Livingston County
Madison County
Montgomery County
Ontario County
Orleans County
Oswego County
Otsego County
Putnam County
Rensselaer County
Schenectady County
Schoharie County
Schuyler County
Seneca County
St. Lawrence County
Steuben County
Sullivan County
Tioga County
Tompkins County
Ulster County
Warren County
Washington County
Wayne County
Wyoming County
Yates County

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2020.

Albany County
Dutchess County
Erie County
Monroe County
Niagara County
Oneida County
Onondaga County
Orange County
Saratoga County
Suffolk County

There are just over 11,000 regulated facilities that possess and use x-ray equipment or radioactive materials. Approximately 20% are in the 44 counties defined as rural based on population and an additional 46% are in those counties defined as rural by population density. As of January 1, 2022, there are just under 7,200 facilities in rural areas. Approximately 50% of the regulated facilities are dental, 10% are veterinarians, 9% are physicians' offices, 8% are non-human use (academic, commercial, or industrial), 7% are hospitals, clinics or imaging centers, and the rest are a mix of podiatrists, chiropractors, and other specialty providers.

Reporting, Recordkeeping and Other Compliance Requirements and Professional Services:

There are no new reporting requirements to the State contained in the proposed regulations for most regulated facilities. However, certain medical users of fluoroscopy will have to report to the patient and maintain records of high patient exposure. This will affect hospitals and ambulatory surgery sites that perform interventional fluoroscopic procedures. No additional professional service costs are anticipated. Facilities are currently required to maintain records of quality assurance test results and accreditation documents for review by the Department’s inspectors. The content of these tests is specified in sections 16.23 and 16.24 of these regulations. Compliance with the recordkeeping requirements will require only a minor incremental amount of time and effort for affected facilities.

Cost:

Fees are increased an average of 68% for all license and registration categories. Specifically, operators of Cone-Beam CT units will also have to get accredited which will cost them $3,000 for a three-year period. These units will now be subject to quality assurance testing

requirements that will cost an additional $800-1,200 per year. This will affect approximately 10% of the dental practices in the State, principally oral surgeons, and other specialty practices.

Schedules for licensing and registration fees currently being assessed by the Bureau of Environmental Radiation Protection (BERP) are published under two separate Titles of the NYCRR. Title 12 NYCRR section 82.8 contains the fee schedule for radioactive materials licenses and radiation equipment registrations issued to industrial and commercial facilities formerly regulated by DOL under Industrial Code Rule number 38 (12 NYCRR 38). Title 10 NYCRR section 16.41 contains the corresponding schedule for radioactive sources regulated by the Department under 10 NYCRR Part 16. The current proposal combines these into one fee schedule to be published in 10 NYCRR § 16.41. Regulated parties would benefit from having a single fee schedule in one location for all radiation sources regulated by the Department.

The current fee schedules were established in 2001 (for the Department) and 2005 (for DOL). The costs of the Department's program have increased due to increased salary, equipment and travel costs. In addition to these cost increases, increased security measures have been adopted requiring closer tracking and more frequent inspection by the Department of certain radiation sources that are of concern for national security reasons. The increased costs from these additional measures must be recovered through fees.

Finally, the proposed rule establishes an annual fee for reciprocity. Reciprocity is required under federal rules as it allows an entity licensed in another state to operate temporarily in New York based on their radioactive materials license in their home state. New York is currently one of only two states that does not charge a reciprocity fee (the other is Alabama). Other states' fees (including 48 other state programs) range from $100 to $1,400 with an average fee of about $900 per year.

Minimizing Adverse Impact:

Most facilities will not need to take a substantial amount of time to comply with these updates. Mitigating the fee increase for commercial licensees is the fact that they will now only pay a 1-year fee instead of a 3-year fee. In addition, late fees for all regulated facilities are dropped. Cone Beam CT facilities will have 90 days to apply for accreditation and 18 months to become accredited. This will allow a facility adequate time to select the accreditation body of their choice, complete an application and budget funds for the accreditation fee. Most users of Cone Beam CT equipment already charge patients a fee for the images made by this equipment and therefore should be able to recoup the increased costs associated with the new regulatory requirements.

Rural Area Participation:

Regulated facilities are invited to comment during the Codes and Regulations Committee meeting of the Public Health and Health Planning Council and as part of the formal public comment process. The diagnostic quality assurance testing changes were reviewed by NYS medical physics and health physics societies for technical content during the past several years. The therapy regulation updates have been developed with input from radiation oncology facilities, based on current professional standards and practices. The majority of the changes are based on existing guidance, published federal regulations, merge DOL regulations into DOH regulations, or were clarifications and modernizations of language. DOH has communicated the nature of these updates with interested professional organizations over the past few years. Fee increases were not discussed with the regulated community in advance of this proposal, however

these same fee increases were made available for public comment when an earlier revision to 10 NYCRR 16 was published in April 2024 and no comments regarding fees were received.

JOB IMPACT STATEMENT

Nature of Impact:

It is anticipated that no jobs will be adversely affected by this rule. Medical providers of diagnostic imaging and radiation therapy will need to become familiar with the new quality assurance requirements.

Categories and Numbers Affected:

There are approximately 10,000 facilities registered to use radiation producing equipment (x-ray machines), and more than 1,100 facilities authorized by license to use radioactive material. Approximately 5,500 of the x-ray facilities are dental practices.

Regions of Adverse Impact:

No areas will be adversely affected.

Minimizing Adverse Impact:

There are no alternatives to the proposed regulations. Many of these changes are required for the State to maintain compatibility with federal regulations. Non-compatibility updates reflect technological change, especially the change from film-based imaging to digital x-ray systems. The Department will revise guidance to assist all licensees, including those in rural areas, with implementation of the proposed regulations.

Self-Employment Opportunities:

The rule may have impact on some dental practices. It imposes an additional cost and a quality assurance requirement on facilities that have Cone-Beam CT units (CBCT). The Department estimates that there are between 500 and 600 practices that have CBCT units.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 225 of the Public Health Law, sections 2.1, 2.2, and 2.5 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are repealed in their entirety and replaced, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

DESIGNATION OF CASES

Section 2.1 - Communicable diseases designated: cases, suspected cases and certain carriers to be reported to the State Department of Health.

(a) When used in the Public Health Law and in this Title, the terms infectious, contagious, or communicable disease shall include the following diseases and any other disease which the commissioner, in the reasonable exercise of their medical judgment, determines to be communicable, rapidly emergent, or a significant threat to public health, provided that the disease, associated condition, or agent identified by laboratory analysis which is added to one or both of these lists solely by the commissioner's authority shall remain on the list or lists only if confirmed by the Public Health and Health Planning Council at its next scheduled meeting.

Diseases and Associated Conditions	**Agents Identified by Laboratory Analysis**
Amebiasis	*Entamoeba histolytica, dispar*
Anthrax	*Bacillus anthracis*
	Arboviruses
	Blastomyces species
Botulism	*Clostridium botulinum, butyricum, baratii,*

	and other species of Clostridium producing botulinum neurotoxin
Brucellosis	Brucella species that cause brucellosis
Campylobacteriosis	Campylobacter species
	Candida auris
	Carbapenem-resistant organisms
Chancroid	*Haemophilus ducreyi*
Chlamydia trachomatis infection, including lymphogranuloma venereum	*Chlamydia trachomatis*
Cholera	*Vibrio cholerae* O1 and O139 serogroups with toxin gene or toxin detected
Coronavirus-related conditions as follows: • COVID-19-associated deaths in persons <18 years of age • multisystem inflammatory syndrome in children (MIS-C) • severe acute respiratory syndrome (SARS) • Middle East respiratory syndrome (MERS) • novel coronavirus infection (specify type)	Coronaviruses as follows: • SARS-CoV-1 • SARS-CoV-2 • MERS-CoV • novel coronaviruses (specify type)
Cronobacter infection (<12 months of age),	Cronobacter species (<12 months of age),

invasive	invasive
Cryptosporidiosis	Cryptosporidium species
Cyclosporiasis	Cyclospora species
Cytomegalovirus infection (≤90 days of age) and congenital cytomegalovirus disease	Cytomegalovirus (≤90 days of age)
Diphtheria	*Corynebacterium diphtheriae*
Encephalitis	Encephalitis, causative organisms
Escherichia coli infection, Shiga toxin-producing	*Escherichia coli*, Shiga toxin-producing
Giardiasis	Giardia species
Glanders	*Burkholderia mallei*
Gonococcal infection	*Neisseria gonorrhoeae*
	Haemophilus influenzae, invasive
	Hantavirus
Hemolytic uremic syndrome	
Hendra virus infection	Hendra virus
Hepatitis A	Hepatitis A virus
	Hepatitis B virus
	Hepatitis C virus
Herpes simplex virus infection (≤60 days of age)	Herpes simplex virus (≤60 days of age)
Influenza-related conditions as follows: • Influenza-associated deaths in persons	Influenza virus

<18 years of age; • Influenza, novel	
	Legionella species
Leprosy (Hansen's disease)	*Mycobacterium leprae, lepromatosis*
	Leptospira species
Listeriosis	*Listeria monocytogenes*
	Plasmodium species
Measles	Measles virus
Melioidosis	*Burkholderia pseudomallei*
Meningitis	Meningitis, causative organisms
Meningococcal disease, invasive	*Neisseria meningitidis*, invasive
Mpox	Monkeypox virus
Mumps	Mumps virus
Nipah virus infection	Nipah virus
Pertussis (whooping cough)	*Bordetella pertussis*
Plague	*Yersinia pestis*
Poliomyelitis and acute flaccid myelitis	Poliovirus
	Chlamydia psittaci
Q fever	*Coxiella burnetii*
Rabies	Rabies virus
Respiratory syncytial virus (RSV)-associated deaths in persons <18 years of age	Respiratory syncytial virus (RSV)
	Rickettsia species

Rubella, including congenital rubella syndrome	Rubella virus
Salmonellosis	Salmonella species
Shigellosis	Shigella species
Smallpox	Variola virus
Staphylococcus aureus, resistant to glycopeptides	*Staphylococcus aureus*, intermediate or resistant to glycopeptides
Staphylococcal enterotoxin poisoning	Staphylococcal enterotoxin
Streptococcal infection, group A, invasive	*Streptococcus pyogenes* (group A beta hemolytic Streptococcus), invasive
Streptococcal infection, group B, invasive	*Streptococcus agalactiae* (group B Streptococcus), invasive
	Streptococcus pneumoniae, invasive
Syphilis (specify stage), including congenital syphilis	*Treponema pallidum*
Tetanus	
Tick-borne disease as follows: Lyme disease with erythema migrans rash	Tick-borne disease-causing organisms and results consistent with alpha gal syndrome
Toxic shock syndrome	
Trichinosis	Trichinella species
Tuberculosis, current active disease (specify site)	*Mycobacterium tuberculosis* complex species, including active or latent infections detected via interferon gamma release assays

Tularemia	*Francisella tularensis*
Typhoid	*Salmonella* Typhi
Varicella (not zoster/shingles)	Varicella zoster virus
Vaccinia disease	Vaccinia virus
Vibriosis	Vibrio species, including *Vibrio cholerae* not meeting criteria for cholera reporting
Viral hemorrhagic fever	Hemorrhagic fever viruses
Yersiniosis	Yersinia species

(b) Upon receipt of a report made pursuant to sections 2.10 or 2.12 of this Title, the city, county, or district health officer shall immediately provide such report to the State Department of Health and shall retain the report and all records related to such report until their destruction is authorized by the State Commissioner of Health. In lieu of an individual report of each case, the city, county or district health officer may, with the written consent of the State Commissioner of Health, make summarized reports.

(c) Any disease outbreak or unusual disease, as defined in section 2.2 of this Title, shall also be reported to the State Department of Health as provided in subdivision (b) of this section.

Section 2.2 - Definitions. As used in this Part, the following terms shall have the following meanings:

(a) *Case* means a person who has been diagnosed to have a particular disease or condition. The diagnosis may be based solely on clinical judgement, including epidemiologic considerations, or solely on laboratory evidence, or on both criteria.

(b) *Suspected case* means a person who has been diagnosed as likely to have a particular disease or condition. The suspected diagnosis may be based solely on clinical judgement, including epidemiologic

considerations, or solely on laboratory evidence, or both criteria.

(c) *Outbreak* means an increased incidence of disease above its expected or baseline level and shall include both healthcare-associated and community outbreaks. While an outbreak usually involves several cases of illness (e.g., food-borne poisoning, influenza), it may consist of just one case for certain rare and/or serious diseases (e.g., botulism, measles) and shall include single cases of disease that may reasonably be considered to portend an outbreak of public health importance. Healthcare-associated outbreaks shall include an outbreak due to microbiological agents or their toxic products occurring in patients, residents, or personnel in settings where healthcare is provided. Because the number of cases which indicate the presence of an outbreak varies according to the infectious agent, size and type of population exposed, previous exposure or lack of exposure to the disease, and time and place of occurrence, the expected or baseline level of disease shall be assessed by hospitals and their infection control committees.

(d) *Unusual disease* means a newly apparent or emerging disease or syndrome that is, or that a healthcare provider or the State Commissioner of Health has reason to believe could possibly be caused by a transmissible agent or toxin and is either of uncertain etiology or of known etiology but demonstrates new epidemiologic or clinical characteristics that are known or suspected to have substantial public health significance.

(e) *Local health authority* means the health officer of a county, part-county, city, town, village, consolidated health district, or any county or public health director having all the powers and duties prescribed in section 352 of the Public Health Law.

(f) *Approved laboratory* or *laboratory approved for the examination* means either a laboratory possessing a certificate of approval for the specified examination pursuant to title 1 of article 5 of the Public Health Law or a laboratory holding a permit for the specified examination pursuant to title 5 of article 5 of the Public Health Law.

(g) *Vaccinia disease* shall mean:

(1) persons with vaccinia infection due to contact transmission; and

(2) persons with the following complications from vaccination: eczema vaccinatum, erythema multiforme major or Stevens-Johnson syndrome, fetal vaccinia, generalized vaccinia, inadvertent inoculation, ocular vaccinia, post-vaccinial encephalitis or encephalomyelitis, progressive vaccinia, pyogenic infection of the vaccination site, and any other serious adverse events (i.e. those resulting in hospitalization, permanent disability, life-threatening illness or death).

INVESTIGATIONS AND DETERMINATIONS

Section 2.5 – Submission of specimens for laboratory examination in cases or suspected cases of certain communicable diseases.

(a) A licensed healthcare provider in attendance on a person affected or suspected of being affected with any of the diseases listed in this section, and whose scope of practice includes the legal authority to diagnose the disease via laboratory examination, shall submit specimens for examination to an approved laboratory together with data concerning the history and clinical manifestations pertinent to the examination. The State Commissioner of Health may direct specimens be sent to the laboratory of the State Department of Health or other approved laboratory, as well as the examination(s) to be conducted.

Anthrax

Arboviral infection

Botulism

Brucellosis

Chancroid

Chlamydia trachomatis infection

Cholera

Conjunctivitis, purulent (≤28 days of age)

Coronavirus infection as follows: severe acute respiratory syndrome (SARS); Middle East respiratory syndrome (MERS); novel coronavirus infection

Cytomegalovirus disease, congenital (≤90 days of age)

Diarrhea, acute infectious non-viral

Diphtheria

Glanders

Gonococcal infection

Hantavirus disease

Haemophilus influenzae infection, invasive

Hemolytic uremic syndrome

Hepatitis A

Herpes simplex virus infection (≤60 days of age)

Influenza infection caused by a novel influenza virus

Legionellosis

Leprosy (Hansen's disease)

Leptospirosis

Listeriosis

Malaria

Measles

Melioidosis

Meningitis: *Haemophilus*, Meningococcal

Meningococcal disease, invasive

Mpox

Mumps

Pertussis (whooping cough)

Plague

Poliomyelitis and acute flaccid myelitis

Q fever

Rabies

Rubella, including congenital rubella syndrome

Smallpox

Staphylococcal enterotoxin poisoning

Streptococcus pyogenes infection (group A beta hemolytic Streptococcus), invasive

Streptococcus agalactiae infection (group B Streptococcus), invasive

Streptococcus pneumoniae infection, invasive

Syphilis, including congenital syphilis

Tick-borne infection, except for Lyme disease cases with erythema migrans rash

Trichinosis

Tuberculosis

Tularemia

Typhoid

Vaccinia disease (as defined in Section 2.2 of this Part)

Vibriosis

Viral hemorrhagic fever

SUMMARY OF REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for the regulatory amendments to Part 2 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is section 225 of the Public Health Law (PHL), which authorizes the Public Health and Health Planning Council (PHHPC), subject to the approval of the Commissioner of Health (Commissioner), to establish and amend the State Sanitary Code (SSC) provisions related to any matters affecting the security of life or health or the preservation and improvement of public health in the State of New York.

Legislative Objectives:

Section 225 of the Public Health Law (PHL) authorizes the PHHPC, subject to the approval of the Commissioner, to establish and amend the SSC related to any matters affecting the security of life or health or the preservation and improvement of public health in the State of New York.

Article 21 of the PHL relates to control of acute communicable diseases. Section 2100 provides that every local board of health and every health officer shall guard against the introduction of such communicable diseases as are designated in the SSC. Section 2101 of the Public Health Law requires physicians and institutions to provide notice of every case of communicable disease required by the Department to be reported. Section 2102 requires clinical laboratories to report suspected or confirmed positive findings or markers of communicable diseases, and other pertinent facts, to local or state health officials. Additionally, section 576-c of the Public Health Law requires clinical laboratories to report such test results, and other data elements, electronically on a schedule determined by the commissioner. Section 2103 of the PHL requires all local health officers to report cases of communicable disease to the New York State Department of Health (the Department).

In line with these statutory provisions and the legislative intent, the proposed regulations address communicable diseases of public health concern. Section 2.1 includes a listing of diseases, conditions, and agents that must be reported; section 2.2 establishes definitions within the scope of Part 2; and section 2.5 specifies those diseases and conditions for which a specimen must be collected for laboratory analysis when a specified disease or condition is diagnosed or suspected.

Needs and Benefits:

The proposed regulations repeal the single list of communicable diseases in section 2.1 and replace it with two lists, one of diseases/conditions for case reporting and the other of agents for laboratory test result reporting.

Regarding the two updated lists in section 2.1, the proposed regulations group tick-borne diseases under a single tick-borne disease category and add alpha gal syndrome and Rickettsia, which will ensure that novel and emerging tickborne diseases are reported to the Department to inform public health response activities. The regulatory amendments include aligning respiratory virus reporting as much as possible; removing "hospital-associated infections" (which will not change reporting requirements); making minor changes to three conditions; and adding certain select agents. The proposed amendments would add certain problematic antimicrobial-resistant organisms: *Candida auris* (an emerging fungal pathogen), carbapenem-resistant organisms (highly-resistant bacteria prevalent in the New York metropolitan area and spreading); and *Staphylococcus aureus* showing intermediate susceptibility or resistance to glycopeptide antibiotics. The proposed regulations also add three conditions that appear to be emerging or expanding in range: blastomycosis (a fungal infection present in the Mohawk Valley), vibriosis (a bacterial illness related to coastal water exposure), and leprosy (which appears to be increasing in Southeastern states and of which the Department is occasionally informed and asked for assistance). The proposed regulations

add two conditions that impact infants: *Cronobacter* (which can cause sepsis and is associated with contaminated formula), and congenital cytomegalovirus infection (which can cause hearing loss, and which can be treated if identified early). This will allow the Department to better conduct activities related to congenital cytomegalovirus described in Public Health Law sections 207 and 266. The proposed amendments to section 2.1 would add *Leptospira* species (associated with social and sanitation issues such as subpar housing) and interferon gamma release assays (to identify latent or active tuberculosis).

Finally, changes to section 2.1 also include several non-substantive changes like correcting spelling errors and streamlining language to reflect that reports are primarily submitted electronically.

The proposed amendments to section 2.2 update existing definitions, delete the definition of "hospital-associated infections" and include a definition of "unusual disease" that was previously included in section 2.1. Additionally, the definition of a "case" has been updated and the definition of an "outbreak" has been clarified and slightly expanded. Finally, the definition of "unusual disease" has been expanded to include diseases of known etiology but exhibiting new epidemiologic or clinical characteristics with substantial public health significance.

Proposed amendments to section 2.5 would require all licensed healthcare providers whose scope of practice includes the legal authority to diagnose a particular disease via laboratory examination, to submit specimens for laboratory examination when in attendance on a person affected with or suspected of being affected with any of the diseases listed within section 2.5. The current regulation only applies to licensed physicians in attendance. Additionally, amendments to section 2.5 clarify the Commissioner of Health's authority to direct specimens to be sent to the Department of Health's laboratory or another approved laboratory, and to direct the examination(s) to be conducted on such specimens.

The proposed amendments to section 2.5 also group together several conditions, simplify coronavirus testing requirements, and add conditions that require testing to be identified with certainty, to allow for appropriate public health response. Additionally, the proposed amendments add several vaccine-preventable illnesses such as measles, mumps, pertussis, and rubella.

Costs:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

Costs to regulated entities are expected to be minimal. New York State has human and electronic resources in place to support compliance with public health reporting requirements. Laboratories have robust reporting infrastructure in place and already report several of the added conditions due to reporting requirements specific to New York City. For organisms that are added, there would be a modest initial cost to update the laboratories' automated reporting systems.

All conditions added to the case reporting list are either of very low incidence or are rarely detected and therefore should not create a financial burden on regulated entities. Additionally, several higher-incidence conditions were removed from case reporting requirements, relieving clinicians of reporting burden. While entities required to report must cooperate with investigations, that cooperation primarily consists of providing information, and no additional compliance costs are expected.

The testing requirements added to section 2.5 may add additional costs for medical care; however, it is likely that many of the specimens required to be examined are already tested as part of standard clinical care.

C**osts to State and Local Governments:**

Great care has been taken during the development of the proposed regulations to minimize costs to the State of New York and to local governments. Costs to the State beyond the Department of Health (see below for Department of Health) are expected to be negligible, if any. Costs to local health

departments (LHDs) have been minimized:

- Case reporting requirements were removed if reporting of a laboratory result would be sufficient.
- Certain organisms which are expected to be reported by laboratories in high or moderate numbers will be accepted by the Department electronically but will not be passed to the LHDs (except upon request), similar to the current process for influenza.
- For added diseases or organisms that will require investigation by LHDs, the investigatory flexibility previously added to Section 2.6 will continue to be used to limit the response to what is needed, rather than requiring a full investigation in all situations.

There are no new or additional compliance costs to the State or to LHDs associated with the proposed amendments to definitions in section 2.2, nor for the newly added conditions in section 2.5.

Costs to the Department of Health:

Costs to the Department are expected to be low. Most of the additions to section 2.1 are expected to be reported in very low numbers. Those conditions which are expected in high numbers (*Candida auris*, carbapenem-resistant organisms) typically occur as part of outbreaks in Article 28 healthcare facilities, which the Department already investigates. There would be an initial cost to update the Department's electronic laboratory reporting system to receive newly reportable laboratory results; however, this can be done within existing resources.

There are no new or additional compliance costs to the Department associated with the proposed amendments to definitions in section 2.2.

A potential increase in specimens being sent to the Wadsworth Center for examination could result in costs to the Department. However, testing for most of the added conditions can be performed at commercial laboratories, so these costs should be minimal and can be absorbed within existing

resources.

Local Government Mandates:

Local health officers will continue to be required to forward reports to the Department and to investigate cases or suspect cases consistent with guidance provided by the Department. There is flexibility regarding investigation requirements in section 2.6, allowing local health departments to limit certain investigations.

Paperwork:

There will be no new paperwork associated with these proposed amendments; however, revisions will need to be made to the Department's existing general communicable disease reporting form (DOH-389), the instructions, and the laboratory guidance.

Duplication:

No relevant laws of the State and/or Federal government exist that duplicate, overlap, or conflict with these proposed amendments.

Alternatives:

Alternatives to the proposed amendments would be to maintain the current list of reportable communicable diseases in section 2.1 and the current definitions in section 2.2. The Department could have also maintained the current list of diseases in section 2.5 and not expanded the scope of the regulation to health care providers beyond just physicians. However, these alternatives were not considered because the proposed amendments increase the likelihood that crucial testing will be conducted and update outdated language. Moreover, the proposed amendments require reporting of the added conditions which is necessary for critically important disease surveillance.

Federal Standards:

The proposed amendments do not exceed any minimum standards of the Federal government.

State and local health departments have primary authority for controlling disease within their jurisdictions.

Compliance Schedule:

The Department is updating existing electronic reporting systems, as well as the form and instructions for manual case reporting, to support reporting of newly added conditions. It is anticipated that regulated entities would be able to immediately comply with the rule upon publication of the Notice of Adoption in the State Register.

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REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for the regulatory amendments to Part 2 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is section 225 of the Public Health Law (PHL), which authorizes the Public Health and Health Planning Council (PHHPC), subject to the approval of the Commissioner of Health (Commissioner), to establish and amend the State Sanitary Code (SSC) provisions related to any matters affecting the security of life or health or the preservation and improvement of public health in the State of New York.

Legislative Objectives:

Section 225 of the PHL authorizes the PHHPC, subject to the approval of the Commissioner, to establish and amend the SSC related to any matters affecting the security of life or health or the preservation and improvement of public health in the State of New York.

Article 21 of the PHL relates to control of acute communicable diseases. Section 2100 provides that every local board of health and every health officer shall guard against the introduction of such communicable diseases as are designated in the SSC. Section 2101 of the Public Health Law requires physicians and institutions to provide notice of every case of communicable disease required by the Department to be reported. Section 2102 requires clinical laboratories to report suspected or confirmed positive findings or markers of communicable diseases, and other pertinent facts, to local or state health officials. Additionally, section 576-c of the Public Health Law requires clinical laboratories to report such test results, and other data elements, electronically on a schedule determined by the commissioner. Section 2103 of the PHL requires all local health officers to report

cases of communicable disease to the New York State Department of Health (the Department). In line with these statutory provisions and the legislative intent, the proposed regulations address communicable diseases of public health concern. Section 2.1 includes a listing of diseases, conditions, and agents that must be reported; section 2.2 establishes definitions within the scope of Part 2; and section 2.5 specifies those diseases and conditions for which a specimen must be collected for laboratory analysis when a specified disease or condition is diagnosed or suspected.

Needs and Benefits:

The proposed amendments modernize 10 NYCRR 2.1 by making updates for clarity and to ensure that certain conditions, organisms, and toxins of public health significance are reportable. The proposed amendments create two lists of communicable disease rather than the current single list, to improve clarity of reporting requirements. One is a list of diseases/conditions for case reporting, and the other is a list of agents for positive laboratory test result reporting. The current single list is confusing with language indicating "lab-confirmed" and has resulted in misunderstandings about what reporting is expected. Separation of case reporting from laboratory result reporting is expected to alleviate the confusion.

The proposed amendments make several non-substantive changes (e.g., spelling, capitalization, formatting, alphabetical order, gender neutrality) to the text of the regulation and moves the definition of "unusual disease" to section 2.2 with the rest of the definitions.

The proposed amendments group tick-borne diseases, which are currently listed separately under a single tick-borne disease category. This would also have the effect of expanding the universe of tick-borne infections that are reportable (new tick-borne pathogens are not infrequently discovered and should be monitored), and includes alpha gal syndrome, an allergy transmitted by exposure to a sugar molecule normally present in tick saliva. Rickettsia, which are often but not always transmitted via ticks, are also added. Because tick-borne disease is investigated based on

positive laboratory results, these categories would be included in the list of organisms for which positive laboratory results would be reportable. The exception is Lyme disease with an erythema migrans rash, for which laboratory testing is generally not conducted; therefore, it is included in the list of conditions for case reporting.

These changes to tick-borne disease and Rickettsia are necessary to ensure that novel and emerging tick-borne diseases are reported to the Department. Tick-borne diseases are an increasingly significant public health threat in the State of New York; at least five new tick-borne diseases have been discovered in the last ten years, and it is expected that the emergence of new tick-borne diseases in the State will continue

The proposed amendments would align reporting of influenza, COVID, and RSV as much as possible. Specifically, positive laboratory reports for each of the three organisms would be reportable, pediatric deaths associated with any of the three infections would be reportable, and cases or suspected cases of novel influenza or novel coronaviruses would be reportable. Reporting requirements for multisystem inflammatory syndrome in children (MIS-C), severe acute respiratory syndrome (SARS), and Middle East respiratory syndrome (MERS) would remain unchanged. The proposed explicit reporting of pediatric deaths for each of the three organisms would provide critical surveillance data to help describe the severity of circulating respiratory disease, to better understand the burden and epidemiology of disease, and to better focus vaccination efforts. Additionally, influenza-associated pediatric mortality has been “nationally notifiable” since 2004. “Nationally notifiable” conditions are those that are deemed to be of national importance and are tracked on a national level. The Centers for Disease Control and Prevention requests that states report case numbers to support this effort.

The proposed amendments would remove “hospital-associated infections” from the list of reportable conditions. Removal will not change reporting requirements as separate regulations already mandate necessary reporting of certain individual infections by hospitals.

The proposed amendments would make minor changes or additions to three currently reportable conditions. Specifically, “E. coli O157:H7 infections” would change to “*Escherichia coli* infection, Shiga toxin-producing” because additional strains of E. coli besides O157:H7 can now be identified that produce Shiga-toxin (as does the O157:H7 strain) and which have similar clinical and public health implications as O157:H7. “Staphylococcal enterotoxin B poisoning” would change to “Staphylococcal enterotoxin poisoning” to include other groups of identified Staphylococcal enterotoxins that can now be identified, are of similar public health concern as the B toxin and are select agents. Finally, “poliomyelitis” would become “poliomyelitis and acute flaccid myelitis,” given that the 2022 New York State poliomyelitis case was initially thought possibly to be acute flaccid myelitis until laboratory testing identified poliovirus.

The proposed amendments would add certain select agents (i.e., organisms or toxins defined by the Federal government as having bioterrorism or other high-consequence potential) that are not already covered elsewhere: Hendra virus, Nipah virus, and epidemic typhus (included under Rickettsia). Although the burden for these organisms is expected to be zero or near zero, it is important to identify cases quickly should they occur and to have full legal authority to conduct a complete investigation via reporting mandates in Part 2.

The proposed amendments would add certain antimicrobial-resistant organisms to the list of reportable organisms:

- *Candida auris* (*C. auris*) is an emerging, multidrug-resistant fungal pathogen that is highly transmissible and can cause significant morbidity and mortality, especially among vulnerable

individuals in high-acuity healthcare settings.

- Carbapenem-resistant organisms (CROs) include a collection of multidrug-resistant bacteria that are resistant to carbapenem class antibiotics. These organisms, including the subset of carbapenemase-producing organisms, can be highly transmissible and can cause significant morbidity and mortality. As with *C. auris*, individuals can be either colonized or infected, and infection control precautions need to be implemented to prevent spread. The proposed amendment will provide critical surveillance data for early identification of geographic spread, help detect clusters, and allow for monitoring of changes in other epidemiologic factors.

The proposed amendments would also add *Staphylococcus aureus* showing intermediate susceptibility (glycopeptide-intermediate *Staphylococcus aureus*, GISA) or resistance (glycopeptide-resistant *Staphylococcus aureus*, GRSA) to a glycopeptide antibiotic. GISA and GRSA are particularly dangerous because of their reduced susceptibility or outright resistance to the glycopeptide class of antibiotics, including vancomycin, an important treatment for certain life-threatening bacterial infections. It is important to add them to the list of reportable organisms to track their spread and prevalence, and, for GRSA, which is extremely rare, it is important to add it to the list of reportable conditions to identify cases urgently, including outside business hours, to implement infection control measures. Monitoring the spread of GISA/GRSA will allow appropriate measures to be taken to prevent or contain exposures.

The proposed amendments would also add three conditions that appear to be emerging or expanding in range: blastomycosis, vibriosis, and leprosy. Blastomycosis is an infection caused by breathing in spores from *Blastomyces*, a fungus found in soil in some parts of the United States. The proposed amendment would provide critical surveillance data to define the geographic presence of *Blastomyces* in New York. The data can be used to raise awareness among healthcare providers of the

organism's presence and range in the State, thereby prompting earlier diagnosis. Due to the non-specific presentation of blastomycosis and the overlap in signs, symptoms, and radiologic appearance with bacterial pneumonia, delays in both diagnosis and treatment are well documented[1]. An estimated 8–10% of patients hospitalized with blastomycosis die annually in the United States[2]. The Department has been made aware of several confirmed cases, primarily in the Capital District and Mohawk River Valley. Veterinary data suggest the organism may be more widespread in the State than currently known, and information from other states indicate that the range of this organism might be expanding.

Vibriosis, caused by Vibrio species of bacteria, can cause severe illness, hospitalization, and death resulting from contact with water where *Vibrio species* naturally occur or by consuming raw or undercooked shellfish. The proposed amendment would provide critical surveillance data to identify cases and therefore identify contaminated waters and shellfish. Because of the public health significance of vibriosis and its emergence in coastal waters where it was not previously seen, New York State agencies and local health authorities have already been informed of some cases. The information allows for prevention messaging to the public, removal of contaminated shellfish from the market, prevention of additional harvesting in affected areas, and ultimately prevention of additional illnesses.

Leprosy, also known as Hansen's disease, is a treatable infection that appears to be increasing in Southeastern states, including Florida. The Department is occasionally informed of cases and asked for assistance, and the possibly increasing prevalence in areas of the United States with high levels of travel to New York is a concern. The proposed amendment would provide critical information that would be used to ensure infected individuals are referred for appropriate treatment and to identify contacts of cases who may be at risk of infection.

[1] https://academic.oup.com/ofid/article/12/8/ofaf499/8237348?login=false
[2] https://www.cdc.gov/blastomycosis/data-research/statistics/index.html

The proposed amendments would also add two conditions that impact infants: *Cronobacter* and congenital cytomegalovirus infection. *Cronobacter* species can cause life-threatening illness in neonates, infants, and other susceptible populations. The incidence of invasive *Cronobacter* infection among infants is estimated at 0.49 cases/100,000 infants, or approximately 19-20 cases annually in the United States (https://pmc.ncbi.nlm.nih.gov/articles/PMC4178417/), although cases are likely underreported. New York investigates approximately 0-2 cases per year. Some *Cronobacter* infections have been traced to powdered infant formula preparation and storage in hospital and home settings, and contaminated formula has been linked to nearly all *Cronobacter* infections for which a source was found. The proposed amendment would provide critical surveillance data to identify contaminated powdered infant formula and assist in local and national cluster and outbreak detection, control, and response activities.

Cytomegalovirus (CMV) is a common virus spread through bodily fluids. When acquired after birth it is not considered a health risk unless the person is immuno-compromised; however, CMV acquired during pregnancy can negatively impact the fetus. Congenital CMV is the leading non-genetic cause of sensorineural hearing loss in children in the United States. Including asymptomatic infants, approximately one in every 200 infants is born with congenital CMV infection, approximately 20% of whom will develop long-term health problems such as hearing or vision loss, intellectual disability, seizures, microcephaly, or developmental delay (https://www.cdc.gov/cytomegalovirus/about/index.html). A baby with congenital CMV disease, if identified and appropriately referred, can be treated with antiviral medication to improve health outcomes, provided additional screenings to detect related conditions early, and provided supportive services. However, in the absence of universal screening, many infections are not identified. Based on information available from a pilot project conducted by the Wadsworth Center's Newborn Screening Program in 2023-2024 and from Birth Defects Registry reports, it is estimated that there will be between 55 and 65 cases of congenital CMV disease (i.e., symptomatic infants) reported annually.

Public Health Law § 207, as amended in 2018, addresses the Department's education and outreach regarding congenital CMV. Public Health Law § 266, as amended in 2022, requires the Department to develop informational materials about congenital CMV, including information on the risks. The proposed amendment will allow the Department to better conduct those activities, improve understanding of the burden of congenital CMV disease, better facilitate the follow-up of affected infants, and determine whether additional guidance or recommendations should be made to physicians or to the public.

The proposed amendments would add *Leptospira* species to the list of reportable organisms. This addition would provide critical surveillance data that could be used to identify social and sanitation factors associated with exposure and disease, such as subpar housing. Additionally, leptospirosis is a nationally notifiable disease.

Finally, the proposed amendments would add interferon gamma release assays (IGRAs) to the list of reportable laboratory results. IGRAs can be used to identify either latent (i.e., asymptomatic) or active tuberculosis. The Department's plans to further combat tuberculosis in coming years involve working to ensure that more people with latent tuberculosis are appropriately treated to prevent active disease in the future, and this work necessitates reportability of IGRAs.

The proposed amendments to section 2.2 of Title 10 of the NYCRR update existing definitions, delete the definition of "hospital-associated infections" and include a definition of "unusual disease" that was previously included in section 2.1.

Hospital-associated infections have been defined in markedly different ways over the decades. The reasons for its inclusion in Part 2 were unclear, as the definition related to outbreaks, which are addressed elsewhere, and its definition appeared to be unnecessary given that reporting of certain hospital and other healthcare-associated infections is mandated elsewhere. As such, it was removed from section 2.2.

The definitions of “case” and “suspect case” have been updated to clarify that “clinical judgement” may include epidemiologic considerations. The definition of “outbreak” has also amended to clarify that both community and healthcare-associated outbreaks are included. Additionally, to detect important or unusual outbreaks early, a statement was added noting that outbreak reporting includes reporting of “single cases of disease that may reasonably be considered to portend an outbreak of public health importance.”

Finally, the definition of “unusual disease” is expanded beyond diseases or syndromes of unknown etiology to include diseases or conditions of known etiology but exhibiting new epidemiologic or clinical characteristics that are known or suspected to have substantial public health significance. This is necessary because laboratory science has advanced to the point that even new, unusual conditions are rarely and generally only briefly of unknown etiology. However, even known organisms still can present in new and perplexing ways, and when that happens, the Department needs to investigate. Additionally, this is consistent with New York City requirements to report “[a]n unusual manifestation of any disease or condition” and “[a] newly apparent or emerging disease, or a syndrome of uncertain etiology that could possibly be communicable” (https://www.nyc.gov/site/doh/providers/reporting-and-services/notifiable-diseases-and-conditions-reporting-central.page).

The definitions of “local health authority”, “approved laboratory” or “laboratory approved for the examination”, and “vaccinia” are unchanged.

The proposed amendments to section 2.5 of Title 10 of the NYCRR would modernize the regulation by expanding its scope, grouping certain organisms together, and adding several organisms.

Section 2.5 is not a reporting regulation. It requires laboratory testing, rather than clinical diagnosis alone, for the listed conditions. As the regulation is currently written, it applies only to

physicians. However, there are several other types of independently-practicing healthcare providers with the legal authority to diagnose one or more of the listed conditions by means of laboratory examination, and it therefore does not make sense to limit the testing requirement to physicians. Therefore, the proposed amendments expand the scope of the regulation to apply to all licensed healthcare providers whose scope of practice includes the legal authority to diagnose a particular disease via laboratory examination.

The proposed amendments to section 2.5 also remove several individually listed conditions and consolidate them into the following groups:

- "Tickborne infection, except for Lyme disease cases with erythema migrans rash". The tick-borne infections babesiosis, ehrlichiosis, Rocky Mountain spotted fever, and tularemia are currently listed individually in section 2.5. The list is outdated, and in many cases it is difficult or impossible to accurately diagnose a specific tick-borne infection without the appropriate laboratory testing. Therefore, tick-borne infections are grouped. An exception is made for Lyme disease with erythema migrans rash, for which laboratory testing is not indicated.

- "Diarrhea, acute infectious non-viral". Several common types of infectious diarrhea are currently listed individually in Section 2.5 (campylobacteriosis, cryptosporidiosis, cyclosporiasis, E. coli O157:H7, giardiasis, salmonellosis, shigellosis, and yersiniosis). However, in most cases it's not possible to definitively identify the causative agent with laboratory testing. Therefore, these entities are grouped under "diarrhea, acute infectious non-viral" to indicate that if any acute, infectious, non-viral diarrhea is suspected based on the clinical presentation, then testing should be conducted.

- "Arboviral infection". These would include the currently listed yellow fever entry along with arboviral infections commonly identified in New York State, which are being carefully monitored

to detect changes in prevalence and range. This information is used to inform public health response activities, including prevention messaging, heightened epidemiologic surveillance, and vector control.

Additionally, the proposed amendments to section 2.5 would simplify and modify conditions related to coronavirus infections for which testing is required, to be more consistent with the Department's needs in a post-pandemic world. Under the proposed regulation, testing would be required only if the clinician suspected SARS, MERS, or a novel coronavirus.

The proposed amendments would add the following conditions to section 2.5:

- Chancroid: While chancroid cases are currently rare, it is highly contagious and can look like other types of infectious genital ulcers. Prompt and accurate diagnosis is key to ensuring cases remain low. Therefore, healthcare providers should send a culture to confirm or rule out the presence of *Haemophilus ducreyi*.

- Congenital cytomegalovirus disease (≤90 days of age): Diagnosis is key to providing treatment and ensuring appropriate linkage to supportive care.

- Hepatitis A: Accurate laboratory diagnosis of hepatitis A is key to conducting an appropriate public health investigation.

- Influenza caused by a novel influenza virus: If there is reason to suspect that a patient is infected with a novel influenza virus, it is extremely important that testing be conducted.

- Leprosy: This has enough public health implications such that the appropriate testing must be conducted when leprosy is suspected. Testing is primarily pathologic but can also include polymerase chain reaction.

- Leptospirosis: This condition is caused by exposure to animal urine or contaminated material and might be an indicator of sub-par housing that would need to be addressed to prevent further cases.

- Measles: Increases in global measles activity and sub-optimal vaccine coverage have contributed to increased measles activity in the United States. Confirmation of measles requires laboratory testing to distinguish it from other febrile rash illnesses and allows molecular testing to be conducted to assist in epidemiologic investigations.
- Mumps: Mumps is an acute viral illness which typically presents as the swelling of the parotid or other salivary glands, but it may present with only non-specific or respiratory symptoms. Laboratory testing should be conducted if mumps is suspected because clinical diagnosis may not be reliable. It is important to accurately identify mumps because outbreaks typically occur in close-contact settings, such as households, schools, and athletic teams.
- Pertussis: Pertussis, also called whooping cough, can be serious; infants are at greatest risk for getting the disease and having severe complications. The signs and symptoms of pertussis can be similar to other circulating respiratory illnesses, necessitating laboratory confirmation to confirm diagnosis, identify outbreaks, and inform the public health response.
- Rubella: Rubella is highly contagious viral rash illness that can lead to serious adverse outcomes during pregnancy. While rubella is rare in the in the United States, it continues to be endemic in some parts of the world and would be a particular concern if vaccination rates drop further. Many rash illnesses mimic rubella infection, so clinical diagnosis is unreliable, and laboratory confirmation of disease is necessary.
- Trichinosis: This is a foodborne condition that typically requires blood testing to diagnosis. It can cause outbreaks, and a public health response would require a definitive diagnosis.
- Vaccinia disease: Vaccinia disease includes infections or reactions caused by the vaccinia virus, the live virus used in older versions of the smallpox vaccine. Due to the presence of live virus and

the administration method of smallpox vaccination, vaccinia virus can occasionally be spread to others from the vaccination site. Testing to confirm vaccinia disease is important to prevent further spread.

- Vibriosis: This condition can be seafood-borne or from coastal water exposure to non-intact skin. It requires laboratory testing to diagnosis, and there are important public health response activities that would be conducted based on this diagnosis.

Costs:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

Costs to regulated entities are expected to be minimal. New York State already has human and electronic resources in place to support compliance with public health reporting requirements.

Laboratories already have robust reporting infrastructure in place and already report several of the added conditions (e.g., carbapenem-resistant organisms, GISA/GRSA, leprosy, leptospirosis, and certain rickettsia) because, for example, they are reportable in New York City. For those organisms that would need to be added to the laboratories' reporting procedures (e.g., Blastomyces species, cytomegalovirus, Hendra virus), there would be an estimated initial cost of up to $10,000 to update the laboratory reporting systems; thereafter, reporting is mostly automated.

All of the conditions added to the case reporting list are either of very low incidence (Cronobacter; leprosy; acute flaccid myelitis; GRSA; vibriosis; pediatric deaths associated with COVID-19, influenza, or RSV) or are rarely detected (congenital cytomegalovirus infection) and so should not present more than a negligible burden, and therefore cost, to clinicians. Additionally, with the proposed separate lists for case reporting and laboratory test reporting, several conditions were removed from case reporting requirements (arboviral infection, invasive *Streptococcus pneumoniae* infection, hantavirus, invasive *Haemophilus influenzae* infection, hepatitis B and C, legionellosis, malaria, and most tick-

borne infections), relieving clinicians of reporting burden for those higher-incidence conditions. The public health investigations based on laboratory reports will proceed as usual and might require input and information from clinicians, even if the report itself comes via laboratory reporting, but this burden is not increased compared with the current regulation that requires case reporting.

While there is a substantial burden on healthcare facilities such as hospitals and nursing homes when a case or cluster of *C. auris* or a carbapenem-resistant organism is identified, identification of these organisms is important for infection control and patient safety reasons. Moreover, any such burden would be present regardless of whether the organism is reportable, and reporting it will lead to public health interventions, which will eventually prevent or mitigate outbreaks, thereby reducing the overall burden.

There are no new or additional compliance costs to regulated entities associated with the proposed amendments to section 2.2 (Definitions) beyond negligible reporting costs that might accrue related to certain minor definition changes: clarification of the definitions for cases and suspect cases; update of the definition of "outbreak" to include single cases that may portend an outbreak of public health importance; and, lastly, update of the definition of "unusual disease" to include conditions of known etiology but demonstrating new clinical or epidemiological characteristics of substantial public health importance.

Finally, testing requirements added to section 2.5 might add additional costs for medical care; however, many of the conditions added are subject to laboratory examination as part of standard clinical care, and others are critical for public health response. For example, arboviral infections are often associated with neurologic illnesses such as encephalitis for which extensive testing would ordinarily be ordered regardless of regulation (but is added to section 2.5 in case the Department needs to compel testing for public health reasons in certain situations). And measles testing is necessary because of the uncertainty surrounding clinical diagnosis, the need for a

definitive diagnosis for the public health response, and the importance of test results in determining the viral strain to better define outbreaks and transmission chains.

C**osts to State and Local Governments:**

Great care has been taken during the development of these proposed amendments to sections 2.1, 2.2, and 2.5 to minimize the burden, and therefore cost, to both the State of New York and to local governments. Costs to the State beyond the Department of Health are expected to be negligible and would relate to minor changes such as alerting mandated reporters who work for other State agencies to changes in reporting.

Regarding local governments, the Department has sought input from the New York State Association of County Health Officials (NYSACHO) and local health departments (LHDs) during the development of these proposed amendments. The Department has carefully considered that input and has made modifications to the regulatory amendments as a result of that input. Burden, and therefore cost, to LHDs has been minimized in a variety of ways, including:

- Case reporting (i.e., reports from providers) can be high burden to LHDs because of the time and costs involved in accepting and processing those reports. Therefore, the number of diseases and associated conditions for which case reporting is required was minimized; if reporting of a positive laboratory result would be sufficient, case reporting is typically not required.
- The Department carefully considered the reasons for reporting for each of the entities proposed to be added. During the development of the proposed amendments, and considering input from NYSACHO and LHDs, the Department opted not to add conditions or organisms for which the benefit was felt not to justify the burden.
- The Department also carefully considered whether any diseases, conditions, or organisms

could be removed from the list in section 2.1. There was robust discussion both internally and with NYSACHO about the possibilities, but it was determined that there are good reasons for the inclusion of each item currently in section 2.1. Instead, efforts were made and will continue to be made to minimize the burden imposed by each of the items listed, such as minimizing case reporting as described above, and modifying laboratory guidance to limit reporting to only what is needed (on-going).

- Certain organisms which are expected to be reported by laboratories in high or moderate numbers (*Candida auris*, carbapenem-resistant organisms, cytomegalovirus (≤90 days of age), GISA, IGRAs, alpha gal) will be accepted via the Department's Electronic Clinical Laboratory Reporting System (ECLRS) but will not be passed through to the LHDs (except upon request). This is a similar process to what is currently done for influenza, COVID-19, and RSV, where the reason for reporting is to monitor trends, detect surges, and identify unusual patterns, not to investigate individual cases except in unusual circumstances. Among those organisms for which this process will apply are organisms that the Department typically investigates because they tend to present in Article 28 healthcare facilities (*C. auris*, carbapenem-resistant organisms, GISA), organisms for which the Department has or plans programs to follow-up or otherwise use the reports (cytomegalovirus (≤90 days of age), IGRAs), and entities for which it's important to follow trends and spread but for which individual case investigation would not be done (e.g., alpha gal). For organisms that the Department currently has programs to deal with, plans are being developed to minimize LHD burden should the Department programs end in future.

- For diseases or organisms that have been added and that will require investigation by LHDs, the investigatory flexibility previously added to section 2.6 of has been and will continue to be used to limit the response to what is needed, rather than requiring a full investigation in all situations. For example, for Blastomycosis, likely-affected counties in the Mohawk Valley area were contacted to

develop a feasible plan to deal with reports that will not strain their resources.

Additionally, local health authorities receive funding through Article 6 of the Public Health Law for core public health work, including investigations of reportable diseases. As local health authorities are the primary entities responsible for controlling diseases within their jurisdictions, the additions proposed here, minimized and streamlined as described above, will become part of the process that local health authorities already have in place to control disease within their jurisdictions. It is expected that the volume of added investigations will be low because the additions that the local health authorities are expected to investigate are expected to be reported at low (e.g., blastomycosis) or zero (e.g., Hendra virus) numbers.

Regarding sections 2.2 and 2.5, there are no new or additional compliance costs to the State or to LHDs associated with the proposed amendments to the definitions nor to the newly added conditions in section 2.5.

Costs to the Department of Health:

Any additional costs to the Department as a result of the proposed regulations are expected to be low. Most of the additions to section 2.1 are expected to be reported in very low numbers, which means the Department's role in providing technical and programmatic assistance to LHDs would present only a minimal burden. A few of the conditions are expected to be reported in high numbers (*Candida auris*, carbapenem-resistant organisms), but these typically occur as part of outbreaks in healthcare facilities such as hospitals and nursing homes, which the Department already investigates and works with the affected facilities to control. Therefore, the burden on the Department would not increase appreciably by adding these conditions to section 2.1, but it would allow for additional mitigation activities and more complete assessment of prevalence and spread of these difficult-to-treat organisms that tend to affect highly vulnerable populations. The infrastructure to electronically receive reports from laboratories is already in place. There would be an initial cost related to updating ECLRS to receive the newly reportable laboratory results, and modest resources, which are already planned for, would be required to

clean and analyze the new incoming data; however, any such costs can be absorbed with existing resources.

There are no additional costs to the Department associated with the proposed amendments to section 2.2.

Regarding section 2.5, there may be minimal costs to the Department resulting from specimens associated with the updated list being submitted to the Department's Wadsworth Center for examination. However, in most cases the Wadsworth Center is already performing such test and the majority of the conditions added to section 2.5 can be examined at commercial laboratories. Existing infrastructure and processes are already in place for receiving, testing, and processing of specimen submissions and reporting of positive results, so any increase in cost can be absorbed within existing resources.

Local Government Mandates:

As is currently the case, local health officers receiving reports of diseases/organisms listed in section 2.1 will continue to be required to forward such reports to the State Department of Health and to investigate and monitor the cases or suspect cases reported, and the sources of disease, based on epidemiological or other relevant information and consistent with guidance provided by the Department. The infrastructure, systems, and procedures to receive, process, and follow up on reportable diseases for case investigation already exist, are well established, and are utilized regularly by LHDs. However, there is flexibility regarding investigation requirements in section 2.6, allowing local health departments to limit certain investigations.

Similar direction to limit LHD burden, while still providing for the required investigation activities and case information, is anticipated to be given for several of the conditions and organisms proposed to be added: *Candida auris*, carbapenem-resistant organisms, GISA, and GRSA are expected to be primarily dealt with by the Department because of their close connection with Article

28 facilities (e.g., hospitals and nursing homes); congenital cytomegalovirus is currently dealt with by a Department grant-funded program using limited reporting to the Birth Defects Registry; and alpha gal data analysis will be performed by the Department without the need for routine individual investigations to be conducted.

Paperwork:

There will be no new paperwork associated with these proposed amendments; however, revisions will need to be made by the Department to the existing general communicable disease reporting form, the instruction document for completing the general communicable disease reporting form (DOH-389), and the laboratory guidance. Pursuant to section 576-c of the PHL, clinical laboratory results are required to be reported electronically.

Duplication:

No relevant laws of the State and/or Federal government exist that duplicate, overlap, or conflict with these proposed amendments.

Alternatives:

Alternatives to the proposed amendments considered by the Department included maintaining the current list of reportable communicable diseases in section 2.1 and not amending the definitions in section 2.2. The Department also considered maintaining the current list of diseases in section 2.5 and not expanding the scope of the regulation to apply health care providers beyond just physicians. However, the proposed amendments increase the likelihood that crucial testing will be conducted and update outdated language. Each condition in section 2.1 was scrutinized to determine whether case reporting, laboratory result reporting, or both, were the best fit. Moreover, the proposed amendments require reporting of the added conditions, which is necessary for critically important disease surveillance. Additionally, the current listing of conditions

for which a specimen must be collected in section 2.5 does not include several vaccine-preventable diseases of extreme public health importance, such as measles. For measles, not requiring physicians and other healthcare providers to submit specimens for laboratory examination impedes appropriate and expedient public health response and increases the difficulty and complexity of the response. As such, these alternatives were not considered viable.

Federal Standards:

The proposed amendments do not exceed any minimum standards of the Federal government. State and local health departments have primary authority for controlling disease within their jurisdictions.

Compliance Schedule:

The Department is updating existing electronic reporting systems, as well as the form and instructions for manual case reporting, to support reporting of newly added conditions. It is anticipated that regulated entities will be able to immediately comply with the rule upon publication of the Notice of Adoption in the State Register.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

The proposed regulatory amendments to 10 NYCRR section 2.1 will apply to all local health departments, as well as physicians, hospitals, nursing homes, diagnostic and treatment centers, and laboratories. The proposed regulatory amendments to section 2.5 will apply to all licensed healthcare providers whose scope of practice includes the legal authority to diagnose disease via laboratory examination. As of January 1, 2026, there are approximately 81,380 licensed and registered physicians in New York State; it is not known how many of them practice in small businesses. As of April 1, 2024, there were over 1.14 million active registrations across all licensed healthcare professions; it is not known how many of them practice in small businesses.

Based on the 2020 Census, there are 44 counties in New York State that have a population of less than 200,000 (https://www.census.gov/quickfacts/), and approximately 17% of small health care facilities are located in rural areas. Currently, there are a total of 1422 diagnostic and treatment centers, including extension clinics, and it is estimated that about 240 of these facilities are in rural areas and may employ less than 100 people and qualify as a small business. There are 601 nursing homes in New York State, 162 of which are in rural counties, many of which may employ fewer than 100 people and qualify as a small business. There are six hospitals that are estimated to employ less than 100 people, qualifying as a small business. There are approximately 626 approved clinical laboratories in New York State, and it is estimated that approximately 206 employ less than 100 people and are considered small businesses.

Compliance Requirements:

Hospitals, clinics, physicians, nursing homes, and clinical laboratories that are small businesses, along with local governments, will utilize updated Department of Health (Department) reporting forms and existing electronic reporting infrastructure to report the amended listing of communicable diseases, conditions, and agents included in the list of communicable diseases set forth in 10 NYCRR section 2.1. Local health officers receiving reports of reportable communicable diseases will continue to be required to forward such reports to the State Health Commissioner and to investigate and monitor the cases reported, with the exception of those conditions which are reported to the Department only for monitoring of trends, State-level program purposes, or that occur in Article 28 regulated health care facilities, which are investigated by the Department.

Professional Services:

The proposed amendments to section 2.1 relate to the reporting of certain communicable diseases and laboratory test results to the Department and subsequent investigation of cases. Affected business entities include laboratories that are authorized to perform tests for communicable diseases on New York State residents, local health authorities that receive and investigate communicable disease reports and test results, as well as physicians and other mandated reporters that report cases. Section 2.5 relates to submission of specimens for laboratory examination by licensed healthcare providers whose scope of practice includes the legal authority to diagnose the disease via laboratory examination. The Department does not expect any entities to need to procure additional professional services as a result of these proposed amendments.

Compliance Costs:

The Department expects that costs associated with these additional requirements will be minimal. Local health authorities receive funding through Article 6 of the Public Health Law for core public health work, including investigations of reportable diseases, and any additional burden created by the regulatory amendments has been minimized.

The Department does not expect that there will be significant cost burdens associated with regulated entities complying with investigations conducted by a local health authority. The proposed regulations would only apply where there are cases, or suspected cases, of reportable diseases or organisms, outbreaks, or unusual diseases. Further, while businesses, organizations, private homes, and those required to report, pursuant to the proposed amendments to section 2.1, would be required to cooperate with such investigations, historically, the type of cooperation sought during disease investigations has primarily consisted of providing information determined to be necessary for the local health authority to control the spread of disease and/or to provide preventive treatment.

The cost of the proposed disease and organism reporting to local governments is expected to be minimal because current systems and procedures already exist for such entities to receive, process, and follow-up on reportable diseases/organisms. Further, by monitoring the spread of reportable diseases/organisms, appropriate precautions can be taken to prevent or contain exposures, thereby reducing costs associated with public health control measures, morbidity, and treatment. Lastly, the Department does not expect that there will be any additional cost burdens to local governments associated with the proposed changes to laboratory submission requirements in section 2.5. The infrastructure to electronically receive reports from laboratories is already in place.

The Department does not anticipate that there will be a substantial cost burden for

government entities related to investigation(s) of newly added reportable conditions because the ones requiring investigation have an extremely low incidence. Local health authorities are the primary entities responsible for controlling diseases within their jurisdictions, the additions proposed here will become part of the requirements that local health authorities already have in place to control disease within their jurisdictions, which already include investigations of other reportable diseases. The infrastructure, current systems and procedures to receive, process, and follow-up on reportable diseases for case investigation already exists, are well established, and utilized regularly by the local health departments.

Furthermore, effective October 02, 2024, 10 NYCRR section 2.6 – Investigations and Response Activities, was amended to incorporate additional flexibility for local health departments in their management and prioritization of investigations of communicable disease. For all these reasons, the proposed amendments are not expected to result in any significant new cost burden to small businesses or local governments.

Economic and Technological Feasibility:

The affected entities will use existing reporting, receiving, and investigation infrastructure that are already in place for reporting of other communicable diseases designated by Public Health Law. As such, there are no economic or technological impediments to the rule change. Most communicable disease reporting is already accomplished via existing electronic reporting mechanisms. Local health departments already conduct investigations of communicable disease within their jurisdictions under existing authorities designated in Public Health Law. Clinical laboratories are required to report results electronically pursuant to Public Health Law section 576-c. As such, there are no economic or technological impediments to the rule change.

Minimizing Adverse Impact:

The affected small business and government entities include clinical laboratories, local health departments, and medical practices. All entities will continue to use existing reporting, receiving, and investigation infrastructure that are already in place for reporting of other communicable diseases designated in Public Health Law. These proposed amendments carefully and intentionally considered the potential burden to local health departments responsible for investigations of communicable disease. As such, and where appropriate, reports of communicable disease involving health care acquired infections (e.g., carbapenem-resistant organisms, *Candida auris*) that occur in health care facilities regulated under Article 28, such as nursing homes, hospitals, and diagnostic and treatment centers, are investigated by the Department. Similarly, other reports of communicable disease that are submitted to support State-level programs and coordination of appropriate follow-up services (e.g., congenital cytomegalovirus) are also managed by the Department. The existing electronic reporting infrastructure already supports incoming laboratory data and communicable disease reports to the State and local health departments. This minimizes impact, and these amendments are not expected to result in significant additional costs or burden to small business or local governments.

Small Business and Local Government Participation:

The Department has consulted with local governments through ongoing communication with local health departments and the New York State Association of County Health Officials (NYSACHO) in the process of developing these proposed amendments, including proposed updates to the list of reportable conditions.

Businesses that are affected by the proposed amendments including private and commercial laboratories, already perform the tests that detect these pathogens, use existing reporting

mechanisms, and many already report some of the added conditions. The Department has already initiated efforts to reach out to laboratory organizations through existing communication networks to advise the laboratory business community about these proposed amendments. Furthermore, existing guidance for laboratories is in the process of being updated to align with the proposed amendments and will be distributed to laboratories prior to the effective date of the amendments.

For Rules That Either Establish or Modify a Violation or Penalties Associated with a Violation:

N/A.

STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS

No Rural Area Flexibility Analysis is required pursuant to section 202-bb(4)(a) of the State Administrative Procedure Act. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas resulting from the proposed amendments. While the proposed amendments to 10 NYCRR Part 2 update the list of communicable diseases to be reported to the New York State Department of Health (Department), the definitions, and the list of conditions for which a specimen is to be collected, the amendments do not impose a unique adverse impact on facilities in rural areas, nor do they impose additional reporting, record keeping or other compliance requirements on facilities in rural areas.

Moreover, the proposed amendments are intended to reduce overall reporting burden, statewide, by further clarifying existing communicable disease reporting requirements, eliminating redundant and duplicative reporting of diseases and conditions that either require laboratory analyses to confirm diagnoses or that are reported to the Department through existing statewide surveillance systems (e.g., influenza, coronavirus, and respiratory syncytial virus).

STATEMENT IN LIEU OF
JOB IMPACT STATEMENT

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 2803 of the Public Health Law, section 415.26 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, as follows:

The first sentence of subparagraph (i) of paragraph (3) of subdivision (d) of section 415.26 is amended to read as follows:

The nurse aide training program shall include classroom and clinical training which enhances both skills and knowledge and, when combined, shall be of at least [100] 75 hours' duration.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) section 2803 authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner of Health, to implement the purposes and provisions of PHL Article 28, including the establishment of uniform standards governing the operation of health care facilities.

Legislative Objectives:

The legislative objectives of PHL Article 28 include protecting the health of the residents of the State by assuring the efficient provision of health services by nursing homes. The establishment of nurse aide certifications and training programs that promote the necessary skills and abilities to demonstrate competent provision of appropriate tasks for certified nurse aids (CNAs) working in nursing homes, meets these legislative objectives.

Needs and Benefits:

Since 2022, the Office of Healthcare Workforce Innovation in the New York State Department of Health (Department) has advanced various initiatives to meet the evolving demands of the healthcare workforce across the State. This regulation furthers the Department's effort to expand the healthcare workforce by easing the requirements for CNA candidates. This regulation will increase the pool of qualified CNAs to deliver needed services to nursing home residents.

These regulations will align the State's required hours of training for CNAs with the requirements of the Federal government in 42 CFR § 483.152(a)(1). Reducing the required hours

of training from 100 to 75 will help attract prospective candidates to become CNAs, while still ensuring an adequate level of training.

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:

The Department anticipates no costs for nursing homes to comply with the amended regulation.

Cost to State and Local Government:

The Department does not anticipate costs to State or local governments to comply with the amended regulation.

Cost to the Department of Health:

There are no expected additional costs to the Department as any necessary programmatic updates will be completed using existing resources.

Local Government Mandates:

This amendment does not impose any new programs, services, duties, or responsibilities on local governments, including those that may operate a nursing home.

Paperwork:

The Department will be required to update forms, order new applications, and update its website. These changes will be completed using existing resources.

Duplication:

These amendments align with the coinciding Federal requirement and do not conflict with any State or Federal rules.

Alternatives:

An alternative would be to leave current standards in place. Leaving the current standards in place is not consistent with the Department's goal to implement creative solutions to expand the number of CNAs throughout the State. Therefore, the Department decided that revising the current regulation was the most appropriate approach.

Federal Requirements:

This regulation aligns with Federal regulations and does not overlap or conflict with any legal requirements.

Compliance Schedule:

This regulation will go into effect upon publication of a Notice of Adoption in the New York State Register.

Contact Person:

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STATEMENT IN LIEU OF REGULATORY FLEXIBILITY ANALYSIS

No Regulatory Flexibility Analysis is required pursuant to section 202-b(3)(a) of the State Administrative Procedure Act. This regulation does not impose an adverse economic impact on small businesses or local governments, nor does it require any new reporting, record keeping, or other compliance requirements on small businesses or local governments.

STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS

A Rural Area Flexibility Analysis for this amendment is not being submitted because the amendment will not impose any adverse impact or new, significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of this regulation.

JOB IMPACT STATEMENT

A Job Impact Statement for this amendment is not being submitted because it is apparent from the nature and purposes of the amendment that it will not have a substantial adverse impact on jobs and/or employment opportunities.

Public Health and Health Planning Council

Project # 252166-C
Hillside Polymedic Diagnostic and Treatment Center

Program: **DTC**
Purpose: **Construction**

County: **Queens**
Acknowledged: **October 28, 2025**

Executive Summary

Description
Hillside Polymedic Diagnostic and Treatment Center (Hillside), an existing Article 28 Diagnostic and Treatment Center (D&TC) requests approval to construct a new, 6-story replacement building and certify multi-specialty ambulatory surgery and associated imaging services. The new building will be built on the same plot of land as the existing building at 18730 Hillside Avenue, Jamaica, NY.

Hillside is currently certified for Dental, Primary Care, and Podiatry. They will add Ambulatory Surgery – Multi Specialty, Magnetic Resonance Imaging (MRI), CT Scanner, and Medical Services – Other Medical Specialties. The multi-specialty surgical services will include podiatry, obstetrics/gynecology (no abortion), vascular/endovascular, cardiothoracic (no cardiac surgery) and general surgery.

The new building will include 2 operating rooms, 2 procedure rooms, and 8 pre- and post-surgical stations as well as support spaces. This project will be completed in phases to avoid any disruptions to operations of the D&TC.

OPCHSM Recommendation
Contingent approval with an expiration of the operating certificate five years from the date of its issuance.

Need Summary
The applicant projects 39,568 total visits (including 2,236 ambulatory surgery visits representing 2,460 procedures) in Year One and 68,785 total visits (including 2,372 ambulatory surgery visits representing 2,609 procedures), with Medicaid at 67.6% and Charity Care at 1.4%, by Year Three.

Program Summary
Based on the results of this review, a favorable recommendation can be made regarding the facility's current compliance pursuant to 2802-(3)(e) of the New York State Public Health Law.

Financial Summary
The total project cost, of $92,224,979 will be financed through a $83,002,481 loan at a 5.7% interest rate of 35 years, land equity of $3,549,519, and a personal loan of $5,672,979 at an interest rate of 12% over a 30-year term.

Budget:	Year One	Year Three
Revenues	$13,010,470	$20,052,942
Expenses	$15,118,492	$17,765,453
Net Income	($2,108,022)	$2,287,489

Health Equity Impact Assessment
This project does not meet the requirements for a Health Equity Impact Assessment under Section 2802-B of the PHL.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

Approval with an expiration of the operating certificate five years from the date of its issuance, contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Architectural Design Development Drawings: Submission of architectural and life safety drawings, acceptable to the Department, as described in the Bureau of Architecture and Engineering Review Drawing Submission Guidelines DSG-1.0. [AER]
3. Engineering Design Development Drawings: Submission of mechanical, electrical, plumbing and fire protection drawings, acceptable to the Department, as described in the Bureau of Architecture and Engineering Review Drawing Submission Guidelines DSG-1.0. [AER]
4. Submission of an executed bank loan that is acceptable to the Department of Health. [BFA]
5. Submission of an executed personal loan for the working capital portion that is acceptable to the Department of Health. [BFA]
6. Submission of an executed personal loan for the construction portion that is acceptable to the Department of Health. [BFA]
7. Submission of an executed working capital loan that is acceptable to the Department of Health. [BFA]
8. Submission of an executed lease agreement that is acceptable to the Department of Health. [BFA]
9. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women and handicapped persons) and the center's commitment to meet the health care needs of the community, including the provision of services to those in need regardless of ability to pay. The statement shall also include commitment to the development of policies and procedures to ensure that charity care is available to those who cannot afford to pay. [RNR]
10. Submission of a signed agreement with an outside, independent entity satisfactory to the Department to provide annual reports to DOH. Reports are due no later than April 1st for the prior year and are to be based upon the calendar year. Submission of annual reports will begin after the first full or, if greater or equal to six months after the date of certification, partial year of operation. Reports should include:
    a. Data displaying actual utilization including procedures;
    b. Data displaying the breakdown of visits by payor source;
    c. Data displaying the number of patients who needed follow-up care in a hospital within seven days after ambulatory surgery;
    d. Data displaying the number of emergency transfers to a hospital;
    e. Data displaying the percentage of charity care provided;
    f. The number of nosocomial infections recorded during the year reported;
    g. A list of all efforts made to secure charity cases; and
    h. A description of the progress of contract negotiations with Medicaid managed care plans. [RNR]

Approval conditional upon:

1. This project must be completed by **April 1, 2031**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before **January 1, 2027**, and construction must be completed by **January 1, 2031**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date, this shall constitute abandonment of the approval. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
4. The staff of the facility must be separate and distinct from the staff of other entities; the signage must clearly denote that the facility is separate and distinct from other entities; the clinical space must be used exclusively for the approved purpose; and the entrance must not disrupt any other entity's clinical program space. [HSP]
5. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary: https://www.health.ny.gov/facilities/hospital/docs/hcs_access_form_new_clinics.pdf. Questions may be directed to the Division of Hospitals and Diagnostic &Treatment Centers at 518-402-1004 or email: hospinfo@health.ny.gov [HSP]
6. The submission of annual reports to the Department as prescribed by the related contingency, each year, for the duration of the limited life approval of the facility. [RNR]
7. Reimbursable TPC shall be limited to $74,446,790 representing Art. 28 spaces and application fees (no APF on shell space costs). [CCC]

Council Action Date
June 24, 2026

Need Analysis

Project Description

Hillside Polymedic Diagnostic and Treatment Center (D&TC) (Hillside or the Center), an existing Article 28 D&TC is seeking approval to construct a new 6-story building to replace the existing 2-story building. The address of the D&TC is 18730 Hillside Avenue, Jamaica, New York 11432 (Queens County), which will not change as a result of this project. The D&TC is currently certified for Dental O/P, Medical Services – Primary Care, and Podiatry – O/P. Through this project, the D&TC will convert to an Ambulatory Surgery Center (ASC) and add Ambulatory Surgery – Multi Specialty; Magnetic Resonance Imaging (MRI), CT Scanner, and Medical Services – Other Medical Specialties. The multi-specialty surgical services will include podiatry, obstetrics/gynecology (no abortion), vascular/endovascular, cardiothoracic (no cardiac surgery) and general surgery. The ASC will include 2 operating rooms, 2 procedure rooms, and 8 pre- and post-surgical stations as well as support spaces. This project will be completed in phases to avoid any disruptions to operations of the D&TC.

Background & Analysis

The primary service area (PSA) consists of the following zip codes (ZCs): 11432, 11433, 11423, 11412, 11429, 11428, 11427, 11364, 11365, and 11366; and to a larger extent Queens County. The facility address is located within a Health Professional Shortage Area for Primary Care. The population of Queens County is estimated to increase to 2,575,100 by 2031 per projection data from the Cornell Program on Applied Demographics, an increase of 10.8%. Demographics for the PSA, and Queens County are noted below, including a comparison with New York State.

Demographics	PSA	Queens County	New York State
Total Population – 2024 Estimate	330,666	2,323,052	19,852,366
Hispanic or Latino (of any race)	17.2%	28.5%	19.8%
White (non-Hispanic)	12.6%	22.5%	52.8%
Black or African American (non-Hispanic)	30.2%	16.3%	13.4%
Asian (non-Hispanic)	31.4%	26.3%	9.0%
Other (non-Hispanic)	8.5%	6.4%	5.0%

Source: 2024 American Community Survey (5-year Estimates Data Profiles)

The PSA and Queens County have a higher minority population compared to the State. According to the applicant, Spanish and Creole are the predominant languages spoken in the PSA and currently served by Hillside. The Black or African American and Asian populations are higher in comparison to the population in Queens County and NYS. Language barriers or limited English proficiency are also an obstacle in seeking care. Hillside plans to provide an outside language interpretation service appropriate for the languages in the PSA including sign-language.

In 2024, 91.8% of the population of Queens County had health coverage as follows:

Employer Plans	39.9%
Medicaid	28.0%
Medicare	11.2%
Non-Group Plans	12.4%
Military or VA	0.273%

Source: Data USA

The table below shows the public health insurance coverage for the zip codes within the PSA. The service area has a higher reliance on public health insurance coverage, particularly in 11432 (where Hillside is located) and 11433.

Payor(s)	ZC 11364	ZC 11365	ZC 11366	ZC 11412	ZC 11423	ZC 11427	ZC 11428	ZC 11429	ZC 11432	ZC 11433
Medicaid alone	16.7%	20.1%	12.3%	21.0%	27.3%	18.4%	23.0%	19.9%	36.5%	33.0%
Medicare alone	8.5%	7.8%	5.6%	5.7%	6.8%	7.9%	8.0%	6.7%	5.2%	3.5%

Source: 2024 American Community Survey (5-year Estimates Data Profiles), Table S2704

As an existing D&TC, Hillside currently contracts with several Medicaid Managed Care plans, including Molina Healthcare of New York; Healthfirst; Fidelis Care; Metroplus Health Plan; Emblem Health; Anthem Blue Cross and Blue Shield and United Healthcare.

In 2024, the applicant reported 13,812 visits and is projecting 39,568 total visits (including 2,236 ambulatory surgery visits representing 2,460 procedures) in Year One and 68,785 total visits (including 2,372 ambulatory surgery visits representing 2,609 procedures) in Year Three. The ambulatory surgery volume is based on the participating surgeons' current caseload. All surgical procedures that will be performed in the proposed ASC will come from the private practices of the participating surgeons. The growth in volume is expected due to the addition of new service lines, including ambulatory surgery service, Imaging, and other medical specialties services. The Center is also projecting an increase in staffing such as new providers and technicians for Year 1 and Year 3 due to the addition of these new services. According to the applicant, the existing space at Hillside is also undersized. The new building will allow for the expansion of medical services and provide modernized spaces based on current standards.

The table below provides a detailed breakdown of the applicant's actual and projected visits for existing and requested services.

	2023	2024	Year 1	Year 2	Year 3
Primary Care**	10,477	10,987	14,138	18,379	22,055
Medical Specialties***	314	1,460	3,956	5,143	6,172
Podiatry	1,246	1,365	1,879	2,443	2,932
Urgent Care (New)			4,000	7,000	8,750
Behavioral Health (New)			2,000	3,500	4,375
Imaging - MRI (New)			1,200	2,100	2,625
Imaging - CT (New)			1,600	2,800	3,500
Imaging - Diagnostic X-Ray	565	551	571	742	890
Imaging - Mammography (New)			2,200	3,850	4,813
Imaging - Ultrasound (New)			2,200	3,850	4,813
Dental (New)			1,600	2,800	3,500
FASC (New)*			2,460	2,533	2,609
TOTAL	**12,602**	**14,363**	**37,804**	**55,140**	**67,034**

* FASC services reflects procedures and non-FASC services reflects visits, as per Schedule 17C-2 requirements.

** Includes Family Medicine, Internal Medicine, Obstetrics & Gynecology and Pediatrics services.

*** Includes Cardiology and Endocrinology services.

The table below shows the projected payor source utilization for Years One and Year Three.

Payor	Year One		Year Three	
	Volume	%	Volume	%
Commercial FFS	5,902	14.9%	10,064	14.6%
Medicare FFS	801	2.0%	1,394	2.0%
Medicare MC	5,377	13.6%	9,348	13.6%
Medicaid FFS	717	1.8%	1,245	1.8%
Medicaid MC	25,926	65.5%	45,264	65.8%
Private Pay	274	0.7%	480	0.7%
Charity Care	571	1.4%	990	1.4%

Source: Applicant

The table below shows the number of patient procedures for relevant facilities providing ambulatory surgery services in Queens County for 2022 through 2025.

Ambulatory Surgery within a 4-mile Radius of the Applicant					
Facility Name	Type	Patient Procedures			
		2022	2023	2024	2025
Queens Hospital Center	Hospital	5,292	7,170	7,707	7,210
Jamaica Hospital Medical Center	Hospital	5,369	5,889	5,803	6,481
Flushing Hospital Medical Center	Hospital	4,830	4,945	4,818	5,231
CitiMed Surgery Center	ASC	4,744	4,534	4,033	4,673
North Queens Surgical Center	ASC	8,774	9,653	10,224	8,804
Medex Diagnostic and Treatment Center	ASC	89[1]	3,318	7,136	8,296
Gramercy Surgery Center, Inc - Queens	ASC	3,055	3,544	3,753	3,637
Total Visits		**32,153**	**39,053**	**43,474**	**44,332**

Source: HFIS & SPARCS
[1]Facility started performing ambulatory surgery services in June 2022.

All the facilities listed above provide multi-specialty services. In addition, the Department recently approved the following CONs with similar services:

- Meridian Surgery Center (CON 241081) provides multi-specialty ambulatory surgery services, approximately 6.4 miles away and 16-minute drive from this site.
- Jay Health, Inc (CON 231223) provides primary care and other medical specialties approximately 4.2 miles away and an 18-minute drive from the applicant.
- Medisys Medical and Pediatric (CON 241272) and Medisys Center for Wellness and Health (CON 242124), with both facilities providing primary care services, both approximately 3.7 miles and 20-minute drive from the applicant.
- MediDental Care (CON 261060) provides dental and primary care services approximately 3 miles and 12-minute drive from the site.

The Department is also currently reviewing:

- Richmond Hill Ambulatory Surgery Center (CON 261079) requesting to provide multi-specialty ambulatory surgery services in gastroenterology, vascular, and podiatry approximately 5.6 miles and 25-minute drive from the applicant.
- International D&TC, LLC (CON 251176) requesting to provide primary care, other medical specialties, audiology, occupational, physical, and speech therapies, approximately 5.1 miles and 16- minutes driving distance from the applicant.

Hillside is a recognized patient-centered medical home (PCMH) by the National Committee for Quality Assurance (NCQA). Through this project Hillside will be a comprehensive health care provider offering primary and specialty care services (including but not limited to cardiology, dermatology, orthopedics, and others), imaging services (MRI, CT, X-ray, and ultrasound), dental services, behavioral health services, urgent care services, podiatry, and multi-specialty surgical services in podiatry, obstetrics/gynecology (no abortion), vascular/endovascular, cardiothoracic (no cardiac surgery) and general surgery.

Prevention Quality Indicators (PQIs) are rates of admission to the hospital for conditions for which good outpatient care can potentially prevent the need for hospitalization, or for which early intervention can prevent complications or more severe diseases. PQIs can also be used to identify areas with poor access to care. The table below provides information on PQI rates for 2024 related to this application. ZC 11432 is included as where the site is located.

Hospital Admissions per 10,000 Adults			
PQI Name	**ZC 11432**	**Queens County**	**New York State**
Diabetes Short-Term Complications	8	6	7
Diabetes Long-Term Complications	11	12	13
Chronic Obstructive Pulmonary Disease or Asthma	24	19	25
Hypertension	11	10	7
Heart Failure	42	33	38
Community Acquired Pneumonia	8	7	12
Urinary Tract Infection	12	11	13
Uncontrolled Diabetes	6	5	5
Prevention Quality Overall Composite	113	98	113
Severe Maternal Morbidity Rate	125	146	149

Source: NYSDOH, Data Hub
Rates are per 10,000 and are rounded crude rates

Queens Hospital Center, a part of the New York City Health + Hospitals (NYC H+H) has submitted a public comment letter in opposition to the approval of this CON application. Specifically stating the conversion of Hillside to an ASC will have a significant negative impact on Queens Hospital Center due to the location of the ASC within Queen's PSA. This will lead to a loss of outpatient surgical volume which will then cause a loss of revenue and have an impact on its finances. Workforce is also a concern as staff might be attracted to work in a new ASC. The applicant submitted a response to the public comment, stating that all surgical procedures that will be performed in the proposed ASC will come from the private practices of the participating surgeons. There will be no financial impact to any hospitals as the surgical procedures are currently being performed in the private practices of the surgeons and to minimize any workforce impact, the ASC will recruit existing staff members of the private practices.

Based on 2024 SPARCS data, the table below provides ambulatory surgery visits by specialty for the nearby facilities noted above. Based on the data below, 13.3% of Queens Hospital Center's visits may overlap with the applicant.

	Ob/ Gyn	Cardio-thoracic	Podiatry	Vascular/ Endo-vascular	General Surgery	Specialty Visit Total	2024 Total Visits	% Specialty Visits
Queens Hospital Center	341	13	35	505	128	1,022	7,707	13.3%
Jamaica Hospital Medical Center	153	1	52	865	166	1,237	5,803	21.3%
Flushing Hospital Medical Center	219	0	42	531	512	1,304	4,818	27.1%
CitiMed Surgery Center	0	0	0	0	0	0	4,033	0%
North Queens Surgical Center	0	0	125	345	0	470	10,224	4.6%
Medex Diagnostic and Treatment Center	0	0	0	479	0	479	7,136	6.7%
Grammercy Surgery Center, Inc - Queens	17	0	135	5	47	204	3,753	5.4%

Source: SPARCS

Conclusion

Approval of this project will provide improved access to primary and specialty services including ambulatory surgery for the residents of Queens County.

Program Analysis

Project Proposal

Proposed Operator	Hillside Polymedic Diagnostic and Treatment Center
To Be Known As	Hillside Polymedic Diagnostic and Treatment Center
Site Address	18730 Hillside Avenue Jamaica, NY 11432 (Queens County)
Specialties	**ADD:** Ambulatory Surgery - Multi-Specialty, CT Scanner, Magnetic Resonance Imaging Medical Services - Other Medical Specialties
Hours of Operation	Monday through Friday - 7 a.m. to 5 p.m.
Staffing (1st Year / 3rd Year)	**AMBULATORY**: 19.10 / 19.10 FTEs **MEDICAL/BEHAVORIAL/IMAGING SERVICES:** 28.5 / 37.25 FTEs
Medical Director	Chudi Chime, M.D.
Emergency, In-Patient and Backup Support Services Agreement and Distance	Long Island Jewish Medical Center (LIJ) 270-5 76th Avenue New Hyde Park, New York 11040 5.5 miles / 17 minutes' drive

The total square footage of The Center will increase from 8,609 square feet to 72,332 square feet and include two (2) operating rooms (ORs), two (2) procedure rooms, and eight (8) pre & post-surgical stations, as well as support spaces within separate and distinct space from the rest of the D&TC. The second floor will be dedicated space for prenatal care services. Two floors will remain shell space for future use.

The proposed Center is intended to provide a wide range of health care services including primary care, other medical specialties and surgical services to help meet the needs of Queens County residents. Queens County has a high minority population which is traditionally medically underserved due to language barriers or limited English proficiency among others. Hillside intends to enter into a service agreement with an outside language interpretation service as well as sign language.

Specialty care services will include cardiology, dermatology, orthopedics, imaging services (MRI, CT, diagnostic X-ray and ultrasound, dental services, behavioral health services, urgent care services, podiatry; and multi-specialty surgical services in podiatry, obstetrics / gynecology (no abortion services), vascular/endovascular, cardiothoracic (no cardiac surgery) and general surgery.

Hillside will continue operating in its present location until completion of Phase-1, after which it will obtain a Certificate of Occupancy (COO) for the newly constructed building and will relocate its D&TC operation to the newly completed section of the building. The existing Hillside medical services will be expanded in size and in scope by this new building which will include provision for this proposed multi-specialty, free-standing ambulatory surgery center (FASC).

All the proposed FASC procedures will come from private practices of participating surgeons. Ambulatory surgery procedures will be performed either under general or local anesthesia, or conscious sedation; and will not require overnight stays in acute care hospitals. The Center will utilize the same protocols, policies and procedures as it currently uses at the main site.

The Center will expand the hours to meet the needs of patients and physicians. There will also be 24 hours per day, 7 days a week, on-call service if a patient requires assistance during the hours when the ASC is not in operation.

The following table shows the FTEs in Year One and Year Three following the completion of this project:

Position	Current	Year One	Year Three
Management and Supervision	2.00	4.10	4.10
Technician and Specialist	9.00	19.50	21.50
Registered Nurses	0.00	5.00	5.00
Physician/Podiatrist/Psychiatrist	3.00	6.00	9.50
Nurse Practitioner	1.00	2.50	4.50
Social Workers & Psychologist	0.00	1.25	3.00
Clerical & Administrative	12.00	22.00	23.00
Maintenance Workers & Others	1.00	3.00	3.00
Dentist, Dental Assistant, Dental Hygienist	0.00	1.25	3.13
Totals	**28.00**	**64.60**	**76.73**

Hillside Polymedic Diagnostic and Treatment Center submitted commitment letters for eight physicians committed to performing surgical procedures at the FASC. The eight surgeons are: Chudi Chime, MD (Obstetrician-Gynecologist), George F. Baah, DPM (Doctor of Podiatric Medicine), Steve Ideyi, MD (Radiologists), William Onyebeke, MD (Obstetrician-Gynecologist), Felix Oviasu, MD (Cardiologist), Syed Rizvi, DO (Vascular), Ali Safavi, MD (Cardiothoracic) and Andrew Smith, MD (General Surgeon).

Hillside has a Transfer and Affiliation Agreement with Long Island Jewish Medical Center (LIJ) at 270-5 76th Avenue, New Hyde Park, New York 11040, approximately 5.5 miles away/17 minutes away.

Chudi Chime, M.D. is the Medical Director.

Integration with Community Resources

Hillside has in place a formal outreach program directed to members of local community, including local physicians and will expand upon that program to include FASC services.

Hillside Polymedic Diagnostic and Treatment Center will benefit community residents by expanding the services it currently provides in Queens County. Most patients expected at the clinic are either currently being treated by the participating surgeons in their private, office-based practices, or are underserved members of the community who need surgical care and who will be referred to Hillside by community-based providers. This project is specifically intended to address a longstanding gap in access in this underserved area of Queens County.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

The staff from the Division of Certification & Surveillance reviewed the ten-year surveillance history of all associated facilities. Sources of information included the files, records, and reports found in the Department of Health. Included in the review were the results of any incident and/or complaint investigations, independent professional reviews, and/or comprehensive/focused inspections. The review found that any citations were properly corrected with appropriate remedial action.

Conclusion

Based on the results of this review, a favorable recommendation can be made regarding the facility's current compliance pursuant to 2802-(3)(e) of the New York State Public Health Law.

Financial Analysis

Total Project Cost and Financing

Total project cost, which is for land acquisition, new construction and the acquisition of movable equipment, is estimated at $92,224,979, further broken down as follows:

	Article 28	Article 28 Shell	Total
Land Acquisition	$2,823,155	$726,364	$3,549,519
New Construction	$42,217,357	$10,862,017	$53,079,374
Renovation and Demolition	$435,461	$112,039	$547,500
Site Development	$870,922	$224,078	$1,095,000
Temporary Utilities	$174,185	$44,815	$219,000
Design Contingency	$4,221,735	$1,086,202	$5,307,937
Construction Contingency	$2,110,868	$543,101	$2,653,969
Architect/Engineering Fees	$5,066,083	$1,303,442	$6,369,525
Construction Manager Fees	$1,266,521	$325,860	$1,592,381
Other Fees	$422,174	$108,620	$530,794
Movable Equipment	$4,939,165	$0	$4,939,165
Financing Costs	$1,650,427	$424,635	$2,075,062
Interim Interest Expense	$7,839,530	$2,017,016	$9,856,546
CON Fee	$2,000	$0	$2,000
Additional Processing Fee	$407,207	$0	$407,207
Total Project Cost	$74,446,790	$17,778,189	$92,224,979

Article 28 reimbursable project costs are $74,446,790. The applicant has provided documentation for an MAI appraisal in support of land acquisition. The applicant could not provide land acquisition agreements for the six pieces of property because some pieces of property were bought years ago, and they don't have the purchase agreements.

The applicants financing plan appears as follows:

Commercial Loan through Brookshire LLC (5.70% interest rate for a 35-year term)	$83,002,481
Land Equity	$3,549,519
Personal Loan (12% interest rate for 30 years). .	$5,354,111
Total	$92,224,979

Operating Budget

The applicant has submitted an operating budget, in 2026 dollars, for the current year, year one after project completion and year three after project completion, summarized below:

	Current (2024)		Year One		Year Three	
	Per Visit	Total	Per Visit	Total	Per Visit	Total
Revenues						
Commercial FFS	$145.41	$296,190	$499.79	$2,980,234	$368.36	$3,730,717
Medicare MC	$115.25	$33,537	$282.35	$227,577	$229.16	$320,592
Medicare FFS	$142.48	$278,118	$273.48	$1,478,695	$236.95	$2,222,837
Medicaid MC	$127.57	$33,167	$252.23	$182,107	$216.88	$270,882
Medicaid FFS	$216.93	$2,064,297	$309.51	$8,061,169	$295.23	$13,400,292
Private Pay	$104.96	$10,496	$130.55	$35,901	$130.63	$62,835
Charity Care		$0		$0		$0
Non-Operating Rev		$44,787		$44,787		$44,787
Total Revenues		$2,760,592		$13,010,470		$20,052,942
Expenses:						
Operating	$161.89	$2,325,267	$212.98	$8,427,098	$162.14	$11,191,202
Capital	$34.92	$501,555	$169.11	$6,691,394	$95.23	$6,574,251
Total Expenses	$196.81	$2,826,822	$382.09	$15,118,492	$257.37	$17,765,453
Net Income (Loss)		($66,230)		($2,108,022)		$2,287,489
Visits		14,363		39,568		68,785

The following is noted with respect to the operating budget:

- Expenses, utilization and revenues for the non-ASC component of this project were based on the experience of Hillside in providing the same or similar services at its main D&TC site.
- The applicant provided physician referral letters in support of their FASC utilization projections.
- The projected operating expenses related to the ASC component are based on the experience of the participating providers and the experience of other FASCs in New York State.
- Revenues and utilization for the ASC services are based on the experience of the participating providers and the experience of ASCs in New York State.

Utilization broken down by payor source for the Current Year (2024), Year One and Year Three are as follows:

	Current Year	Year One	Year Three
Commercial FFS	14.18%	14.92%	14.63%
Medicare FFS	2.03%	2.03%	2.03%
Medicare MC	13.59%	13.59%	13.59%
Medicaid FFS	1.81%	1.81%	1.81%
Medicaid MC	66.25%	65.52%	65.81%
Private Pay	0.70%	0.69%	0.70%
Charity Care	1.44%	1.44%	1.44%
Total	100.00%	100.00%	100.00%

Lease Rental Agreement

The applicant has submitted a draft lease rental agreement for the site they will occupy, which is summarized below:

Premises	100,208 sq.ft. located at 18730 Hillside Avenue, Jamaica, New York
Lessor	Chime Family Holdings, L.P.
Lessee	Hillside Polymedic Diagnostic and Treatment Center
Term	35 years
Rental	$5,518,650 annually (55.07 per sq.ft.)
Provisions	The lessee shall be responsible for utilities, maintenance and real estate taxes.

The applicant has indicated the lease arrangement will be a non-arm's length lease. The applicant submitted two letters from real estate brokers attesting to the reasonableness of the per square foot rental.

Land Purchase Agreements

The new building will be located on six parcels of land that the applicant currently owns. The applicant only has purchase agreements for three of the parcels. They did not provide the land purchase agreements for the other three because the transactions took place years ago and the legal counsel that they used for the transactions has retired and documentation is not accessible.

Capability and Feasibility

The total project cost of $92,224,979, will be financed with a personal loan of $5,354,111, with Bridgett Chime as the borrower, at an interest rate of 5.75% for a 30-year term, $3,549,519 in land equity, and a Commercial Loan of $83,002,481 at an interest rate of 5.70% for a 35-year term. There will be no debt service payments for the first two years of the personal loan. The debt service payments starting in the third year will be paid from facility operations.

The working capital requirements for this application are estimated at $2,960,702, which is equivalent to two months of third year expenses. Bridget Chime will personally borrow $1,480,351 at an interest rate of 12% for a five-year term. The applicant has provided letters of interest. Per the letter of interest, there will be a two-year deferral of debt service payments, so payments will begin in Year Three when the facility is profitable. The real estate, owned by Bridget Chime, will be used as collateral. BFA Attachment A, Net Worth Statement of Sole Shareholder of Hillside Polymedic Diagnostic and Treatment Center, shows the availability of real estate to be used as collateral. Also, the applicant will finance $1,480,351 at an interest rate of 5.7% for a two-year term with a loan from Brookshire CRE, a commercial real estate brokerage company.

The submitted budget projects a net loss of ($2,108,022) in Year One and a net income of $2,287,489 during Year Three. Year One losses will be offset by working capital funds. Revenues are based on current reimbursement methodologies for Hillside. The submitted budget appears reasonable.

BFA Attachment B, 2023 -2024 Certified Financial Statements of Hillside Polymedic Diagnostic and Treatment Center, shows Hillside maintained average positive working capital positions, average negative net asset positions, and a net loss of ($385,345) in 2023 and ($66,230) in 2024. These losses stem primarily from the lasting financial impact of the COVID-19 pandemic, which caused a significant decline in patient utilization and revenues. Hillside faced elevated costs during this period due to a heavy reliance on expensive contract labor. Despite these challenges, they have made meaningful progress in rebuilding their patient volume.

BFA Attachment C, 2025 Internal Financial Statements of Hillside Polymedic Diagnostic and Treatment Center, show the entity had a negative working capital position, negative net asset position, and a net loss of ($464,391) through December 31, 2025.

Conclusion

The applicant has demonstrated the capability to proceed in a financially feasible manner.

Attachments

BHFP Attachment	Map
BFA Attachment A	Net Worth Statement of Sole Shareholder of Hillside Polymedic Diagnostic and Treatment Center
BFA Attachment B	2023 -2024 Certified Financial Statements of Hillside Polymedic Diagnostic and Treatment Center
BFA Attachment C	2025 Internal Financial Statements of Hillside Polymedic Diagnostic and Treatment Center.

NEW YORK STATE OF OPPORTUNITY. Department of Health

Public Health and Health Planning Council

Project # 261138-E
Saratoga-Schenectady Endoscopy Center, LLC

Program: **Diagnostic and Treatment Center** ***County:*** **Saratoga**
Purpose: **Establishment** ***Acknowledged:*** **April 13, 2026**

Executive Summary

Description

Saratoga-Schenectady Endoscopy Center LLC (SSEC), an existing Article 28, Single-Specialty Ambulatory Surgery Center, is seeking approval to add one new member. Dr. Sidney Olefson will join the existing fourteen members, all of whom will have equal membership of 6.667%. SSEC has exceeded the 25% threshold for membership changes over the past five years, requiring this application to be submitted as a full review.

Membership before and after the requested change is as follows:

Current Members	
Saratoga Schenectady Endoscopy Center, LLC.	
Member	Ownership %
Howard Malamood, M.D.	7.14%
John DeFrancisco, M.D.	7.14%
William Gusten, M.D.	7.14%
David Goetz, M.D.	7.14%
Natalya Belova, M.D.	7.14%
Mark Metwally, M.D.	7.14%
Justin Provost, M.D.	7.14%
Chad Cornish, M.D.	7.14%
Vinay Sood, M.D.	7.14%
Zachary Feinberg, M.D.	7.14%
Christopher Brown, M.D.	7.14%
Leon Averbukh, M.D.	7.14%
Matthew Josephson, M.D.	7.14%
Mohammad Sohail, M.D.	7.14%
Total	100.00%

Proposed Members	
Saratoga Schenectady Endoscopy Center, LLC.	
Member	Ownership %
Howard Malamood, M.D.	6.667%
John DeFrancisco, M.D.	6.667%
William Gusten, M.D.	6.667%
David Goetz, M.D.	6.667%
Natalya Belova, M.D.	6.667%
Mark Metwally, M.D.	6.667%
Justin Provost, M.D.	6.667%
Chad Cornish, M.D.	6.667%
Vinay Sood, M.D.	6.667%
Zachary Feinberg, M.D.	6.667%
Christopher Brown, M.D.	6.667%
Leon Averbukh, M.D.	6.667%
Matthew Josephson, M.D.	6.667%
Mohammad Sohail, M.D.	6.667%
Sidney Olefson, M.D.	6.667%
Total	100.00%

OPCHSM Recommendation

Approval

Need Summary

There will be no need review per Public Health Law §2801-a (4).

Program Summary

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary

There is no project cost associated with this application. The total purchase price for the 6.667% membership interest is $567,142 and will be funded with a 5-year loan at 6.39% interest. There is no operating budget presented with this application as this transaction is for a change in membership, with no changes to services or locations served. Upon BFA review, the facility is in good financial standing.

Health Equity Impact Assessment

This project does not meet the requirements for a Health Equity Impact Assessment under Section 2802-B of the PHL.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

Approval conditional upon:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Council Action Date

June 24, 2026

Program Analysis

Project Proposal

Proposed Operator	Saratoga-Schenectady Endoscopy Center, LLC
Site Address	1 Wellness Drive, Burnt Hills, NY 12027 (Saratoga County)
Specialties	Ambulatory Surgery - Single Specialty - Gastroenterology
Hours of Operation	Monday through Friday, 7a.m.- 4p.m.
Staffing (1st Year / 3rd Year)	63.0 FTEs / 65.0 FTEs
Medical Director(s)	William Gusten, M.D.
Emergency, In-Patient and Backup Support Services Agreement and Distance	Saratoga Hospital, located 13.4 miles, 27-minute drive time away Ellis Hospital, located 8.5 miles away, 19-minute drive time away

Saratoga-Schenectady Endoscopy Center LLC has been operating since 2004 as a single-specialty endoscopy ambulatory surgery center and is accredited by the Accreditation Association of Ambulatory Health Care. This application is being submitted to add one new owner, Dr. Sidney Olefson, to join the existing fourteen members, all to be equal members of 6.667%.

The following table shows the projected FTEs in Year One and Year Three following completion of this project:

Position	Year One	Year Three
Management and Supervision	2.0	2.0
Technician and Specialist	18.0	19.0
Registered Nurses	34.0	35.0
Clerical and Other Administrative	9.0	9.0
Totals	**63.0**	**65.0**

Character and Competence

Sideny Olefson, M.D. has worked as a Gastroenterologist at Saratoga Schenectady Gastroenterology Associates since February of 2025. Prior to this, Dr. Olefson worked as a Gastroenterologist at Prima Care, P.C. from 2020 to 2025, and at Greater Boston Gastroenterology, P.C. from 2019-2020. Dr. Olefson also worked as a Hospitalist at Hospital of Central Connecticut from 2017 to 2019. Dr. Olefson graduated from Union Graduate College with a Master of Business Administration in 2010 and from Albany Medical College with a Doctor of Medicine in 2013. Dr. Olefson completed an Internal Medicine Residency at Warren Alpert Medical School of Brown University in 2014, followed by a Residency in Internal Medicine in 2016. Dr. Olefson completed a Fellowship in Gastroenterology-Hepatology at the University of Connecticut School of Medicine in 2019. Dr. Olefson is Board Certified in Internal Medicine and Gastroenterology.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the U.S. Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Additionally, the staff from the Division of Certification & Surveillance reviewed the ten-year surveillance history of all associated facilities. Sources of information included the files, records, and reports found in the Department of Health. Included in the review were the results of any incident and/or complaint investigations, independent professional reviews, and/or comprehensive/focused inspections. The review found that any citations were properly corrected with appropriate remedial action.

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

Operating Budget

There is no operating budget presented with this application as this transaction is for a change in membership, with no changes to services or locations served. Upon a BFA review, the facility is in good financial standing.

Membership Interest Purchase Agreement

The applicant submitted a Membership Interest Subscription Agreement for the proposed member; the terms are summarized below:

Date	April 1, 2026
Description	Transfer a combined 6.667% ownership interest of the 14 members in SSEC LLC to Dr. Sidney Olefson, M.D.
Transferers	Howard Malamood, M.D., John DeFrancisco, M.D., William Gusten, M.D., David Goetz, M.D., Natalya Belova, M.D., Mark Metwally, M.D., Justin Provost, M.D., Chad Cornish, M.D., Vinay Sood, M.D., Zachary Feinberg, M.D., Christopher Brown, M.D., Leon Averbukh, M.D., Matthew Josephson, M.D., Mohammad Sohail, M.D.
Transferee	Dr. Sidney Olefson, M.D.
Purchase Price	$567,142.00
Percentage Interest	Howard Malamood, M.D., 6.667%, John DeFrancisco, M.D. 6.667%, William Gusten, M.D., 6.667%, David Goetz, M.D., 6.667%, Natalya Belova, M.D., 6.667%, Mark Metwally, M.D., 6.667%, Justin Provost, M.D., 6.667%, Chad Cornish, M.D., 6.667%, Vinay Sood, M.D., 6.667%, Zachary Feinberg, M.D., 6.667%, Christopher Brown, M.D., 6.667%, Leon Averbukh, M.D., 6.667%, Matthew Josephson, M.D., 6.667%, Mohammad Sohail, M.D., 6.667%.
Total Transfer	Sidney Olefson, M.D. 6.667%

Lease Agreement

The applicant provided an executed Lease agreement for the existing site; the terms are summarized below:

Date	May 1, 2020
Premises	1 wellness Drive, Burnt Hills, NY 12027
Landlord	Saratoga-Schenectady real Property, LLC.
Lessee	Saratoga-Schenectady Endoscopy center, LLC
Term	Initial term of 10 years with option to extend for successive periods of five (5) years with the base rental increasing by five percent (5%) in each successive five (5) year term.
Rent	Fixed rent is $29.00 per square foot, $1,028,572 per annum, $85,714.33 per month.
Provisions	Taxes, Utilities, Insurance, Maintenance

The applicant submitted a Statement indicating the tenant and the landlord have similar ownership and the applicant has submitted 2 letters of rent reasonableness submitted with the original lease and the original lease has not changed since May 1, 2020.

Capability and Feasibility

There is no project cost associated with this application. The total purchase price for the transfer of 6.667% ownership to the new member is $567,142 and will be funded with a bank loan to Dr. Sidney H. Olefson, Ballston Spa National Bank has provided a letter of interest. BFA Attachment A, Proposed New Member Net Worth Statement, shows that the proposed member has sufficient liquid resources available for the purchase.

BFA Attachment C, 2023-2024 Certified Financial Statements of Saratoga-Schenectady Endoscopy Center, LLC, shows positive working capital, a positive net asset position, and a net income of $6,468,206 and $9,824,757 in 2023 and 2024, respectively.

BFA Attachment D, 2025 Internal Financial Statements of Saratoga-Schenectady Endoscopy Center, LLC, shows positive working capital, a positive net asset position, and a net income of $9,032,594.

Conclusion

The applicant has demonstrated the capability to proceed in a financially feasible manner.

Attachments

BFA Attachment A	Proposed New Member Net Worth Statement
BFA Attachment B	Organization Chart
BFA Attachment C	2023-2024 Certified Financial Statements of Saratoga-Schenectady Endoscopy Center, LLC
BFA Attachment D	2025 Internal Financial Statements of Saratoga-Schenectady Endoscopy Center, LLC

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 24th day of June 2026, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to transfer 6.667% ownership interest from the fourteen (14) current members to one (1) new member, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:	FACILITY/APPLICANT:
261138 E	Saratoga-Schenectady Endoscopy Center, LLC

APPROVAL CONTINGENT UPON:

N/A

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **one year from the date of the recommendation letter**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a complete response to each individual contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in the Contingencies Tab in NYSE-CON.

NEW YORK STATE OF OPPORTUNITY. Department of Health

Public Health and Health Planning Council

Project # 252183-B
St. Mary's Center, Inc.

Program: **Diagnostic and Treatment Center** ***County:*** **New York**
Purpose: **Establishment and Construction** ***Acknowledged:*** **November 26, 2025**

Executive Summary

Description
St. Mary's Center, Inc. ("SMC"), a New York not-for-profit corporation, requests approval to establish and construct an Article 28 Diagnostic and Treatment Center (D&TC) in leased space at 73 Lenox Avenue in Central Harlem. The project will also relocate a 50-slot AIDS-Adult Day Health Care (ADHC) program from its existing site at 512-516 West 126th Street, New York, to separate leased space at 73 Lenox Avenue.

St. Mary's Center will be certified for Medical Services – Primary Care and Certified Mental Health Services O/P. The D&TC will occupy the first floor and a portion of the third floor of an existing three-story building. The first floor will have seven (7) exam rooms, as well as an isolation exam room. The ADHC will occupy the cellar and second floor.

Argus Community, Inc. (Argus), a New York not-for-profit corporation, is the sole corporate member of St. Mary's Center, Inc.

Stuart Wasser, M.D., board-certified in Internal Medicine, will serve as the Medical Director.

St. Mary's Center has a Transfer and Affiliation Agreement for backup and emergency services with Harlem Hospital Center, 1.1 miles/9 minutes away.

OPCHSM Recommendation
Contingent Approval

Need Summary
The applicant projects 3,285 visits in Year One and 10,951 visits in Year Three, with 85% Medicaid and 5% Charity Care. The ADHCP projects 6,750 visits in Year One and 12,000 visits in Year Three with 100% Medicaid.

Program Summary
The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary
The total project cost of $5,833,509 will be funded by $33,899 in equity from St. Mary's Center, Inc., and a $5,799,610 Statewide Health Care Facility Transformation Program II Grant.

Budget:	Year One	Year Three
Revenues	$2,009,812	$6,001,880
Expenses:	3,623,350	5,469,375
Net Income/(Loss)	($1,613,538)	$532,505

Health Equity Impact Assessment
This project does not meet the requirements for a Health Equity Impact Assessment under Section 2802-B of the PHL.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

Approval contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Architectural Design Development Drawings: Submission of architectural and life safety drawings, acceptable to the Department, as described in the Bureau of Architecture and Engineering Review Drawing Submission Guidelines DSG-1.0. [AER]
3. Engineering Design Development Drawings: Submission of mechanical, electrical, plumbing and fire protection drawings, acceptable to the Department, as described in the Bureau of Architecture and Engineering Review Drawing Submission Guidelines DSG-1.0. [AER]

Approval conditional upon:

1. This project must be completed by **July 15, 2027**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before **November 15, 2026**, and construction must be completed by **April 15, 2027**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date, this shall constitute abandonment of the approval. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
4. The staff of the facility must be separate and distinct from the staff of other entities; the signage must clearly denote the facility is separate and distinct from other entities; the clinical space must be used exclusively for the approved purpose; and the entrance must not disrupt any other entity's clinical program space. [HSP]
5. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary: https: www.health.ny.gov/facilites/hospitals/docs/hcs_access_forms_new_clinics.pdf. Questions may be directed to the Division of Hospitals and Diagnostic &Treatment Centers at 518-402-1004 or email: hospinfo@health.ny.gov. [HSP]

Council Action Date

June 24, 2026

Need Analysis

Project Description

St. Mary's Center, Inc. (SMC), an affiliate of Argus Community, an organization which provides comprehensive health, housing, and social services to vulnerable New Yorkers, focusing on those with substance use disorders (SUD), mental health challenges, and histories of homelessness or incarceration, and operator of Article 28 – Licensed RHCF and ADHCP services, is seeking approval to establish and construct an Article 28 diagnostic and treatment center (D&TC) at 73 Lenox Avenue, New York, NY 10026 (New York County). The Center will be certified for Medical Services – Primary Care, Certified Mental Health Services O/P, and a 50 slot AIDs Adult Day Health Care Program.

Background and Analysis

The primary service area (PSA) for this project includes New York County and Bronx County specifically within Manhattan neighborhoods of West Harlem (within Manhattan Community District 9 PUMA), Central Harlem (within Manhattan Community District 10 PUMA), and East Harlem (within Manhattan Community District 11 PUMA), as well as the Bronx neighborhood of Melrose/Mott Haven (within Bronx Community Districts 1&2 PUMA). The primary service area is in a Health Professional Shortage Area (HPSA) for Primary Care, Dental Health, and Mental Health. It is also within a Medically Underserved Area (MUA).

The population of New York County is projected to increase to 1,730,911, a 6.2% increase, and the population of Bronx County is projected to increase to 1,610,332, an increase of 14.6% by 2031, according to the Cornell Program on Applied Demographics. Demographics for the primary service area are noted below, including a comparison with New York State.

Demographics	Manhattan Community District 9	Manhattan Community District 10	Manhattan Community District 11	Bronx Community Districts 1&2	Bronx County	New York County	New York State
Total Population	112,952	135,011	127,516	154,955	1,404,779	1,629,477	19,852,366
Hispanic or Latino (of any race)	37.8%	24.7%	41.0%	69.6%	55.1%	24.4%	19.8%
White (non-Hispanic)	24.4%	15.8%	14.6%	2.2%	8.7%	45.5%	52.8%
Black or African American (non-Hispanic)	22.4%	49.3%	30.7%	24.6%	28.7%	12.5%	13.4%
Asian (non-Hispanic)	10.5%	4.1%	9.1%	0.7%	4.0%	12.4%	9.0%
Other (non-Hispanic)	4.9%	6.1%	4.7%	2.9%	3.5%	5.2%	5.0%

Source: 2024 American Community Survey (5-Year Estimates Data Profiles)

In 2023, 95.7% of New York County and 92.7% of Bronx County had health coverage as follows.

Health Plans	Bronx County	New York County
Employer plans	29.5%	52.4%
Medicaid	43.4%	19.3%
Medicare	7.06%	11.0%
Non-group plans	12.3%	12.8%
Military or VA plans	0.392%	0.284%

Source: Data USA

The population within the service area had health coverage as follows.

Health Coverage	Manhattan Community District 9 PUMA*	Manhattan Community District 10 PUMA*	Manhattan Community District 11 PUMA*	Bronx Community Districts 1&2 PUMA**
Medicare coverage alone	3.6%	3.3%	6.5%	3.2%
Medicaid/means-tested coverage alone	21.5%	28.5%	30.1%	47.9%

**Source 2021: ACS 5-Year Estimates, Table S2704*
***Source: 2024: ACS 5-Year Estimates, Table S2704*

The projected payor mix for the D&TC is shown below.

Applicant Projected Payor Mix		
Payor	**Year One**	**Year Three**
Commercial	0%	5.00%
Medicare	4.99%	5.00%
Medicaid	90.02%	84.99%
Charity Care	4.99%	5.00%

Source: Applicant

The applicant projects 3,285 visits in Year One and 10,951 visits in Year Three for the proposed D&TC (excluding ADHCP visits). The ADCHP visits are projected at 6,750 for Year One and 12,000 in Year Three, with 100% Medicaid as the payor.

The ADHCP services are currently operated under the organization's RHCF operating certificate and will be transferred to the D&TC through this application. The ADHCP will be relocated from its existing site at 512–516 West 126th Street, New York, NY 10027, and will maintain its approved capacity of 50 AIDS slots. At present, the program serves approximately 50 registrants daily, provides approximately 5,000 annual visits and projects an increase due to the new location and the benefits of co-location with primary care services. According to the applicant, St. Mary's Center's ADHCP is one of only five AIDS-designated ADHC programs in New York City and one of two located in Harlem.

SMC anticipates a significant demand for the proposed Center's services due to its long-standing service to the populations in Harlem and South Bronx, with barriers to healthcare access. Although SMC does not currently operate a D&TC, the proposed site will provide comprehensive primary and behavioral healthcare. Patient engagement will be supported through SMC's partnerships with community organizations (SMC's ADHCP, community outpatient and residential substance use and HIV treatment programs, as well as food pantries and transitional housing programs). According to the applicant, the center will offer services designed to meet the needs of the community, especially in managing chronic conditions such as hypertension, diabetes, asthma, and HIV. They will also provide nutrition counseling and health education. SMC will serve all New Yorkers, however, will specialize in serving those with mental health needs, those who use substances, people living with HIV, individuals experiencing homelessness, and people residing in public housing. SMC will provide walk-in appointments and flexible scheduling. Outreach and signage will make clear that all individuals can access care at SMC regardless of their insurance status.

The proposed D&TC will be near several public housing complexes. It will be directly across from the King Towers, and will be one avenue from the Taft complex, which houses New York City Housing Authority residents. Its goal is to eliminate obstacles to care by providing culturally sensitive services and preventive screenings and continuous care coordination. By being conveniently located, they aim to build trust and collaboration with patients to provide comprehensive and accessible health care.

Prevention Quality Indicators (PQIs) are rates of admission to the hospital for conditions for which good outpatient care can potentially prevent the need for hospitalization, or for which early intervention can prevent complications or more severe diseases. The table below provides information on PQI rates for 2024 related to this application.

PQI Name	Bronx County	New York County	New York State
Diabetes Short-Term Complications	12	7	7
Diabetes Long-Term Complications	27	13	13
Chronic Obstructive Pulmonary Disease or Asthma	59	25	25
Hypertension	16	7	7
Heart Failure	61	36	38
Community-Acquired Pneumonia	15	9	12
Uncontrolled Diabetes	11	5	5
Urinary Tract Infection	17	10	13
Prevention Quality Overall Composite	202	103	113

Source: NYSDOH, Data Hub
Rates are per 10,000 and are rounded crude rates

Conclusion

Approval of this project will allow SMC to provide access to primary care and behavioral health services while addressing health disparities in the communities served.

Program Analysis

Program Proposal

Proposed Operator	St. Mary's Center, Inc.
Doing Business As	St. Mary's Center, Inc.
Site Address	73 Lenox Avenue, New York, NY 10026 (New York County)
Shift/Hours/Schedule	Monday through Friday from 8 am to 6 pm Saturday from 9 am to 2 pm
Approved Services	Medical Services - Primary Care Certified Mental Health Services O/P 50-bed Adult Day Health Care-Aids
Staffing (1st Year/3rd Year)	13.0 FTEs for 1st year and 24.5 in 3rd year
Medical Director(s)	Dr. Stuart Wasser
Emergency, In-Patient and Backup Support Services Agreement and Distance	Harlem Hospital Center 506 Lenox Avenue, New York, NY 10037 Nearest hospital is Harlem Hospital Center - 1.1 miles / 9 minutes.

SMC's D&TC will specialize in serving patients with HIV/AIDs as well as those with co-occurring Mental Health and Substance Use Disorder (SUD). SMC's goal is to provide expanded primary care for residents from Argus's residential programs and for individuals across NYC. SMC will offer Medical Services - Primary Care and Certified Mental Health Services O/P. An additional fifty (50) Adult Day Health Care - AIDS slots will be included on the operating certificate. SMC will provide comprehensive and integrated behavioral health services which will include Mental Health screenings, therapy, psychiatric care, primary care, HIV services and case management; and other basic services such as wound care, screenings and vaccines.

St. Mary's Center, Inc. has an executed Transfer and affiliation agreement with Harlem Hospital which is located at 506 Lenox Avenue, New York, New York. Harlem Hospital is located 1.1 miles away/9 minutes away from this proposed D&TC.

All administrative aspects of SMC will be overseen by Argus Community's CEO, Dr. Miriam Vega. Dr. Vega is a nationally known turnaround specialist who developed the CHANGE (customized, holistic, analytical, network building, grassroots & evaluator) model of capacity program. Prior to joining Argus Community, Dr. Vega served as CEO and as COO of multiple Federally Qualified Health Centers (FQHCs), including Joseph P. Addabbo in NYC. Dr. Vega has a Ph.D. in Social Psychology from the University of California, Berkeley and a BA from Vassar College in Psychology; and completed a 2-year Prevention Fellowship at SUNY Downstate Medical Center, sponsored by the Centers for Disease Control and Prevention (CDC).

The following table shows the projected FTEs in Year One and Year Three following completion of the project.

Positions	Year One	Year Three
Management & Supervision	2.0	2.0
Physicians	1.0	1.0
Social Worker & Psychologist	2.4	4.8
Nurse Practitioners	0.1	2.2
Licensed Practical Nurse	1.0	3.0
Registered Nurse	1.5	2.0

Positions	Year One	Year Three
Infection Control, Environment and Food Service	0.2	0.5
Clerical & other Administrative	2.0	4.0
Psychiatrist	0.1	0.1
Business Development Associate	1.0	2.0
ADHC Intake Associate	1.0	2.0
Other Therapists and Assistants	0.5	1.0
Totals	13.0	24.5

Argus Community, Inc. is the sole corporate member (passive parent corporation) of St. Mary's Center, Inc. They share the same Board of Directors.

Board Member/Title
William S. Friedman / Director, Chairperson & Treasurer
Leslie A. Ross / Vice-Chair, Director & Secretary
Tom Javits / Director
Peter G. Samuels / Director
Ayanna Y. Thomas / Director
Frederick Harris / Director
Father Larry Ford / Director
Diane B. Pollard / Director

Character and Competence

Dr. Stuart Wasser will serve as Medical Director. He received a Doctor of Medicine degree from the New York University School of Medicine in 1986 and received a Bachelor of Arts degree from Columbia University in 1982. Dr. Stuart is certified by the American Board of Addiction Medicine and the American Board of Internal Medicine.

Since 1998, Dr. Wasser has operated private medical practice in Internal Medicine and Addiction Medicine in Rockville Centre, Long Island. He has worked in an Urgent Care Medicenter in Huntington, NY since 2003, and has held directorships of outpatient substance abuse clinics at EDNY in Hempstead, NY, Peninsula Counseling Center in Valley Stream, NY and at Friends of Bridge Valley Stream in New York.

William S. Friedman is the current chairperson, director and treasurer of the board. He graduated from Columbia University School of Law in 1970 and was admitted to the New York Bar in 1971. Mr. Friedman is also a graduate of Brandeis University. Mr. Friedman practiced law primarily in real estate and tax law until 1990 when he retired to devote more time to real estate investments and management. He is the founder and former general partner and chief executive officer of Beachwold Partners LP and was a former member of the Peace Corps.

Leslie A. Ross is currently the board's vice-chair, secretary and director. In 1993 Ms. Ross completed a master's degree in education from Bank Street College in New York City and received a bachelor's degree from Hunter College/CUNY in New York City. She was an educator at the Barnard Center for Toddler Development at Columbia University and from 1971-1975, Ms. Ross was the assistant to Elizabeth L. Sturz, who was the founder of Argus Community, Inc.

Tom Javits is currently a director of the board and serves on the Trust for Public Land - NYC Advisory Council. Mr. Javits completed a Master of Business Administration at Harvard Business School in Boston, Massachusetts in 1984; completed a Master of Science degree at Antioch University in San Francisco, California in 1977, and received a Bachelor of Science degree from the University of California in Berkeley, California in 1974. Mr. Javits has been a licensed NY State Real Estate Broker since 1992. Mr. Javits is a Principal and Real Estate executive at Javits Development Consulting in New York City. He was the Vice President for Construction and Facilities at the Metropolitan Museum of Art in New York City from 2010 – 2020 and is has been retired since January 1, 2021.

Peter G. Samuels is currently a director of the board. Mr. Samuels completed a Jurist Doctorate degree from Harvard Law School in 1974 and has been an attorney since 1975. Mr. Samuels has been a partner at Proskauer Rose Law Firm in New York City since 1971. He served for six years as co-head of the Firm's Mergers & Acquisitions Group. He advises on corporate governance and issues relating to strategic considerations and related matters. Mr. Samuels plays a leading role with Proskauer's pro bono initiatives and serves on the Independent Commission on NYC Criminal Justice and Incarceration Reform.

Ayanna Yasmin Thomas is currently a director on the board. She serves as an Associate at Bond Schoeneck & King; is affiliated with the New York City Bar Association and the New York State Bar Association. Ayanna Thomas has been a board member for nine (9) years; possesses a license as an Associate Broker; received a law degree from St. John's University School of Law in Queens, New York in 2015 and is a licensed Notary. Ayanna Thomas completed a Bachelor of Arts degree in Political Science at the State University of New York at New Paltz, New York in 2012; was admitted to the Bar in 2016 and admitted to the Southern and Eastern district of New York in 2023. Since 2024, Ayanna Thomas has been the general counsel for the Democracy Prep Public Schools in New York City; and was a member and partner at Bond, Schoeneck & King, PLLC in White Plains, New York from 2023 to 2024.

Fred Harris has been a director of the board since 2018. Mr. Harris has advanced degrees in Engineering and Law and is currently the executive vice president of development at Vornado Realty Trust. Mr. Harris served as a special advisor for real estate development of Jonathan Rose Companies; was a governor of the Real Estate Board of New York; was a Trustee of Brooklyn Hospital and was an adjunct professor at Columbia University.

Larry Ford is currently a director of the board; serves as a director with the Office Revitalization and Restructuring for US Franciscans; serves on the Board of St. Bonaventure University, and was formerly the board chair of CREATE, Inc. Father Ford is also a member of the Presbyteral Council of the Archdiocese of New York. Father Ford serves as the secretary for the Province of Our Lady of Guadalupe; and was the Pastor for Holy Name of Jesus-St. Gregory The Great Parish in New York City. Father Ford holds degrees in Industrial Relations, Divinity and non-Profit Administration with completed Doctorial work in Higher Education.

Diane B. Pollard is currently a director on the board and was the board chair for the St. Mary's Center. She was the founder of the St. Mary's Episcopal AIDS Center which is a residential community for individuals with HIV/AIDS; and established the outpatient center.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

Total Project Cost and Financing

Total project costs for renovations and movable equipment are estimated at $5,833,509, broken down as follows:

Renovation & Demolition	$3,828,125
Design Contingency	382,813
Construction Contingency	382,813
Planning Fees	48,750
Architect/Engineering Fees	420,000
Other Fees	237,110
Movable Equipment	500,000
CON Application Fee	2,000
CON Processing Fee	31,898
Total Project Cost	$5,833,509

The applicant's financing plan appears as follows:

Applicant Equity	$33,899
Grant - Statewide Health Care Facility Transformation Program II	5,799,610
Total	$5,833,509

BFA Attachment C, 2023-2024 St. Mary's Center, Inc. and SMC Manhattan Health Center, Inc.'s Certified Financial Statements, indicate sufficient resources to meet the equity requirement.

Operating Budget

The applicant has submitted first and third-year operating budgets in 2026 dollars, as summarized below:

	Year One		Year Three	
Revenues-D&TC:	Per Visit	Total	Per Visit	Total
Medicaid-FFS	$328.48	$108,069	$379.82	$208,144
Medicaid-MC	$263.18	691,644	$380.13	3,330,296
Medicare-MC	$155.02	25,424	$161.19	88,169
Commercial-MC		0	$100.10	54,756
Other Operating Income*		16,210		243,243
Sub-Total -		$841,347		$3,924,608
Revenues-ADHC				
Medicaid-MC	$173.11	$1,168,465	$173.11	$2,077,272
Total Revenues		$2,009,812		$6,001,880
Expenses:				
Operating	$551.85	$1,812,813	$275.29	$3,014,660
Capital	$162.81	534,825	$48.84	534,825
Operating-ADHC	$188.99	1,275,712	$159.99	1,919,890
Total		$3,623,350		$5,469,375
Net Income (Loss)		($1,613,538)		$532,505
Visits – D&TC		3,285		10,951
Visits - ADHC		6,750		12,000

**First Year Indigent Care $16,210, Third Year Indigent Care $62,443, and New York State Patient Centered Medical Home incentive program $180,800*

The following is noted concerning the submitted budget:

- Revenue and rates for the D&TC assume Federally Qualified Health Center (FQHC) with a Look-Like designation 6 months into the first year.
- Revenue and rate for the ADHC is based on the amounts the Center expects to be entitled and collected.
- The staffing plan aligns with standard provider productivity ratios and complies with Federal and NYS regulations for primary care and ADHC. The staff will be attentive to the patient's cultural and linguistic factors.
- Expenses are based on experience, staffing ratios, and input from Argus Community.
- SMC will actively engage patients from nearby public housing complexes, shelters, and supportive housing programs. It will use outreach, walk-in appointments, and trauma-informed care models to reduce barriers to access and build trust within the community.
- SMC has incorporated several strategies to ensure success.
    - The D&TC and ADHC will be situated in a visible, easily accessible location on Lenox Avenue, improving patient access and community visibility
    - The ADHC will help in transportation planning and will provide Metro Cards or transportation reimbursement.
    - SMC will leverage Argus Community's outreach and engagement networks to foster referral pathways and partnerships with local agencies and community organizations.
    - Argus Community will oversee operational planning and financial management for sustainability and assist in adapting to unforeseen challenges.
- Breakeven utilization for the third year is 9,905 D&TC visits and 11,091 ADHC visits.

Utilization broken down by payor source during the Year One and Year Three is as follows:

	Year One		Year Three	
	Visits	%	Visits	%
Medicaid-FFS	329	10.02%	548	5.00%
Medicaid-MC	2,628	80.00%	8,761	80.00%
Medicare-MC	164	4.99%	547	5.00%
Commercial-MC	0	0.00%	547	5.00%
Charity	164	4.99%	548	5.00%
Total	3,285	100%	10,951	100%
ADHC Payor:	Visits	%	Visits	%
Medicaid-MC	6,750	!00%	12,000	100%

Lease Rental Agreement

The applicant has submitted an executed lease for the proposed site; the terms are summarized below:

Date:	March 2, 2026
Premises:	Total 8,830 sq ft at 73 Lenox Avenue, NY, NY 10026 D&TC (5,143 sq ft) (3,434 sq ft on 1st floor and 1,709 sq ft on 2nd floor), ADHC (3,687 sq ft.) (816 sq ft in basement and 2,871 on 2nd floor)
Landlord:	Create, Inc.
Lessee:	St. Mary's Center, Inc.
Term:	10 Years, two (2) ten (10) year automatically renewals
Payment:	$220,750 annually ($25 per square foot) for the initial term, $309,050 annually ($35 per square foot) for the first renewal term, and $397,350 annually ($45 per square foot) for the second renewal term.
Provisions:	Utilities, Maintenance, and Insurance. The property is exempt from real property taxation.

The applicant has provided an affidavit attesting that the lease is a non-arms-length agreement. Letters from two NYS licensed realtors have been provided attesting to the rental rate being fair market value.

Capability and Feasibility

The total project costs of $5,833,509 will be funded by $33,899 in equity from St. Mary's Center, Inc., and a $5,799,610 grant from the Statewide Health Care Facility Transformation Program.

The working capital requirement, estimated at $2,217,430 based on two months of first-year expenses plus a projected loss of ($1,613,538), will be funded from operations.

The submitted budget projects a net loss of ($1,613,538) in Year One and a net income of $532,505 in Year Three. The budget appears reasonable. Argus Community, Inc.'s Chief Strategy Officer, has submitted a letter committing to supporting the projected loss and to meet working capital needs that may arise.

BFA Attachment A, Argus Community, Inc. and Affiliates' June 30, 2024, Certified Consolidated Financial Statements, show $44,763,783 in net assets, including $15,544,486 in liquid resources. BFA Attachment B, Argus Community, Inc. June 30, 2025, Internal Financial Statements, shows a negative working capital position, a positive net asset position, and a net income of $2,465,138.

BFA Attachment C, St. Mary's Center, Inc., and SMC Manhattan Health Center, Inc., 2024 Consolidated Financial Statements show negative working capital, positive net assets, and an operating loss of ($890,074). BFA Attachment D, St. Mary's Center, Inc., and SMC Manhattan Health Center, Inc., October 31, 2025, Internal Financial Statements, show a negative working capital position, a positive net asset position, and a net loss of ($472,675).

The applicant has demonstrated the capability to proceed in a financially feasible manner.

Conclusion

The applicant has demonstrated the capability to proceed in a financially feasible manner.

Attachments

BHFP Attachment	Map
BFA Attachment A	Argus Community Inc. June 30, 2024, Certified Financial Statements
BFA Attachment B	Argus Community, Inc.'s July 1, 2024 - June 30, 2025, Internal Financial Statements.
BFA Attachment C	St. Mary's Center, Inc. and SMC Manhattan Health Center, Inc.'s 2024 and 2023 Certified Financial Statements.
BFA Attachment D	St. Mary's Center, Inc. and SMC Manhattan Health Center, Inc., October 31, 2025, Internal Financial Statements

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 24th day of June 2026, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish and construct a new Diagnostic and Treatment Center at 73 Lenox Avenue, New York - SW2, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:	FACILITY/APPLICANT:
252183 B	St. Mary's Center, Inc.

APPROVAL CONTINGENT UPON:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Architectural Design Development Drawings: Submission of architectural and life safety drawings, acceptable to the Department, as described in the Bureau of Architecture and Engineering Review Drawing Submission Guidelines DSG-1.0. [AER]
3. Engineering Design Development Drawings: Submission of mechanical, electrical, plumbing and fire protection drawings, acceptable to the Department, as described in the Bureau of Architecture and Engineering Review Drawing Submission Guidelines DSG-1.0. [AER]

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **July 15, 2027**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before **November 15, 2026**, and construction must be completed by **April 15, 2027**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date, this shall constitute abandonment of the approval. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
4. The staff of the facility must be separate and distinct from the staff of other entities; the signage must clearly denote the facility is separate and distinct from other entities; the clinical space must be used exclusively for the approved purpose; and the entrance must not disrupt any other entity's clinical program space. [HSP]
5. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary: https: www.health.ny.gov/facilites/hospitals/docs/hcs_access_forms_new_clinics.pdf. Questions may be directed to the Division of Hospitals and Diagnostic &Treatment Centers at 518-402-1004 or email: hospinfo@health.ny.gov. [HSP]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a complete response to each individual contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in the Contingencies Tab in NYSE-CON.

NEW YORK STATE OF OPPORTUNITY. Department of Health

Public Health and Health Planning Council

Project # 252210-E
Amsterdam SNF LLC d/b/a
Wilkinson Rehabilitation and Nursing Center

Program: **Residential Health Care Facility** ***County:*** **Montgomery**
Purpose: **Establishment** ***Acknowledged:*** **December 4, 2025**

Executive Summary

Description
Amsterdam SNF LLC, a Nevada limited liability company authorized to conduct business in New York, requests approval to be established as the new operator of Wilkinson Residential Health Care Facility, an existing not-for-profit residential health care facility (RHCF). Wilkinson Residential Health Care Facility is a160-bed skilled nursing facility with an adult day health care program, located at 4988 State Highway 30, Amsterdam, (Montgomery County). Upon PHHPC approval, the name of the facility will be changed to Wilkinson Rehabilitation and Nursing Center.

The current operator, St. Mary's Healthcare, has entered into an Asset Purchase Agreement dated October 16, 2025, with Amsterdam SNF LLC for the acquisition of the operating interests. Concurrently, 4988 State HWY 30 LLC, entered into Purchase and Sale Agreement with St. Mary's Healthcare for the sale and acquisition of the real property interest of the nursing facility. 4988 State HWY LLC, as landlord, and Amsterdam SNF LLC, as tenant, have entered into a proposed lease agreement for site control of the facility.

The sole member of Amsterdam SNF LLC is Amsterdam SNF Holdco LLC, whose sole member is David Lichtschein.

OALTC Recommendation
Contingent Approval

Need Summary
There will be no change in beds as a result of this application. As of April 28, 2026, the facility reported 93.3% occupancy of its staffed beds, while Montgomery County had 96.7% occupancy of its staffed beds.

Program Summary
The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary
There are no project costs associated with this application. The purchase price for the operations is the assumption of certain liabilities and account receivables. The purchase price for the realty is $13,600,000, which will be funded with $500,000 in members' equity and a $13,100,000 loan for five years at an interest rate of 6.67%.

The proposed budget is as follows:

Budget	Year One	Year Three
Revenues	$18,191,500	$19,045,800
Expenses	17,514,200	18,091,950
Net Income	$677,300	$953,850

Health Equity Impact Assessment
This project does not meet the requirements for a Health Equity Impact Assessment under Public Health Law §2802-B.

Recommendations

Long Term Care Ombudsman Program

The LTCOP recommends Approval. (See LTCOP Attachment A)

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Aging and Long-Term Care

Approval contingent upon

1. Submission of executed real property loan commitment acceptable to the Department of Health. [BFA]
2. Submission of a commitment signed by the applicant which indicates that, within two years from the date of the council approval, the percentage of all admissions who are Medicaid and Medicare/Medicaid eligible at the time of admission will be at least 75 percent of the planning area average of all Medicaid and Medicare/Medicaid admissions, subject to possible adjustment based on factors such as the number of Medicaid patient days, the facility's case mix, the length of time before private paying patients became Medicaid eligible, and the financial impact on the facility due to an increase in Medicaid admissions. [RNR].

Approval conditional upon:

1. This project must be completed by one year from the date of the approval letter, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Council Action Date

June 24, 2026

Need Analysis

Background and Analysis

The primary service area is Montgomery County, which has a population projected to decrease by 1.0% to 49,047 by 2031 based on Cornell Program of Applied Demographic estimates. Demographics for the primary service area are noted below, including a comparison with New York State.

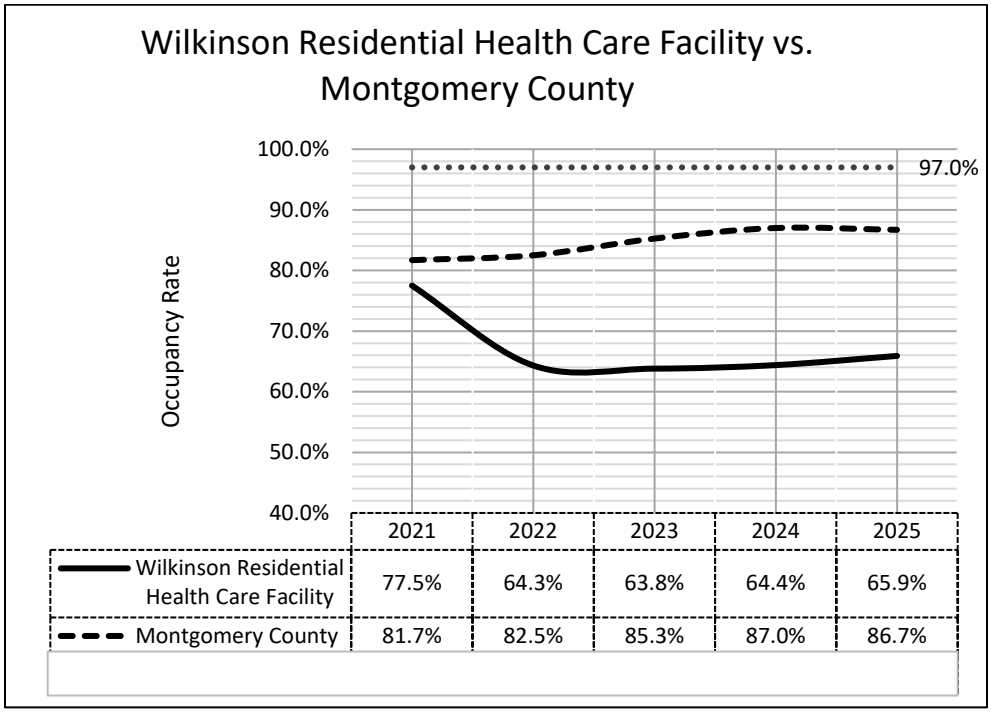
Demographics	Montgomery County	New York State
Total Population (2024 Estimate)	49,528	19,852,366
Hispanic or Latino (of any race)	15.4%	19.8%
White (non-Hispanic)	77.0%	52.8%
Black or African American (non-Hispanic)	2.5%	13.4%
Asian(non-Hispanic)	0.8%	9.0%
Other (non-Hispanic)	4.2%	5.0%

Source: 2024 American Community Survey (5-year Estimates Data Profiles)

The table below provides population estimates of individuals 65 years old and above in Montgomery County and New York State.

	Montgomery County Age Group 65-84	Montgomery County Age Group 85+	New York State Age Group 65-84	New York State Age Group 85+
Estimated 2024 Population	8,271	1,355	3,108,608	445,420
Population Projection by 2031	10,121	1,861	3,749,085	638,383
Percent Change	+22.4%	+37.3%	+20.6%	+43.3%

Source: 2024 American Community Survey (5-Year Estimates) and Cornell Program on Applied Demographics



Occupancy through 2024 is from the RHCF cost reports and 2025 data is from non-certified Health Electronic Response Data System (HERDS)

The table below shows the CMS Rating and the utilization of the closest RHCF to Wilkinson Residential Health Care Facility.

Facility Name	CMS Overall Rating	Beds	Distance from other RHCFs	Occupancy			
	As of 4/2026		Miles/Time	2022	2023	2024	2025
Wilkinson Residential Health Care Facility	2	160	0 miles/0 mins	64.3%	63.8%	64.4%	65.9%
River Ridge Living Center	1	120	3.8 miles/11 mins	79.5%	87.9%	93.7%	90.5%
Capstone Center for Rehabilitation and Nursing	1	120	6.9 miles/13 mins	93.4%	94.9%	95.7%	96.5%
Nathan Littauer Hospital Nursing Home	1	84	14 miles/21 mins	65.6%	67.4%	60.1%	69.3%
Wells Nursing Home Inc	1	100	19 miles/13 mins	71.8%	82.6%	86.5%	88.8%

Source: CMS and RHCF Cost Reports. Occupancy through 2024 is from the RHCF cost reports and 2025 data is from non-certified Health Electronic Response Data System (HERDS)

Based on weekly census data, the facility reported 75% of their 160 licensed beds were staffed and 70.0% occupied on April 28, 2026, for a 93.3% occupancy of staffed beds. Montgomery County had 91.5% of the county's 590 licensed beds staffed and 88.5% occupied for a 96.7% occupancy of staffed beds.

The facility's utilization has been between 63.8% to 65.9% over the past 4 years. According to the applicant, the current operator is a healthcare system and did not dedicate sufficient resources to the RHCF's marketing and admissions activities. The utilization has led to operating losses and the eventual decision to pursue a change of operator application by the current operator.

The applicant proposes the following efforts to increase occupancy at the facility:

- Meetings with local community leaders to determine community needs from a communal perspective.
- Meetings with local hospitals to ensure a cooperative effort in identifying and developing programs to determine what the hospitals feel is needed from a local nursing facility.
- Meetings with local physicians to determine what the medical community feels is lacking in the area (i.e. IV care, pulmonary services, trachea care, etc.).
- They note that once this information is compiled, the operator will implement the programs that are responsive to the needs of the community.

The following table provides the Case Mix Index (CMI) for the facility and surrounding RHCFs, which reflects the relative resources predicted to provide care to a resident. The New York State average CMI was 1.3520 and 1.2360 for Montgomery County. The higher the case mix weight, the greater the resource requirement for the residents.

Case Mix Index	2023	
	All Payor Mix	Medicaid Only
Wilkinson Residential Health Care Facility	1.2653	1.1529
River Ridge Living Center	1.2569	1.3011
Capstone Center for Rehabilitation and Nursing	1.051	0.9725
Nathan Littauer Hospital Nursing Home	1.1636	0.9541
Wells Nursing Home Inc	0.9255	0.843

Medicaid Access

To ensure that the Residential Health Care Facility needs of the Medicaid population are met, 10 NYCRR §670.3 requires applicants to accept and admit a reasonable percentage of Medicaid residents in their service area. The benchmark is 75% of the annual percentage of residential health care facility admissions that are Medicaid-eligible individuals in their planning area. This benchmark may be increased or decreased based on the following factors:

- the number of individuals within the planning area currently awaiting placement to a residential health care facility, and the proportion of total individuals awaiting such placement that are Medicaid patients and/or alternate level of care patients in general hospitals.
- the proportion of the facility's total patient days that are Medicaid patient days and the length of time that the facility's patients who are admitted as private paying patients remain such before becoming Medicaid eligible.
- the proportion of the facility's admissions who are Medicare patients or patients whose services are paid for under provisions of the federal Veterans' Benefit Law.
- the facility's patient case-mix based on the intensity of care required by the facility's patients or the extent to which the facility provides services to patients with unique or specialized needs.
- the financial impact on the facility due to an increase in Medicaid patient admissions.

An applicant will be required to make appropriate adjustments in their admission policies and practices to meet the resultant percentage. Based on the applicant's data, the facility's Medicaid admissions rate has been above the threshold of 75% of the Montgomery County rate.

Medicaid Access	**2022**	**2023**	**2024**
Montgomery County Total	44.6%	54.8%	55.8%
Montgomery County Threshold Value	*33.5%*	*41.1%*	*41.9%*
Wilkinson Residential Health Care Facility	86.0%	93.2%	91.7%

Conclusion

There will be no changes in beds as a result of this application. As of April 28, 2026, the facility reported 93.3% occupancy of its staffed beds, while Montgomery County had 96.7% occupancy of its staffed beds.

Program Analysis

Program Description

	Existing	Proposed
Facility Name	Wilkinson Residential Health Care Facility	Wilkinson Rehabilitation and Nursing Center
Address	4988 Street Highway 30 Amsterdam, New York 1201	Same
RHCF Capacity	160 beds	Same
ADHCP Capacity	38	Same
Type of Operator	Not-for-Profit Corporation	Limited Liability Company
Class of Operator	Voluntary	Proprietary
Operator	**St. Mary's Healthcare**	**Amsterdam SNF LLC** Member: Amsterdam SNF HOLDCO LLC 100% Member: David Lichtschein* 100% **Managing Member*

Amsterdam SNF LLC d/b/a Wilkinson Rehabilitation and Nursing Center have indicated there will be an administrative services agreement with Advanced Health Inc. owned by David Heinemann. Advanced Health Inc. consults and assists the established operator with the following as noted in the administrative services agreement: Financial and back-office services, administrative services, and clinical consulting. There is no common ownership between the Advanced Health Inc. and the proposed operator of Wilkinson Rehabilitation and Nursing Center. It was disclosed in the application that Advanced Health Inc. also provides consulting and/or administrative services to the following facilities Lilac Manor Rehabilitation and Nursing Center, Beacon Rehabilitation and Nursing Center, Regal Heights Rehabilitation and Health Care Center, Schervier Nursing Care Center, San Simeon by the Sound Center for Nursing & Rehabilitation, Fairport Rehabilitation and Nursing Center, The Grand Rehabilitation and Nursing at Batavia, The Grand Rehabilitation and Nursing at Pawling, and Waterview Heights Rehabilitation and Nursing Center.

Amsterdam SNF LLC will lease the property from 4988 State HWY 30 LLC as the sole member of 4988 State HWY 30 RE HOLDCO LLC. The applicant filed an affidavit stating that there are no common members between Amsterdam SNF LLC as tenant and 4988 State HWY 30 LLC as the landlord.

Character and Competence

David Lichtschein holds concurrent employment as an operator of Highland Care Center Inc. a skilled nursing facility located in Jamaica, NY and as a self-employed consultant based in Lakewood, NJ. Prior employment includes a role as clergy at Surf Manor Home for Adults located in Brooklyn, NY. David Lichtschein holds an advanced degree in Talmudic Studies from Beth Medrash Govoha and discloses the following health facility ownership interests:

New York Nursing Homes

Highland Care Center (23%)	05/2017 to present
Achieve Rehab and Nursing Facility	Pending
Beacon Rehabilitation and Nursing Center	Pending

Quality Review

The proposed owner has been evaluated, in part, on the distribution of CMS Star ratings for their portfolio. For the proposed owner, the distribution of CMS star ratings for their facilities meets the standard described in state regulations.

CMS Star Rating Criteria					
		Duration of Ownership*			
		< 48 Months		48 months or more	
Owner	Total Nursing Homes	Number of Nursing Homes	Percent of Nursing Homes With a Below Average Rating	Number of Nursing Homes	Percent of Nursing Homes With a Below Average Rating
David Lichtschein	1	**0**	N/A	**1**	0%

**Duration of Ownership as of 06/24/2026* *Data date: 04/2026*

New York. The proposed owner's portfolio includes ownership in one New York facility. Highland Care Center has a CMS overall quality rating of above average.

Facility	*Ownership Since*	*Overall*	*Health Inspection*	*Quality Measure*	*Staffing*
New York					
Wilkinson Residential Health Care Facility	Subject Facility	**	**	***	****
Highland Care Center	Current	****	****	****	**
	05/2017	***	****	****	*

Data date:04/2026

Enforcement History

New York

Residential Health Care Facilities

A review of the operations of Highland Care Center under 10 NYCRR§ 600.2 requirements for approval reveals the following:

- The facility was assessed CMPs of $655.10 on 06/08/2020, $975.00 on 06/15/2020, $1,300.00 on 06/22/2020, $1,625.00 on 06/29/2020, $1,965.30 on 08/03/2020, and $2,292.70 on 08/10/2020 under F884 for failure to report National Health Safety Network data.
- The facility was fined $2,000.00 pursuant to Stipulation and Order NH-22-040 for surveillance findings on 12/12/2021. Deficiencies were found under 10 NYCRR §415.19(a) Infection Control. The facility failed to ensure infection prevention control practices were followed to help prevent the spread, development, and transmission of communicable diseases and infections. Specifically, the facility water management plan was not reviewed/revised within the last year, and the facility lacked a legionella sampling plan based on facility risk assessment. In addition, a resident's oxygen tubing was observed not being changed and labelled within the prescribed time period.
- The facility was fined $20,000.00 pursuant to Stipulation and Order NH-21-117 for surveillance findings on 12/15/2020. Deficiencies were found under 10 NYCRR §415.19(a) and (b) Infection Control. The facility failed to comply with all applicable Federal and State laws, rules, and regulations having general application when it failed to maintain and implement an infection control program in accordance with its own policy, guidance, and directives issued by the Federal and State regulators. Specifically, the facility failed to place residents in Units 3 and 4 on contact and droplet protection when personnel working those units tested positive for COVID-19. The facility also failed to appropriately isolate and separate residents with possible COVID-19 exposure from residents with negative COVID-19 status.

Conclusion

The individual background review indicates the applicants have met the standards set forth in Public Health Law §2801-a(3).

Financial Analysis

Operating Budget

The applicant has provided the Current Year (2024) results and the Years One and Three operating budgets, in 2026 dollars, after the change in ownership as summarized below:

	Current Year		**Year One**		**Year Three**	
Revenues (RHCF)	Per Diem	Total	Per Diem	Total	Per Diem	Total
Medicaid FFS	$193.48	$4,773,171	$209.52	$7,316,764	$210.00	$7,572,864
Medicaid MC	$	0	$209.52	408,564	$209.52	408,564
Medicare FFS	$669.81	2,742,202	$771.17	5,386,600	$789.35	5,692,800
Medicare MC	$	0	$660.00	1,306,800	$680.00	1,411,000
Commercial FFS	$381.22	1,659,839	$387.80	767,836	$389.62	809,636
Private	$372.08	1,668,801	$415.52	2,455,750	$426.31	2,601,750
Other Income*		3,278,068		1,200		1,200
Sub-Total		$14,122,081		$17,643,514		$18,497,814
Revenue (ADHC)						
Medicaid FFS	$121.25	556,681	$113.16	520,536	113.16	520,536
Private	$183.00	27,633	$183.00	27,450	183.00	27,450
Total Revenues		$14,706,395		$18,191,500		$19,045,800
Expenses (RHCF)						
Operating	$426.27	$16,029,111	$286.99	15,419,200	$283.10	$15,706,300
Capital	1.84	69,014	$29.98	1,611,000	$34.28	1,901,650
Sub-total	$428.11	$16,098,125	$316.97	17,030,200	$317.38	$17,607,950
Expenses (ADHC)						
Operating	$186.89	$886,219	$101.89	$484,000	$101.89	$484,000
Capital	$0.00	0	$0.00	$0.00	$0.00	0.00
	$186.89	$886,219	$101.89	$484,000.	$101.89	$484,000
Total Expenses		$16,984,344		$17,514,200		$18,091,950
Net Income (Loss)		($2,277,949)		$677,300		$953,850
RHCF Patient Day		37,603		53,727		55,480
RHCF Utilization %		64.38%		92.00%		95.00%
ADHC Visits		4,742		4,750		4,750

The following is noted concerning the submitted RHCF operating budget:

- The Current Year reflects the facility's 2024 revenues and expenses.
- Medicaid revenue is based on the reimbursement methodology of the 2025 Nursing Home Medicaid Rate.
- Medicare rates are based on the full Federal rates for the Medicare Prospective Payment System in effect for FY 2025 and are increased by approximately 2.50% per annum for inflation to reflect 2026 dollars. Private and other rates are based on similar facilities in the same geographical area increased by 2.50% per annum for inflation to reflect 2026 dollars.
- Staffing is based on historical operations, analysis of similar facilities, and the proposed operator's experience. Staffing will increase by 29.55 FTEs for infection control, environment and food service.
- Expenses are based on relining 2024 operating expenses between categories, taking inflation into consideration and adjusting for current operator's expense allocation. Overall increase in expenses of $529,856 is due to a $1,541,986 increase in capital expenses, primarily rent increasing from $69,014 to $1,610,001 per year offset by a $1,012,130 decrease in other direct expenses (primarily professional fees and purchase services).
    - The projected percentage of direct care staffing costs to projected facility revenues is 48.17% in Year One and 45.92% in Year Three, exceeding the 40% requirement in Public Health Law §2828.
    - The percentage of direct resident care costs to projected facility revenue is 76.75% in Year One and 73.61% in Year Three, exceeding the 70% requirement in Public Health Law §2828.
    - The facility's projected profit percentage is forecasted to be 3.95% in Year One and 5.30% in Year Three, passing the 5% maximum outlined in Public Health Law §2828 in Year One and slightly failing in Year Three.
    - The staffing ratio is 3.87 hours in Year One and 3.75 hours in Year Three, exceeding the required 3.5 hours care per resident/day under 10 NYCRR §415.13.
- The facility's projected utilization for Year One is 92% and Year Three is 95%. It is noted that utilization for (2022-2024) averaged 64.51%. As of March 10, 2026, occupancy was 70.63% while 71.88% of the available beds were staffed.
    - The applicant plans to improve occupancy by developing new programs based on information obtained from community leaders, area hospitals, and local physicians.

Utilization by payor for Years One and Three after the change in ownership is summarized below:

	Current Year		**Year One**		**Year Three**	
Payor (RHCF)	Patient Days	%	Patient Days	%	Patient Days	%
Medicaid FFS	24,670	65.61%	34,922	65.00%	36,062	65.00%
Medicaid MC	0	0.00%	1,950	3.62%	1,950	3.51%
Medicare FFS	4,094	10.89%	6,985	13.00%	7,212	13.00%
Medicare MC	0	0.00%	1,980	3.69%	2,075	3.74%
Commercial FFS	4,354	11.58%	1,980	3.69%	2,078	3.75%
Private Pay	4,485	11.92%	5,910	11.00%	6,103	11.00%
Total RHCF	37,603	100%	53,727	100%	55,480	100%
Payor (ADHC)						
Medicaid FFS	4,591	96.82%	4,600	96.84%	4,600	96.84%
Private Pay	151	3.18%	150	3.16%	150	3.16%
Total ADHC	4,742	100%	4,750	100%	4,750	100%

Asset Purchase Agreement (APA)

The applicant submitted an executed APA to acquire the operations associated with the RHCF and ADHC, which will become effective upon PHHPC approval. The terms are summarized below:

Date:	October 16, 2025, (Effective Date)
Seller:	St. Mary's Healthcare
Buyer:	Amsterdam SNF, LLC
Asset Acquired:	Rights, title, and interest as of the closing date. Increase balance from the effective date and beyond, cash, and accounts receivable. From the effective date: tangible personal property, transferable Healthcare Reimbursement Payor agreements, books and records, patient agreements, websites, domain names, email addresses, warranties, intellectual property, goodwill, and claims.
Excluded Assets:	Before 10/16/25, Cash, accounts receivable, prepaids, deposits, retroactive adjustments, claims, corporate records, proprietary materials, and transaction documents.
Assumption of Liabilities:	Liabilities expressly assume. And other liabilities arising on or after the effective date.
Excluded Liabilities:	Any liability before the closing date
Purchase Price	Assumption of Certain Liabilities on or after the effective date offset by Accounts Receivables (per applicant as of 12/31/25 Accounts Receivable were $1,930,498 and assumed current liabilities were $1,488,776. If balance continues it will result in positive cash flow of $441,722 to the applicant's operations
Payment of the Purchase Price	Determined 30 days prior to closing

The applicant has submitted an original affidavit, which is acceptable to the Department, in which the applicant agrees, notwithstanding any agreement, arrangement, or understanding between the applicant and the transferor to the contrary, to be liable and responsible for any Medicaid overpayments made to the facility and surcharges, assessments or fees due from the transferor under Article 28 of the Public Health Law concerning the period before the applicant acquiring its interest, without releasing the transferor of its liability and responsibility. As of April 24, 2026, the facility had no outstanding Medicaid liabilities.

Purchase and Sale Agreement – Real Property

The applicant has submitted an executed Purchase and Sale Agreement for the sale and acquisition of the real property. The terms are summarized below:

Date:	October 16, 2025.
Seller:	St. Mary's Healthcare
Purchaser:	4988 State Hwy 30, LLC
Asset Transferred:	Real Property located at 4988 State Highway 30, Amsterdam, NY 12010
Subdivision Section 2(b):	The Parties acknowledge and agree that the conveyance and sale of the Seller's fee simple interest in the Premises pursuant to this Agreement is conditioned upon the completion of the subdivision of the Hospital Campus (the "Subdivision") into two separate lots consisting of the Premises and the remaining portion of the Hospital Campus being retained by the Seller.
Ground Lease Contingency Section 2 c:	In the event the applicable governmental authorities do not issue the necessary variances and other approvals required to effectuate the Subdivision as contemplated in Section 2(b) prior to the date APA Purchaser receives noncontingent approval from the DOH to operate the Facility, the Parties agree that, in lieu of the conveyance and sale of the fee simple interests in the Premises, Seller shall sell to Purchaser, and Purchaser shall purchase from Seller, a leasehold interest in the Premises with a purchase option pursuant to a 99-year ground lease and purchase option.
Purchase Price:	$13,600,000
Payment:	$ 700,000 deposit (three business after Execution date) 12,900,000 at closing $13,600,000

The purchase price of the real property is proposed to be satisfied as follows:

Equity – 4988 State Hwy 30, LLC member(s)	$500,000
Popular Bank Loan: 5-years. Interest at 3.0% above the SOFR rate (approximately 3.67%) or 6.67%. Repayment: 18 months interest only, then interest and principal amortized over 25 years.	13,100,000
Total	$13,600,000

Popular Bank has provided a term sheet. The members of 4988 State Hwy 30, LLC have sufficient resources to fund the $500,000 equity payment as shown on BFA Attachment A-2. The applicant has provided an affidavit stating his willingness to fund the balloon payment with equity should terms acceptable to the Department of Health be unavailable when refinancing.

Service Agreement

Amsterdam SNF, LLC entered an executed Service Agreement with Advanced Health, Inc.; terms are summarized below:

Date:	November 12, 2025
Facility Operator:	Amsterdam SNF, LLC
Service Provider:	Advanced Health, Inc.
Term:	One year and automatically renews for one (1) year term.
Services:	Provide or assist with financial and back-office services, administrative services, and clinical consulting.
Compensation:	$720,000 per year ($60,000 per month)

The applicant attested that the service agreement is arm's length agreement. Amsterdam SNF, LLC has submitted an executed attestation stating that the applicant understands and acknowledges that there are powers that must not be delegated, the applicant will not willfully engage in any illegal delegation and understands that the Department will hold the applicant accountable.

Lease Agreement

The applicant submitted an executed lease agreement, the terms of which are summarized below:

Dated:	November 12, 2025
Premises:	A 160-bed RHCF is located at 4988 State Highway 30, Amsterdam, NY, 12010.
Landlord:	4988 State Hwy 30, LLC
Lessee:	Amsterdam SNF, LLC
Term:	Ten years
Rent:	$1,360,000 (yr 1); $1,496,000 (yr 2); $1,645,600 (yr 3); $1,810,160 (yr 4) (Which equals 10% per year). Fifth year base rent reset to greater 3% increase or the fair market value set by Landlord. Sixth year 3% increase. Seventh year 3% increase or market value set by Landlord. Eighth year 3% increase. Ninth year 3% increase or market value set by Landlord. Tenth year 3% increase.
Provisions:	Triple Net

The applicant attested that the lease arrangement is an arm's length agreement. The applicant has provided two letters from NYS licensed realtors attesting to the reasonableness of the rental rate.

The applicant's justification for the 10% annual rent increase in the second through fourth years is that rent starts off at less than fair market value (FMV). The 10% rent increases are expected to bring the rent up to FMV.

As part of the negotiating process between the buyer and seller, it was acknowledged that the new operator would need to make physical plant improvements. According to the current operator some of the improvements will include:

- Updates to resident rooms, new lighting, furniture and flooring (in some current rooms, furniture is non-matching).
- Improvements to the rehab center.
- Improvements to the food service program.

Until the proposed applicant becomes the operator of the existing RHCF, a scope of work has not been defined relating to the necessary capital improvements.

Capability and Feasibility

There are no project costs associated with this application. The purchase price for the operations is the assumption of certain liabilities and account receivables. As of December 31, 2025, assumed account receivables exceed assume liabilities. The purchase price for the realty is $13,600,000 to be funded by 4988 State Hwy 30, LLC with $500,000 member equity and a $13,100,000 loan for five years. The interest rate is 3.0% above SOFR rate (which is approximately 3.67%), for a total rate of 6.67%. Repayment terms, interest only for the first 18 months and then interest and principal amortized over 25 years. Popular Bank has provided a letter of interest at the stated terms.

The working capital requirement is estimated at $2,919,033 based on two months of Year One expenses, funded with member's equity. BFA Attachment A-1, Net Worth Statement Amsterdam SNF, LLC reveals sufficient equity to meet the funding requirements of this project.

The budget projects a net income of $677,300 in Year One and $953,850 by Year Three. Total revenues in Year One are expected to increase by $3,485,105 as projected utilization climbs from 64.38% to 92%. Overall expenses are projected to increase by $529,856 in Year One, primarily from a $1,541,986 increase in capital expenses (all rent except $999 in interest expense) and $1,012,130 reduction in other direct expenses. The reduction in other direct expenses is composed of $2,005,308 increase in wage and benefits, $1,220,574 increase in supplies, utilities and other direct expenses, offset by $1,150,039 reduction in professional fees and $3,087,973 reduction in purchase services.

Department staff note as of March 10, 2026, utilization was approximately 70.63%, which is less than the Year One projection by 21.37%. BFA Attachment F, Budget Sensitivity Analysis, incorporated a 70.63% occupancy rate while using the applicants projected payer mix, rates and applying their reduced per diem operating cost of $286.99 to their Year One budget (note Capital and ADHC cost were not adjusted for the reduced utilization rate). Based upon this scenario, net profits would decline by $514,534, going from $677,300 to $162,766.

BFA Attachment B, Pro Forma Balance Sheet for Amsterdam SNF, LLC, shows the entity will start with $3,040,000 in members' equity.

BFA Attachment C, 2023-2025 St. Mary's Healthcare (Balance Sheet) and Wilkinson Residential Health Care Facility's (Revenue and Expenses for the RHCF and ADHC departments), shows positive working capital and positive net assets, while Wilkinson Residential Health Care Facility (RHCF and ADHC departments) generate operating losses between $2.3M and $4M.

BFA Attachment D, Proposed Members' Ownership Interest in the Affiliated RHCFs and Financial Summary, shows average positive working capital, positive net assets, and an average net income of $150,564. In 2024, the facility incurred a $4,016,859 loss as the result of $8 million accrual for a proposed residual equity retroactive takeback. The 2025 Internal Financial Statement showed a positive net income of $4,282,361.

Conclusion

The applicant has demonstrated the capability to proceed in a financially feasible manner.

Attachments

LTCOP Attachment A	Long Term Care Ombudsman Program Review
BHFP Attachment	Map
BFA Attachment A-1	Net Worth Statement Amsterdam SNF, LLC
BFA Attachment A-2	Net Worth Statement 4988 State Hwy 30, LLC
BFA Attachment B	Pro Forma Balance Sheet, Amsterdam SNF, LLC
BFA Attachment C	2023-2025 St. Mary's Healthcare (Balance Sheet) and Wilkinson Residential Health Care Facility's (Revenue and Expenses for the RHCF and ADHC departments)
BFA Attachment D	Proposed Members' Ownership Interest in the Affiliated RHCFs and Financial Summary
BFA Attachment E	4988 State Hwy 30, LLC Organizational Chart
BFA Attachment F	Budget Sensitivity Analysis

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 24th day of June 2026, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish Amsterdam SNF LLC as the new operator of Wilkinson Residential and Nursing Center, a 160 Bed Residential Health Care Facility, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:	FACILITY/APPLICANT:
252210 E	Amsterdam SNF LLC d/b/a Wilkinson Rehabilitation and Nursing Center

APPROVAL CONTINGENT UPON:

1. Submission of executed real property loan commitment acceptable to the Department of Health. [BFA]
2. Submission of a commitment signed by the applicant which indicates that, within two years from the date of the council approval, the percentage of all admissions who are Medicaid and Medicare/Medicaid eligible at the time of admission will be at least 75 percent of the planning area average of all Medicaid and Medicare/Medicaid admissions, subject to possible adjustment based on factors such as the number of Medicaid patient days, the facility's case mix, the length of time before private paying patients became Medicaid eligible, and the financial impact on the facility due to an increase in Medicaid admissions. [RNR].

APPROVAL CONDITIONAL UPON:

1. This project must be completed by one year from the date of the approval letter, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a complete response to each individual contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in the Contingencies Tab in NYSE-CON.

NEW YORK STATE OF OPPORTUNITY. Department of Health

Public Health and Health Planning Council

Project # 222245-E
Family Respite Homecare Agency, Inc.

Program: **LHCSA** ***County:*** **Kings**
Purpose: **Establishment** ***Acknowledged:*** **December 23, 2022**

Executive Summary

Description
Family Respite Homecare Agency, Inc., a Licensed Home Care Services Agency (LHCSA) located at 818 57th Street, Unit 2a, Brooklyn, New York, 11220, requests approval for the transfer of 90.1% ownership interest from one withdrawing shareholder to the remaining shareholder.

There are no proposed changes to the counties served or services provided.

OALTC Recommendation
Approval

Need Summary
In accordance with 10 NYCRR §765-1.16(c)(2), this application is exempt from Public Need review as the agency is actively serving over 25 patients, as attested to by the current operator.

Program Summary
The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §3605.

Financial Summary
The total purchase price for the acquisition of the LHCSA is $280,000. The applicant reports that they intend to fund the projected operating costs during the first two months after being licensed by utilizing existing financial resources from ongoing operations and current assets held by Family Respite Homecare Agency, Inc., as well as personal financing from Justin Zhu.

In accordance with 10 NYCRR §765-1.2(b)(3) the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating the financial feasibility of the agency.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Aging and Long-Term Care

Approval conditional upon:

1. This project must be completed by one year from the date of the approval letter, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Council Action Date

June 24, 2026

Program Analysis

Program Description

Family Respite Homecare Agency, Inc. requests approval for the transfer of 90.1% ownership interest from one withdrawing shareholder to the remaining shareholder.

There are no proposed changes to the counties served or services provided.

The current membership of Family Respite Homecare Agency, Inc. is as follows:

- Karen Rabinovich (90.1%)
- Justin Zhu (9.9%)

The proposed membership of Family Respite Homecare Agency, Inc. will be as follows:

- Justin Zhu (100%)

The applicant will continue to serve the residents of the following counties:

- Bronx
- Kings
- Nassau
- New York
- Queens
- Richmond

The applicant will continue to provide the following healthcare services:

- Audiology
- Home Health Aide
- Homemaker
- Housekeeper
- Medical Social Services
- Medical Supplies, Equipment and Appliances
- Nursing
- Nutritional
- Personal Care
- Therapy – Occupational
- Therapy – Physical
- Therapy – Respiratory
- Therapy – Speech Language Pathology

Character and Competence Review

Family Respite Homecare Agency, Inc. will be comprised of the following individual:

Justin Zhu (100%)

Employment:

- Billing Manager, Family Respite Homecare Agency, Inc., (July 2020 – Present)

Affiliations:

- Family Respite Homecare Agency, Inc. (LHCSA), (February 2018 – Present)

A search of the individuals and entities named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

Facility Compliance/Enforcement

The information provided by the Center of Home and Community Based Services has indicated that the applicant has provided sufficient supervision to prevent harm, maintain the health, safety, and welfare of residents, and to prevent recurrent code violations.

Need Review

In accordance with 10 NYCRR §765-1.16(c)(2), this application is exempt from Public Need review as the agency is actively serving over 25 patients, as attested to by the current operator.

Financial Review

The total purchase price for the acquisition of the LHCSA is $280,000. The applicant reports that they intend to fund the projected operating costs during the first two months after being licensed by utilizing existing financial resources from ongoing operations and current assets held by Family Respite Homecare Agency, Inc., as well as personal financing from Justin Zhu.

In accordance with 10 NYCRR §765-1.2(b)(3) the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating the financial feasibility of the agency.

Workforce Review

The applicant's response regarding the recruitment and retention of the workforce was adequately addressed in their project narrative. Please refer to Attachment A for the agency's Workforce Summary.

Conclusion

A review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a Licensed Home Care Services Agency.

The individual background review indicates the proposed members have met the standard for approval as set forth in New York State Public Health Law §3605

Attachments

OALTC Attachment A	Workforce Summary

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 3605 of the Public Health Law, on this 24th day of June, 2026 having considered any advice offered by the staff of the New York State Department of Health and the Establishment and Project Review Committee of the Council, and after due deliberation, hereby approves the following application for licensure, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:	FACILITY:
222245 E	Family Respite Homecare Agency, Inc.

APPROVAL CONTINGENT UPON:

N/A

APPROVAL CONDITIONAL UPON:

1. This project must be completed by one year from the date of the approval letter, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a **complete** response to each **individual** contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in th*e Contingencies Tab in NYSE-CON.*

Department of Health | Public Health and Health Planning Council

Project # 231025-E
Family Home Care Agency Inc.

Program: **LHCSA**
Purpose: **Establishment**
County: **Queens**
Acknowledged: **March 2, 2023**

Executive Summary

Description
Establish Family Home Care Agency Inc. as the new operator of a Licensed Home Care Services Agency (LHCSA), currently operated by One Stop Home Care Agency, at 108-10 72nd Avenue, Forest Hills, New York11375.

There are no proposed changes to the counties served or services provided.

OALTC Recommendation
Approval

Need Summary
In accordance with 10 NYCRR §765-1.16(c)2, this application is exempt from Public Need review as the agency is actively serving over 25 patients, as attested to by the current operator

Program Summary
The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §3605.

Financial Summary
The total purchase price for the acquisition of the LHCSA is $150,000. The applicant intends to fund the projected operating costs during the first two months after being licensed by utilizing existing financial resources from ongoing operations and current assets held by Family Home Care Agency, Inc. and by assets held by Min Kyung An.

In accordance with 10 NYCRR §765-1.2(b)3 the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating the financial feasibility of the agency.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Aging and Long-Term Care

Approval conditional upon:

1. This project must be completed by one year from the date of the approval letter, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Council Action Date

June 24, 2026

Program Analysis

Program Description

Family Home Care Agency, Inc. is requesting approval to become the established operator of One Stop Home Care Agency. The agency will continue to be located at 108-10 72nd Avenue, 2nd Floor, Forest Hills, NY 11375

The current membership of One Stop Home Care Agency, LLC. is as follows:

- Elionora Zavlanova 51%
- Eduard Zavlanov 49%

The proposed membership of Family Home Care Agency, Inc. will be as follows:

- Min Kyung An 100%

The applicant will continue to serve the residents of the following counties:

- Bronx
- New York
- Queens
- Richmond
- Kings

The applicant will continue to provide the following healthcare services:

- Nursing
- Home Health Aide
- Homemaker
- Housekeeper
- Medical Social Services
- Nutritional
- Personal Care
- Therapy – Occupational
- Therapy – Physical
- Therapy – Speech Language Pathology

Character and Competence Review

Family Home Care Agency, Inc. will be comprised of the following individual:

Min Kyung An (100%)

Employment:

- President, One Stop Academy, Inc., (September 2021 – Present)
- Administrator, One Stop Home Care Agency, LLC, (January 2021 – Present)
- President, Homeassist Direct, Inc., (June 2019 – Present)

Affiliations:
No offices held or ownership interests in other health facilities.

A search of the individuals and entities named above revealed no matches on either the Medicaid Disqualified Provider List or the OIG Exclusion List.

Facility Compliance/Enforcement

Not applicable, as there are no affiliated licensed healthcare agencies

Need Review

In accordance with 10 NYCRR §765-1.16(c)2, this application is exempt from Public Need review as the agency is actively serving over 25 patients, as attested to by the current operator.

Financial Review

The total purchase price for the acquisition of the LHCSA is $150,000. The applicant intends to fund the projected operating costs during the first two months after being licensed by utilizing existing financial resources from ongoing operations and current assets held by Family Home Care Agency, Inc. and by assets held by Min Kyung An.

In accordance with 10 NYCRR §765-1.2(b)3 the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating the financial feasibility of the agency.

Workforce Review

The applicant's response regarding the recruitment and retention of the workforce was adequately addressed in their project narrative. Please refer to Attachment A for the agency's Workforce Summary.

Conclusion

A review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a Licensed Home Care Services Agency.

The individual background review indicates the proposed members have met the standard for approval as set forth in New York State Public Health Law §3605.

Attachments

OALTC Attachment A	Workforce Summary

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 3605 of the Public Health Law, on this 24th day of June, 2026 having considered any advice offered by the staff of the New York State Department of Health and the Establishment and Project Review Committee of the Council, and after due deliberation, hereby approves the following application for licensure, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:	FACILITY:
231025 E	Family Home Care Agency Inc.

APPROVAL CONTINGENT UPON:

N/A

APPROVAL CONDITIONAL UPON:

1. This project must be completed by one year from the date of the approval letter, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a **complete** response to each **individual** contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in th*e Contingencies Tab in NYSE-CON.*

NEW YORK STATE OF OPPORTUNITY. Department of Health

Public Health and Health Planning Council

Project # 242060-E
High Standard Home Care Inc.

Program: **LHCSA**
Purpose: **Establishment**
County: **Kings**
Acknowledged: **August 20, 2024**

Executive Summary

Description
High Standard Home Care Inc., an existing Licensed Home Care Services Agency (LHCSA) located at 103 Quentin Road, Unit G1-2, Brooklyn, requests approval to transfer 100% ownership interests from two withdrawing shareholders to a new member LLC, Superior Care 91, LLC.

There are no proposed changes to the counties served or services provided.

OALTC Recommendation
Approval

Need Summary
In accordance with 10 NYCRR §765-1.16(c)(2), this application is exempt from Public Need review as the agency is actively serving over 25 patients, as attested to by the current operator.

Program Summary
The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §3605.

Financial Summary
The total purchase price for the acquisition of the LHCSA is $5.7 million. The applicant reports that they intend to fund the projected operating costs during the first two months after being licensed by utilizing existing financial resources from ongoing operations from both High standard Home Care, Inc. and Superior Care 91, LLC.

In accordance with 10 NYCRR §765-1.2(b)(3), the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating the agency's financial feasibility.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Aging and Long-Term Care

Approval conditional upon:

1. This project must be completed by one year from the date of the approval letter, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Council Action Date

June 24, 2026

Program Analysis

Program Description

High Standard Home Care, Inc. is requesting to transfer 100% shareholder interest from two withdrawing shareholders to Superior Care 91, LLC, which consists of two members.

There are no proposed changes to the counties served or services provided.

The current membership of High Standard Home Care, Inc. is as follows:

- Marina Adelman (50%)
- Ludmila Varobey (50%)

The proposed membership of High Standard Home Care, Inc. will be as follows:

- Superior Care 91, LLC (100%)

The members of Superior Care 91, LLC are as follows:

- Chana Bernath (50%)
- Meyer Wertheimer (50%)

The applicant will continue to serve the residents of the following counties:

- Bronx
- Kings
- Nassau
- New York
- Queens
- Richmond

The applicant will continue to provide the following healthcare services:

- Nursing
- Home Health Aide
- Nutritional
- Personal Care
- Therapy – Occupational
- Therapy – Physical Therapy
- Therapy – Speech Language Pathology

Character and Competence Review

The sole shareholder of High Standard Home Care, Inc., Superior Care 91, LLC, will be comprised of the following individuals:

Chana Bernath (50%), President

Employment

Currently unemployed and no employment listed for the last 7 years.

Affiliations

No offices held or ownership interests in other health facilities.

Experience
As per 10 NYCRR §765-1.3(b)(3), regarding experience, the applicant affirms the following:

Chana possesses a fundamental understanding of LHCSA operations, encompassing both regulatory compliance and strategic planning. Her expertise extends to financial cost reporting and revenue structure analysis, enhancing her ability to drive operational excellence in healthcare environments. With over seven years of invaluable experience, Chana has been instrumental in the growth trajectory of a vital healthcare startup organization. Her journey spans various facets of healthcare operations, from financial management to compliance oversight. With a keen eye for detail and an analytical mindset, Chana has navigated complex regulatory landscapes, ensuring adherence to stringent standards. Her meticulous approach, coupled with a comprehensive understanding of programs and systems, has consistently driven operational efficiency and excellence within healthcare environments. Furthermore, Chana's profound grasp of healthcare intricacies, coupled with her extensive experience as a CFO and comptroller in finance in Hamaspik of Rockland, positions her as a formidable asset in the proposed facility's operations. Her ability to synthesize vast amounts of information and distill actionable insights empowers strategic decision-making, fostering sustainable growth and innovation.

Meyer Wertheimer (50%), Vice President & Secretary

Employment
- Executive Director, NYSHA (NYS Hamaspik Association) Brooklyn/Monroe NY, Inc. (2017–Present)

Affiliations
- NYSHA (New York State Hamaspik Association), (Not-For Profit) (2017 – Present)
- Tri-County Care, (Care Coordination Organization) (July 2018 – Present)
- Hamaspik of Rockland, (Office for People with Developmental Disabilities), (November 1998 – August 2023)
- Hamaspik of Kings, (Office for People with Developmental Disabilities), (April 1997 – August 2023)
- Hamaspik of Orange, (Office for People with Developmental Disabilities), (January 1997 – August 2023)
- Hamaspik HomeCare, (LHCSA) (2001 – August 2023)
- Hamaspik Choice, (Managed Long Term Care Program), (November 2013 – August 2023)
- Hamaspik School, (Special Needs Education School) (July 2022 – August 2023)
- Hamaspik Medicare Select, (Dual Eligible Special Needs Plans) (February 2019 – August 2023)

Facility Compliance/Enforcement
The information provided by the Center of Home and Community-Based Services indicates that the applicant has provided sufficient supervision to prevent harm, maintain the health, safety, and welfare of residents, and prevent recurrent code violations.

A review of Hamaspik Choice indicates that the organization is in good standing.

Need Review
In accordance with 10 NYCRR §765-1.16(c)(2), this application is exempt from Public Need review as the agency is actively serving over 25 patients, as attested to by the current operator

Financial Review
The total purchase price for the acquisition of the LHCSA is $5.7 million. The applicant intends to fund the projected operating costs during the first two months after being licensed by utilizing existing financial resources from ongoing operations from both High standard Home Care, Inc. and Superior Care 91, LLC.

In accordance with 10 NYCRR §765-1.2(b)(3), the applicant has submitted financial documents prepared by a Certified Public Accountant (CPA) demonstrating the agency's financial feasibility.

Workforce Review

The applicant's response regarding the recruitment and retention of the workforce was adequately addressed in their project narrative. Please refer to Attachment A for the agency's Workforce Summary.

Conclusion

A review of the Personal Qualifying Information indicates that the applicant has the required character and competence to operate a Licensed Home Health Agency.

The individual background review indicates the proposed members have met the standard for approval as set forth in New York State Public Health Law §3605.

Attachments

OALTC Attachment A	Workforce Summary

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 3605 of the Public Health Law, on this 24th day of June, 2026 having considered any advice offered by the staff of the New York State Department of Health and the Establishment and Project Review Committee of the Council, and after due deliberation, hereby approves the following application for licensure, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:	FACILITY:
242060 E	High Standard Home Care Inc.

APPROVAL CONTINGENT UPON:

N/A

APPROVAL CONDITIONAL UPON:

1. This project must be completed by one year from the date of the approval letter, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a **complete** response to each **individual** contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in th*e Contingencies Tab in NYSE-CON.*

NEW YORK STATE | Department of Health

MEMORANDUM

To: Colleen Leonard, Executive Secretary
Public Health and Health Planning Council

From: Sarah Gold, Senior Attorney
Bureau of Program Counsel

Date: June 3, 2026

Subject: Approval of the Certificate of Assumed Name of Cayuga Ridge, LLC

This is to request that the above matter be included on the agendas for the next Establishment and Project Review Committee and Public Health and Health Planning Council (PHHPC) meetings.

The attachments relating to this matter include the following:

1) Memorandum to the Public Health and Health Planning Council from Darren Cohen, Deputy Commissioner General Counsel;
2) A Written Consent of the Members and Manager of Cayuga Ridge, LLC authorizing the submission of the Certificate of Assumed Name dated November 21, 2024.
3) A letter from counsel to Cayuga Ridge seeking approval of the proposed Certificate of Assumed Name dated September 19, 2024.
4) A photocopy of the proposed Certificate of Assumed Name.
5) A certified copy of the Articles of Organization.
6) A photocopy of the letter from the Department of Health consenting to the modification of their application to change the applicant's name from LNH, LLC to Cayuga Ridge, LLC dated October 28, 2009.
7) A photocopy of the Certificate of Amendment of Certificate of Assumed Name changing the entity's assumed name from "Cayuga Ridge Extended Care" to "Cayuga Nursing and Rehabilitation Center" which was approved by the Public Health and Health Planning Council in connection with their re-establishment application in 2016.
8) A photocopy of the Operating Certificate for Cayuga Ridge, LLC.

NEW YORK STATE | Department of Health

MEMORANDUM

To: Public Health and Health Planning Council

From: Darren Cohen DC
Deputy Commissioner & General Counsel
Division of Legal Affairs

Date: June 3, 2026

Subject: Approval of the Certificate of Assumed Name of Cayuga Ridge, LLC

Cayuga Ridge, LLC requests Public Health and Health Planning Council ("PHHPC") approval of its Certificate of Assumed Name in order to use the name “Ithaca Nursing and Rehabilitation” for its residential health care facility.

Cayuga Ridge, LLC was formed as limited liability company on October 25, 2009 to provide skilled nursing services in Tompkins County. It is licensed to operate a residential health care facility at 1229 Trumansburg Road, Ithaca. The applicant's original name was LNH, LLC and their establishment application was modified, pursuant to 10 NYCRR 600.3(b), to change the applicant's name to Cayuga Ridge, LLC. In 2016, the applicant included a Certificate of Amendment of Certificate of Assumed Name in their application for re-establishment which changed their assumed name from Cayuga Ridge Extended Care to Cayuga Nursing and Rehabilitation Center.

Cayuga Ridge, LLC now seeks PHHPC approval pursuant to 10 NYCRR 600.11(a)(4) to file a Certificate of Assumed Name to use the name "Ithaca Nursing and Rehabilitation." The applicant indicated that it is seeking to use this name to reflect their services and location more directly. The proposed Certificate of Assumed Name was authorized by Written Consent of the Members and Manager of Cayuga Ridge, LLC dated November 21, 2024.

There is no legal objection to the proposed Certificate of Assumed Name, and it is in legally acceptable form.

Attachments.

WRITTEN CONSENT OF THE MEMBERS AND MANAGER
OF CAYUGA RIDGE, LLC
DATED AS OF NOVEMBER 21, 2024

The undersigned, being all of the members (the "***Members***") and the duly appointed manager (the "***Manager***") of CAYUGA RIDGE, LLC, a New York limited liability company (the "***Company***"), acting by written consent in lieu of a meeting, do hereby approve and adopt the following resolutions:

WHEREAS, the Company currently operates a skilled nursing facility located in Tompkins County, New York as Cayuga Nursing and Rehabilitation Center on land located at 1229 Trumansburg Road, Ithaca, New York 14850 (the "***Facility***");

WHEREAS, the Members and Manager desire that the Company operate the Facility as "Ithaca Nursing & Rehabilitation".

NOW, THEREFORE BE IT RESOLVED by the Manager and the Members of the Company, acting on behalf of the Company that:

1. Subject to the approval of the New York State Department of Health, the proposed Certificate of Assumed Name is hereby adopted and the Company is hereby authorized and directed to operate the Facility as "Ithaca Nursing & Rehabilitation".

2. Shalom Braunstein (a/k/a Shully Braunstein) (the "***Authorized Signatory***") acting individually, is hereby authorized to do such acts and to execute and deliver any and all agreements, documents, instruments, undertakings and certificates, on behalf of the Company as may be useful or appropriate to carry out the intent and purpose of these resolutions.

3. This written consent, may be (a) executed in one or more counterparts, each of which shall be deemed to be an original, and all of which, when taken together, shall be deemed to constitute one and the same document and (b) executed and delivered by facsimile (or other electronic means) and upon such delivery the facsimile (or other electronic means) signature will be deemed to have the same effect as if the original signature had been delivered.

4. These resolutions shall take effect immediately.

{NO FURTHER TEXT ON THIS PAGE}

IN WITNESS WHEREOF, this Written Consent of the Members and Manager of the Company has been executed as of the date first written above.

MEMBERS:

Barry Braunstein, an individual

Shalom Braunstein

Shalom Braunstein, an individual

Esther M. Manela, an individual

Brenda Bertram, an individual

MANAGER:

Barry Braunstein, an individual

GARFUNKEL WILD, P.C.
ATTORNEYS AT LAW

111 GREAT NECK ROAD • GREAT NECK, NEW YORK 11021
TEL (516) 393-2200 • FAX (516) 466-5964
www.garfunkelwild.com

FILE NO.: 90641.1002

September 19, 2024

By FedEx & EMAIL

Vincent DiCocco, Senior Attorney
Bureau of Program Counsel
New York State Department of Health - Division of Legal Affairs
Room 2480, Corning Tower
Empire State Plaza
Albany, NY 12237
Vincent.DiCocco@health.ny.gov

Re: Proposed Assumed Name for Cayuga Ridge, LLC (dba Ithaca Nursing and Rehabilitation (the "Cayuga")

Dear Mr. DiCocco:

I enclose a copy of the proposed Certificate of Assumed name for the Cayuga to operate as Ithaca Nursing & Rehabilitation. Cayuga currently holds an operating certificate in the name referenced above and wishes to use the dba. For your reference, attached are the current copies of the charter documents and a copy of the current operating certificate. We request your approval to proceed with this assumed name. Also enclosed is a self-addressed stamped envelope. Please stamp a copy of the letter received (or just sign it) and return in the envelope. An additional envelope is provide for the consent transmittal, if approved.

Please contact me at (516) 393-2578 or via e-mail at mstringfellow@garfunkelwild.com, if there is any additional information that you require, or if you have any further questions.

Regards,

Michael Stringfellow
Paralegal

Enclosure
cc: Andrew Schulson, Esq.
Michelle G. Scanlon, Esq.

NEW YORK STATE OF OPPORTUNITY.

Division of Corporations, State Records and Uniform Commercial Code

New York State
Department of State
Division of Corporations, State Records and Uniform Commercial Code
One Commerce Plaza
99 Washington Avenue
Albany, NY 12231
www.dos.ny.gov

Certificate of Assumed Name

(Pursuant to General Business Law §130)

1. REAL NAME OF ENTITY:

Caygua Ridge, LLC

1a. FICTITIOUS NAME, IF ANY, OF FOREIGN ENTITY (Not Assumed Name):

2. THE ENTITY WAS FORMED OR AUTHORIZED UNDER THE FOLLOWING NEW YORK LAW (Check one):

☐ Business Corporation Law ☒ Limited Liability Company Law ☐ Religious Corporations Law
☐ Education Law ☐ Not-for-Profit Corporation Law ☐ Revised Limited Partnership Act

☐ Other (specify law):

3. ASSUMED NAME OF ENTITY:

Ithaca Nursing and Rehabilitation

4. PRINCIPAL PLACE OF BUSINESS IN NEW YORK STATE (MUST INCLUDE NUMBER AND STREET). IF NONE, CHECK THIS BOX ☐ AND PROVIDE OUT-OF- STATE ADDRESS:

1229 Trumansburg Road, Ithaca, New York 14850

5. COUNTY(IES) IN WHICH ENTITY DOES OR INTENDS TO DO BUSINESS:

☐ ALL COUNTIES (or check applicable county(ies) below)

☐ Albany	☐ Cattaraugus	☐ Chenango	☐ Delaware	☐ Franklin	☐ Hamilton	☐ Lewis	☐ Montgomery
☐ Allegany	☐ Cayuga	☐ Clinton	☐ Dutchess	☐ Fulton	☐ Herkimer	☐ Livingston	☐ Nassau
☐ Bronx	☐ Chautauqua	☐ Columbia	☐ Erie	☐ Genesee	☐ Jefferson	☐ Madison	☐ New York
☐ Broome	☐ Chemung	☐ Cortland	☐ Essex	☐ Greene	☐ Kings	☐ Monroe	☐ Niagara
☐ Oneida	☐ Orleans	☐ Queens	☐ St. Lawrence	☐ Schuyler	☐ Sullivan	☐ Warren	☐ Wyoming
☐ Onondaga	☐ Oswego	☐ Rensselaer	☐ Saratoga	☐ Seneca	☐ Tioga	☐ Washington	☐ Yates
☐ Ontario	☐ Otsego	☐ Richmond	☐ Schenectady	☐ Steuben	☒ Tompkins	☐ Wayne	
☐ Orange	☐ Putnam	☐ Rockland	☐ Schoharie	☐ Suffolk	☐ Ulster	☐ Westchester	

6. ADDRESS OF EACH LOCATION, INCLUDING NUMBER AND STREET, IF ANY, OF EACH PLACE WHERE THE ENTITY CARRIES ON, CONDUCTS OR TRANSACTS BUSINESS IN NEW YORK STATE. (Use page 2 if needed. The address(es) must be a number and street, city, state and zip code. The address(es) must be within the county(ies) indicated in paragraph 5.) If none, check this box ☐: No New York State Business Location.

1229 Trumansburg Road, Ithaca, New York 14850

Print or Type Name of Signer: Shalom Braunstein Signature: Shalom Braunstein

Capacity of Signer (Check one): ☐ Authorized Person ☐ Officer of the Corporation ☐ General Partner of the Limited Partnership ☒ Member of the Limited Liability Company ☐ Manager of the Limited Liability Company

6. ADDRESS OF EACH LOCATION, INCLUDING NUMBER AND STREET, IF ANY, OF EACH PLACE WHERE THE ENTITY CARRIES ON OR CONDUCTS OR TRANSACTS BUSINESS IN NEW YORK STATE: (Continued)

Filer's Name and Mailing Address:

Michael Stringfellow, Paralegal

Name:

Garfunkel Wild, P.C.

Company, if Applicable:

111 Great Neck Road, 6th Floor

Mailing Address:

Great Neck, New York 11021-5406

City, State and Zip Code:

NOTE: You are not required to use this form. This certificate should be prepared under the guidance of an attorney.

FEE: Limited Liability Companies and Limited Partnerships - $25.
Corporations - $25 plus the fee for each county indicated in paragraph 5. The additional fee for each county within New York City (Bronx, Kings, New York, Queens and Richmond) is $100 additional. The fee for each county outside New York City is $25. Checks over $500 must be certified.

(For office use only)

STATE OF NEW YORK
DEPARTMENT OF STATE

I hereby certify that the annexed copy for CAYUGA RIDGE, LLC, File Number 091029000684 has been compared with the original document in the custody of the Secretary of State and that the same is true copy of said original.

WITNESS my hand and offical seal of the Department of State, at the City of Albany, on October 21, 2020.

Brendan C. Hughes
Executive Deputy Secretary of State

Rev. 10/2020

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091029000684

ARTICLES OF ORGANIZATION
OF
CAYUGA RIDGE, LLC

Under Section 203 of the Limited Liability Company Law of the State of New York:

THE UNDERSIGNED, being a natural person of at least eighteen (18) years of age and acting as the organizer of the limited liability company (the "Company") hereby being formed under Section 203 of the Limited Liability Company Law of the State of New York (the "LLCL"), certifies that:

FIRST: The name of the Company is:
CAYUGA RIDGE, LLC

SECOND: The county within the State of New York in which the principal office of the Company is to be located is 1229 Trumansburg Road, Ithaca, NY in Tompkins County.

THIRD: The Secretary of State is designated as the agent of the Company upon whom process against the Company may be served. The post office address within or without the State of New York to which the Secretary of State shall mail a copy of any process against the Company served upon such Secretary of State is **C/O MARK D. FARCHIONE, 120 WALTON STREET, SUITE 500, SYRACUSE, NY 13202.**

FOURTH: The Company shall be member-managed according to the provisions set forth in the Operating Agreement and such management structure shall not be deleted, modified or amended without the prior approval of the New York State Department of Health.

FIFTH: The purpose for which the Company is formed is limited to the establishment, maintenance, and operation of a skilled nursing facility known as Cayuga Ridge Extended Care at 1229 Trumansburg Road, Ithaca, NY, in Tompkins County.

SIXTH: No person may own any membership interest or voting rights in the Company without the prior written approval of the New York State Department of Health. All transfers, assignments or other dispositions of membership interest or voting rights in the Company must be approved by the New York State Department of Health. Notwithstanding anything to the contrary in this document or the Operating Agreement, transfers, assignments or other dispositions of membership interests or voting rights must be effectuated in accordance with section 2801-a(4)(b) of the Public Health Law.

IN WITNESS WHEREOF, I have subscribed these Articles of Organization and do hereby affirm the foregoing as true under penalties of perjury, this 17 day of September 2009.

Mark D. Farchione
Member
120 Walton Street, Suite 500
Syracuse, NY 13202

N. Y. S. DEPARTMENT OF STATE
DIVISION OF CORPORATIONS AND STATE RECORDS ALBANY, NY 12231-0001

CERTIFICATE OF RESERVATION

==========

ENTITY NAME: CAYUGA RIDGE LLC

DOCUMENT TYPE: RESERVATION (DOM LLC)

==========

FILED:10/15/2009 DURATION:12/15/2009 CASH#:091015000709 FILM #:091015000653

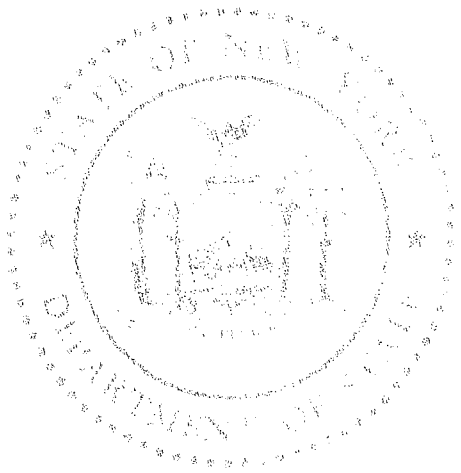
FILER:

STEVEN BOWMAN
120 WALTON ST., STE. 500

SYRACUSE, NY 13202

ADDRESS FOR PROCESS:

REGISTERED AGENT:



** SUBMIT RECEIPT WHEN FILING CERTIFICATE **
APPLICANT NAME : STEVEN BOWMAN

==========

SERVICE COMPANY: BLUMBERG/EXCELSIOR CORPORATE SERVICES SERVICE CODE: 39

FEES	45.00	PAYMENTS	45.00
FILING	20.00	CASH	0.00
TAX	0.00	CHECK	0.00
CERT	0.00	CHARGE	0.00
COPIES	0.00	DRAWDOWN	45.00
HANDLING	25.00	OPAL	0.00
		REFUND	0.00

==========

DOS-1025 (04/2007)

STATE OF NEW YORK
DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.
Commissioner

James W. Clyne, Jr.
Executive Deputy Commissioner

October 28, 2009

Mr. Mark Farchione
Vice President
Peregrine Companies
120 Walton Street, Suite 500
Syracuse, New York 13202

Re: 002445 - B
Cayuga Ridge, LLC d/b/a Cayuga Ridge
Extended Care
(Tompkins County)

Dear Mr. Farchione:

The Department has received the modification to CON # 002445 that was submitted on October 20, 2009 pursuant to 10 NYCRR § 600.3 (b). The modification, which merely changes the name of the applicant from "LNH, LLC" to "Cayuga Ridge, LLC," is hereby approved.

The letter dated October 13, 2009 to you from Colleen Frost, Executive Secretary of the Public Health Council, that states the Council's consent to the filing of the Articles of Organization of LNH, LLC, should be construed as the Council's consent to the filing of the Articles of Organization of Cayuga Ridge, LLC, dated September 17, 2009.

Sincerely,

Richard M. Cook
Deputy Commissioner
Office of Health Systems Management

STATE OF NEW YORK
DEPARTMENT OF HEALTH
CORNING TOWER BUILDING
ALBANY, N.Y. 12237

PUBLIC HEALTH COUNCIL

October 13, 2009

Mr. Mark Farchione
Vice President
Peregrine Companies
120 Walton Street, Suite 500
Syracuse, New York 13202

Re: Articles of Organization of LNH, LLC

Dear Mr. Farchione:

AFTER INQUIRY and INVESTIGATION and in accordance with action taken at a meeting of the Public Health Council held on the 2nd day of May, 2008, I hereby certify that the Public Health Council consents to the filing of the Articles of Organization of LNH, LLC, dated October 5, 2009.

Sincerely,

Colleen M. Frost

Colleen M. Frost
Executive Secretary

/cf

091029000 684

ARTICLES OF ORGANIZATION

OF

CAYUGA RIDGE, LLC

Under Section 203 of the Limited Liability Company Law of the State of New York

BLU-39
DRAWDOWN

MOL FILED 2009 OCT 29 PM 2:30

FILED BY:

BLUMBERGEXCELSIOR CORPORATE SERVICES INC.
52 SOUTH PEARL STREET, 2ND FLR
ALBANY, NY 12207

STATE OF NEW YORK
DEPARTMENT OF STATE
FILED OCT 29 2009
TAX $
BY: MOL

2009 OCT 29 PM 12:05
RECEIVED

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NEW YORK STATE OF OPPORTUNITY.
Division of Corporations, State Records and Uniform Commercial Code

New York State
Department of State
DIVISION OF CORPORATIONS, STATE RECORDS AND UNIFORM COMMERCIAL CODE
One Commerce Plaza
99 Washington Ave.
Albany, NY 12231-0001
www.dos.ny.gov

CERTIFICATE OF AMENDMENT OF CERTIFICATE OF ASSUMED NAME OF

CAYUGA RIDGE, LLC

(Insert Real Name of Entity)

Under Section 130 of the General Business Law

FIRST: The real name of the entity is: **CAYUGA RIDGE, LLC**.

SECOND: *Foreign entities only.* If applicable, the fictitious name the entity agreed to use in New York State is: _____.

THIRD: If the real name of the entity is different on the last Certificate of Assumed Name or Certificate of Amendment of Certificate of Assumed Name, the previous name of the entity is:

_____.

FOURTH: The entity was formed or authorized under (indicate law):

- ☐ Business Corporation Law
- ☐ Not-for-Profit Corporation Law
- ☐ Education Law
- ☐ Revised Limited Partnership Act
- ☐ Insurance Law
- ☐ Other (specify law): _____.
- ☑ Limited Liability Company Law

FIFTH: The present assumed name is **Cayuga Ridge Extended Care**.

SIXTH: The date the original Certificate of Assumed Name was filed is: **02/13/2014**.

SEVENTH: The date, if applicable, the last Certificate of Amendment of Certificate of Assumed Name was filed is: _____.

EIGHTH: The following change(s) are being made (check the appropriate change(s)):

☐ **Entity Name:**
The new name of the entity is: _____.

☑ **Assumed Name:**
The new assumed name is: **Cayuga Nursing and Rehabilitation Center**.

☐ **Principal Place of Business:**
The principal place of business is changed to *(include the number and street, city, state and zip code)* : _____.

☐ **County(ies), Added or Deleted, in Which Business Will be Conducted Under the Assumed Name:**

County(ies) Added: County(ies) Deleted:

☐ **Address(es) of Specific Business Location(s), Added or Deleted:**

Business Location(s) Added *(include the number and street, city, state and zip code):*

Business Location(s) Deleted *(include the number and street, city, state and zip code):*

INSTRUCTIONS FOR SIGNING:

1. If a corporation, by an officer; if a limited partnership, by a general partner; if a limited liability company, by a member or manager; or by an authorized person or attorney-in-fact for such corporation, limited partnership or limited liability company.
2. If the certificate is signed by an attorney-in-fact, include the name and title of the person for whom the attorney-in-fact is acting. (Example, John Smith, attorney-in-fact for Robert Johnson, president.)

Diana Johnson
(Name of Signer)

X /s/ Diana Johnson
(Signature)

Authorized Person
(Title of Signer)

CERTIFICATE OF AMENDMENT
OF CERTIFICATE OF ASSUMED NAME
OF

CAYUGA RIDGE, LLC

(Insert Real Name of Entity)

Under Section 130 of the General Business Law

Filer's Name: **Novack Burnbaum Crystal LLP**

Address: **675 Third Avenue, Fl 8**

City, State and Zip Code: **New York, NY 10017**

NOTES:

1. This form was prepared by the New York State Department of State. You are not required to use this form. You may draft your own form or use forms available at legal stationery stores.
2. The Department of State recommends that all documents be prepared under the guidance of an attorney.
3. **Filing Fee:**
   a. Limited Liability Companies $25.
   b. Limited Partnerships - $25.
   c. Corporations - $25 plus the additional fee for each county affected by the amendment. The additional fee for each county within New York City (Bronx, Kings, New York, Queens and Richmond) is $100. The additional fee for each county outside New York City is $25.
4. Checks are payable to the Department of State.
5. All checks over $500 must be certified.

For Office Use Only

NCR-26

201402130 38

NYS Department of State
Division of Corporations, State Records and Uniform Commercial Code
One Commerce Plaza, 99 Washington Ave,
Albany, NY 12231-0001
www.dos.ny.gov

Certificate of Assumed Name

Pursuant to General Business Law§130

1. REAL NAME OF ENTITY: CAYUGA RIDGE, LLC

1a. FICTITIOUS NAME, IF ANY, OF FOREIGN ENTITY (Not Assumed Name):

2. FORMED OR AUTHORIZED UNDER THE FOLLOWING NEW YORK LAW (Check one):

☐ Business Corporation Law ☒ Limited Liability Company Law ☐ Religious Corporations Law
☐ Education Law ☐ Not-for-Profit Corporation Law ☐ Revised Limited Partnership Act
☐ Other (specify law):

3. ASSUMED NAME: Cayuga Ridge Extended Care

4. PRINCIPAL PLACE OF BUSINESS IN NEW YORK STATE (MUST INCLUDE NUMBER AND STREET). IF NONE, CHECK THIS BOX ☐ AND PROVIDE OUT-OF-STATE ADDRESS:

1229 Trumansburg Road, Ithaca, New York 14850

5. COUNTY(IES) IN WHICH ENTITY DOES OR INTENDS TO DO BUSINESS: ☐ ALL COUNTIES (or check applicable county(ies) below)

☐ Albany	☐ Cattaraugus	☐ Chenango	☐ Delaware	☐ Franklin	☐ Hamilton	☐ Lewis	☐ Montgomery
☐ Allegany	☐ Cayuga	☐ Clinton	☐ Dutchess	☐ Fulton	☐ Herkimer	☐ Livingston	☐ Nassau
☐ Broome	☐ Chautauqua	☐ Columbia	☐ Erie	☐ Greene	☐ Jefferson	☐ Madison	☐ New York
☐ Broome	☐ Chemung	☐ Cortland	☐ Essex	☐ Genesee	☐ Kings	☐ Monroe	☐ Niagara
☐ Cattaraugus	☐ Orleans	☐ Queens	☐ St. Lawrence	☐ Schuyler	☐ Steuben	☐ Warren	☐ Wyoming
☐ Onondaga	☐ Oswego	☐ Rensselaer	☐ Saratoga	☐ Seneca	☐ Suffolk	☐ Washington	☐ Yates
☐ Ontario	☐ Otsego	☐ Richmond	☐ Schenectady	☒ Tompkins	☐ Sullivan	☐ Wayne	
☐ Orange	☐ Putnam	☐ Rockland	☐ Schoharie	☐ Ulster	☐ Tioga	☐ Westchester	

6. ADDRESS OF EACH LOCATION, INCLUDING NUMBER AND STREET, IF ANY, OF EACH PLACE WHERE THE ENTITY CARRIES ON, CONDUCTS OR TRANSACTS BUSINESS IN NEW YORK STATE. Use page 2 if needed. The address(es) must be a number and street, city state and zip code. The address(es) listed in paragraph 6 must be within the county(ies) indicated in paragraph 5. If none, check the box: ☐ No New York State Business Location

1229 Trumansburg Road, Ithaca, New York 14850

STATE OF NEW YORK
DEPARTMENT OF STATE
FILED FEB 13 2014
TAX $ 19620
BY:

Name of Signer: Diana Johnson Signature: /s/ Diana Johnson

Capacity of Signer (Check one): ☐ Officer of the Corporation ☐ General Partner of the Limited Partnership
☐ Member of the Limited Liability Company ☐ Manager of the Limited Liability Company
☒ Authorized Person

Filer: Name: Novack Burnbaum Crystal LLP

Mailing Address: 675 Third Avenue, 8th Floor

City, State and Zip Code: New York, NY 10017

RECEIVED 2014 FEB 13 AM 11:03

NOTE: This form was prepared by the New York State Department of State. You are not required to use this form. All documents should be prepared under the guidance of an attorney. The certificate must be submitted with a $25 fee. For corporations, the Department of State also collects the following, additional, county clerk fees for each county in which a corporation does or intends to do business as indicated in paragraph 5: $100 for each county within New York City (Bronx, Kings, New York, Queens and Richmond) and $25 for each county outside New York City. All checks over $500 must be certified.

DOS-1336-f (Rev. 10/13) G9102900068 4 MJ

Facility Id. 984
Certificate No. 5401311N

State of New York
Department of Health
Office of Primary Care and Health Systems Management

Certified Beds - Total **144**
RHCF 144

OPERATING CERTIFICATE

Effective Date: 03/06/2020
Expiration Date: NONE

Residential Health Care Facility - SNF

Cayuga Nursing and Rehabilitation Center
1229 Trumansburg Road
Ithaca, New York 14850

Operator: Cayuga Ridge, LLC
Operator Class: Proprietary LLC

Has been granted this Operating Certificate pursuant to Article 28 of the Public Health Law for the service(s) specified.

Baseline

Respite 2

20200608

Deputy Commissioner, Office of Primary Care and Health Systems Management

This certificate must be conspicuously displayed on the premises.

Howard Zucker M.D.

Commissioner

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, on this 24th day of June 2026, approves the filing of the Certificate of Assumed Name of Cayuga Ridge, LLC, as attached.

Public Health and Health Planning Council

Project # 261080-B
Hawkins ASC, LLC d/b/a Vanguard Specialty Surgery Center

Program: **DTC** ***County:*** **Suffolk**
Purpose: **Establishment and Construction** ***Acknowledged:*** **March 2, 2026**

Executive Summary

Description
Hawkins ASC, LLC d/b/a Vanguard Specialty Surgery Center requests approval to establish and construct a multi-specialty Freestanding Ambulatory Surgery Center specializing in Pain Management, Orthopedics (spine), Podiatry, and Vascular surgical services in leased space at 640 Hawkins Avenue, Ronkonkoma, New York (Suffolk County). The proposed center will be comprised of two (2) operating rooms and one (1) procedure room.

The sole proposed member of Hawkins ASC, LLC, is Daniel Choi, MD. Dr. Daniel Choi, board-certified in Orthopedics, will also serve as the Medical Director of the proposed FASC.

Catholic Health-Good Samaritan University Hospital provided a letter of intent to enter into an affiliation agreement with Vanguard Special Surgery Center to provide back-up services 19 miles/22 minutes away.

OPCHSM Recommendation
Contingent approval with an expiration of the operating certificate five years from the date of its issuance.

Need Summary
The applicant projects 1,736 procedures in Year One and 2,101 procedures in Year Three, with Medicaid at 5% and Charity Care at 2% by the third year.

Program Summary
The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Summary
The total project cost of $9,364,688 will be met with $1,201,888 in member equity, a bank loan of $3,500,000 at an interest rate of 6.00% for an eight-year term, and an equipment lease of $4,662,800 at an interest rate of 9.60% for an eight-year term.

Budget:	Year One	Year Three
Revenues	$9,335,891	$11,310,177
Expenses	$8,492,169	$10,205,026
Net Income	$843,722	$1,105,151

Health Equity Impact Assessment
This project does not meet the criteria requiring a Health Equity Impact Assessment under Section 2802-B of the PHL.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

Approval with an expiration of the operating certificate five years from the date of its issuance, contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Architectural Design Development Drawings: Submission of architectural and life safety drawings, acceptable to the Department, as described in the Bureau of Architecture and Engineering Review Drawing Submission Guidelines DSG-1.0. [AER]
3. Engineering Design Development Drawings: Submission of mechanical, electrical, plumbing and fire protection drawings, acceptable to the Department, as described in the Bureau of Architecture and Engineering Review Drawing Submission Guidelines DSG-1.0. [AER]
4. Submission of an executed loan that is acceptable to the Department of Health. [BFA]
5. Submission of an executed working capital loan that is acceptable to the Department of Health. [BFA]
6. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
7. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women, and handicapped persons) and the centers commitment to meet the health care needs of the community, including the provision of services to those in need, regardless of ability to pay. The statement shall also include a commitment to the development of policies and procedures to ensure that charity care is available to those who cannot afford to pay. [RNR]
8. Submission of a signed agreement with an outside, independent entity satisfactory to the Department to provide annual reports to DOH. Reports are due no later than April 1st for the prior year and are to be based upon the calendar year. Submission of annual reports will begin after the first full or, if greater or equal to six months after the date of certification, partial year of operation. Reports should include:
    a. Data displaying actual utilization including procedures;
    b. Data displaying the breakdown of visits by payor source;
    c. Data displaying the number of patients who needed follow-up care in a hospital within seven days after ambulatory surgery;
    d. Data displaying the number of emergency transfers to a hospital;
    e. Data displaying the percentage of charity care provided;
    f. The number of nosocomial infections recorded during the year reported;
    g. A list of all efforts made to secure charity cases; and
    h. A description of the progress of contract negotiations with Medicaid managed care plans. [RNR]

Approval conditional upon:

1. This project must be completed by **December 1, 2027**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before **January 1, 2027**, and construction must be completed by **September 1, 2027**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date, this shall constitute abandonment of the approval. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
4. The staff of the facility must be separate and distinct from the staff of other entities; the signage must clearly denote that the facility is separate and distinct from other entities; the clinical space must be used exclusively for the approved purpose; and the entrance must not disrupt any other entity's clinical program space. [HSP]
5. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary: https://www.health.ny.gov/facilities/hospital/docs/hcs_access_form_new_clinics.pdf. Questions may be directed to the Division of Hospitals and Diagnostic &Treatment Centers at 518-402-1004 or email: hospinfo@health.ny.gov. [HSP]
6. The submission of annual reports to the Department as prescribed by the related contingency, each year, for the duration of the limited life approval of the facility. [RNR]

Council Action Date
June 24, 2026

Need Analysis

Project Description

Hawkins ASC, LLC, D/B/A Vanguard Special Surgery Center seeks approval to establish and construct a multi-specialty freestanding ambulatory surgery center (FASC) to be located at 640 Hawkins Avenue, Ronkonkoma, 11779 (Suffolk County). The center will specialize in Pain Management, Orthopedics (spine), Podiatry, and Vascular surgical services. The proposed site of the Center is not in a Health Professional Shortage Area (HPSA) or in a Medically Underserved Area (MUA).

Background and Analysis

The primary service area is Suffolk County, whose population is projected to decrease to 1,486,821 by 2031 based on Cornell Program on Applied Demographics estimates. Demographics for the primary service area are noted below, including a comparison with New York State.

Demographics	Suffolk County	New York State
Total Population	1,530,146	19,852,366
Hispanic or Latino (of any race)	22.8%	19.8%
White (non-Hispanic)	62.0%	52.8%
Black or African American (non-Hispanic)	6.9%	13.4%
Asian (non-Hispanic)	4.4%	9.0%
Other (non-Hispanic)	3.8%	5.0%

Source: 2024 American Community Survey (5-year Estimates Data Profiles)

In 2024, 95.3% of the population of Suffolk County had health coverage as follows:

Employer Plans	54.9%
Medicaid	12.8%
Medicare	13.3%
Non-Group Plans	13.8%
Military or VA	0.457%

Source: Data USA

Ambulatory Surgery within a 10-Mile Radius of Proposed Center

Facility Name	Type	Patient Procedures		
		2023	2024	2025*
PrecisionCare Surgery Center	ASC	2,487	2,968	2,547
Stony Brook University Hospital	Hospital	32,535	32,868	32,113
St Catherine of Siena Hospital	Hospital	9,712	9,310	8,951
The Center for Advanced Spine and Joint Surgery	ASC	3,048	3,940	5,418
John T Mather Memorial Hospital of Port Jefferson New York Inc	Hospital	9,573	9,495	9,338
Advanced Surgery Center of Long Island	ASC	10,383	10,692	10,445
Port Jefferson Ambulatory Surgery Center	ASC	3,636	3,889	3,624
Total Visits		**71,374**	**73,162**	**72,436**

Source: HFIS and SPARCS

** Data may not reflect a full year of submissions*

The facilities listed above provide multi-specialty, single specialty orthopedics, or single specialty pain management ambulatory surgical services.

The following applications are approved for multi-specialty ambulatory surgery centers and within a 10-mile radius of the applicant:

- CON 212260 - SurgiCore Suffolk, LLC, to provide pain management, podiatry, and orthopedic surgery
- CON 251234 - Smithtown ASC, to provide gastroenterology, pain management, general surgery and vascular surgery
- CON 231348 - Long Island Community Hospital at NYU Langone Health, a hospital extension clinic to provide orthopedic, podiatry, general, vascular, and endoscopy surgery

Additionally, CON 251025 - Stony Brook University Hospital/Ambulatory Surgery Center, located in Suffolk County, has approval to construct a hospital extension clinic in Commack (outside of the 10-mile radius noted above) providing multi-specialty ambulatory surgery services for pain management, orthopedic, ophthalmology, and urology surgery.

The majority of patients will be referred to the Center by the participating physicians, followed by referrals from independent physicians practicing in Suffolk County, referrals through Sun River Health (a Federally Qualified Health Center/FQHC), and patient self-referral through community advertising. Participating physicians currently work closely with the Catholic Health hospital system, primarily Good Samaritan University Hospital, and plan to triage their case mix between the hospital and the proposed FASC based on acuity.

The projects 1,736 procedures in Year One and 2,101 in Year Three, with Medicaid at 5% and Charity Care at 2%. These projections are based on the current practices of participating surgeons. The table below shows the applicant's projected payor source utilization for Years One and Three.

Payor	Year One		Year Three	
	Volume	%	Volume	%
Commercial FFS	0	0.0%	0	0.0%
Commercial MC	590	34.0%	714	34.0%
Medicare FFS	0	0.0%	0	0.0%
Medicare MC	590	34.0%	714	34.0%
Medicaid FFS	0	0.0%	0	0.0%
Medicaid MC	87	5.0%	106	5.0%
Charity Care	35	2.0%	42	2.0%
Other (Workers Comp/No Fault)	434	25.0%	525	25.0%

The applicant has contacted the following Medicaid Managed Care entities: HealthFirst, Fidelis Care, and UHC Community Plan. In addition, they will provide charity care (or a sliding fee scale) for individuals who are uninsured or under-insured, which includes a formal relationship with Sun River Health, an FQHC with multiple locations throughout Long Island.

Conclusion

Approval of this project will bring existing procedures into the regulatory environment of Article 28 health care facilities, providing more choices in surgical venues for the residents of Suffolk County.

Program Analysis

Project Proposal

Proposed Operator	Hawkins ASC, LLC dba Vanguard Specialty Surgery Center
To Be Known As	Hawkins ASC, LLC dba Vanguard Specialty Surgery Center
Site Address	640 Hawkins Avenue, Ronkonkoma, NY 11779 (Suffolk County)
Specialties	Ambulatory Surgery - Multi Specialty Pain Management Orthopedics (spine) Podiatry Vascular
Hours of Operation	Monday through Friday, 7:00 a.m. to 6:00 p.m.
Staffing (1st Year / 3rd Year)	18 FTEs / 21 FTEs
Medical Director	Dr. Choi, M.D.
Transfer Agreement and Distance	**PENDING:** Catholic Health-Good Samaritan University Hospital 19 miles away / 25 minutes away
Nearest Hospital	Stony Brook University Hospital 101 Nicolls Road, Stony Brook, NY 11794 7 miles away / 20 minutes away

The sole member of Hawkins ASC, LLC, D/B/A Vanguard Special Surgery Center is Daniel Choi, M.D. Dr. Daniel Choi's private medical practice, Spine Medicine and Surgery of Long Island P.C., specializes in spine surgery and pain management. Currently, Spine Medicine and Surgery of Long Island P.C. experiences delays in scheduling surgeries as it utilizes several different surgical facility sites. The current practice does not have stable operating room (OR) time because the practice does not control surgical schedules of facilities it utilizes. Projected utilization will provide additional facility access as patients wait for available ORs across multiple facilities.

Several physicians and Dr. Choi have committed to perform surgeries at the new FASC. High acuity surgical cases generated by the practice will continue to be referred to Catholic Health Hospital. This relationship with Catholic Health Hospital will allow the hospital system to focus their OR utilization on higher acuity cases that are more appropriate for their setting while lower acuity will be referred and seen more quickly in the proposed FASC. Sun River Health, a Federally Qualified Health Center (FQHC) serving Long Island, has and will continue to refer patients to Dr. Choi's Spine Medical Long Island facility for services.

Certain individuals who currently work in the physician's practice may transition to the ASC to facilitate the ramp-up period, and a clear delineation of roles, responsibilities, and reporting structures will be maintained between the two entities. Additional employees needed will be recruited from accredited schools, training programs and job fairs. Outsourced staffing and recruiting firms will be engaged as needed.

Patients who will be treated at Vanguard Special Surgery Center will be existing patients of each participating physician's private practice as well as from independent physicians practicing in Suffolk County. All physicians who practice at the Center will be Board-Certified or Board-Eligible. After the Center is established, participating physicians will continue to be on call and see patients at hospitals they are currently affiliated with. The physicians/surgeons will also continue to perform inpatient and ambulatory procedures that are more appropriately performed in a hospital setting. All anesthesia will be administered and monitored by a qualified, board-certified anesthesiologist. The Center intends to engage anesthesiology services through a board-certified anesthesiologist with demonstrated experience serving ambulatory surgery centers.

The Center will seek accreditation from the Accreditation Association for Ambulatory Health Care (AAAHC) within three (3) years of operations. The proposed ASC will be located on the first floor of an existing commercial building with medical and office tenants. The ASC will include:

(2) Operating Rooms,
(1) Procedure room, and
(18) Pre/Post-op Patient Holding Bays.

Eight (8) bays will be used for pre-op, and ten (10) bays will be used for post-op.

Proposed renovations will include 9,893 square feet of the existing 42,718 square feet of space to be completed within three years. The interior space scope of work will involve installing new HVAC, plumbing, electrical and fire protection systems.

This proposed surgery center has a Development Agreement with Gramercy Prime, who has direct experience overseeing operations of other freestanding ambulatory surgery centers in New York. The Center will utilize SIS Charts, a cloud-based electronic medical record (EMR) platform developed by Surgical Information Systems (SIS) and designed specifically for freestanding ambulatory surgery centers.

Catholic Health-Good Samaritan University Hospital provided a letter of intent to enter into an affiliation agreement with Vanguard Special Surgery Center to provide back-up services. Catholic Health-Good Samaritan University Hospital is located at 1000 Montauk Highway, West Islip, New York, which is 19 miles away.

The following table shows the projected FTE's in Year One and Year Three following completion of this project:

Position	**Year One**	**Year Three**
Management and Supervision	1.0	1.0
Technician & Specialist (Surgical Tech, Rad Tech, Central Sterile Tech)	6.0	6.5
Registered Nurses	7.0	8.5
Physician / Medical Director	1.0	1.0
Clerical and Other Administrative	3.0	4.0
Totals	18.0	21.0

The private practice, Spine Medicine and Surgery of Long Island, P.C., and Vanguard Specialty Surgery Center will be maintained as separate, independently managed entities.

Medical Director

Dr. Choi, MD, FAAOS is a board-certified Orthopedic who will serve as the Center's Medical Director as well as perform Orthopedic procedures at the center. Dr. Choi will oversee the clinical operations of the facility and serve as the Chairman of the Quality Improvement Committee.

Character and Competency

Dr. Daniel Eun-suk Choi received a Medical Degree from the Northwestern University Feinberg School of Medicine located in Chicago, Illinois in 2011; completed a Bachelor's degree in Psychology from the Northwestern University Weinberg School of Arts and Sciences located in Evanston, Illinois in 2006; completed an Orthopedic Surgery Residency at Rutgers New Jersey Medical School located in Newark, New Jersey in 2016; and completed an Orthopedic and Neurosurgical Spine Surgery Fellowship at the Harvard Medical School-Beth Israel Deaconess Medical Center in located in Boston, Massachusetts in 2017.

Since 2021, Dr. Choi has been the Chief Executive Officer, Owner, and Operator of Spine Medicine and Surgery of Long Island, PLLC **/** New Jersey Spine Medicine and Surgery, LLC located in Ronkonkoma, NY with a focus on Spine Surgery and Interventional Pain Management Practice; and was an Attending Orthopedic Spine Surgeon at Long Island Spine Specialists, P.C. located in Commack, NY from 2017 to 2021.

Currently, Dr. Choi serves as a Clinical Assistant Professor in the Department of Orthopedic Surgery at Zucker School of Medicine at Hofstra/Northwell since 2019; is a Medical School Admissions Committee Member at the Zucker School of Medicine at Hofstra/Northwell since 2020; and served as an Orthopedic Surgery Residency Spine Education Chair at Plainview Hospital since 2019.

Dr. Choi is an attending Orthopedic Surgeon at eleven (11) hospitals in New York and in New Jersy: privileges at Saint Francis Hospital (Roslyn), Huntington Hospital, Lenox Hill Hospital, Good Samaritan Hospital (West Islip), Mount Sinai South Nassau, North Shore University Hospital, Mercy Medical Center (Rockville Centre) as well in other hospitals in New Jersey.

Dr. Choi was the first physician on Long Island to perform dual-portal endoscopic spinal surgery and performs several other innovative procedures that are now performed at FASCs (SI joint fusions, percutaneous posterior cervical fusion (minimally invasive), Spinal Cord Stimulator permanent implant placement).

Dr. Choi disclosed that he is a partner in the following companies:

Spine Medicine and Surgery of Long Island,
Spine Medicine and Surgery of New Jersey,
Agility Management Services LLC,
Agility Billing Services LLC, and
DAE Realty LLC

These affiliated business ventures focus on Spine, Orthopedic and Pain Management medical practices serving patients of Long Island and northern New Jersey. Services focus on practice management, billing, and administrative services that support medical practices.

Integration with Community Resources

All patients undergoing procedures at the Center will be required to have an established primary care physician or provider prior to scheduling elective surgery. The Center will maintain a directory of primary care resources in central Suffolk County, including community health centers, Federally Qualified Health Centers (FQHCs), and private primary care practices, and will actively refer any unaffiliated patients to these resources.

The Center has developed a collaborative relationship with Sun River Health, an FQHC with multiple locations throughout Long Island. Sun River Health has referred patients to Dr. Choi's Spine Medicine & Surgery of Long Island practice in the past. This relationship will continue and will serve as a formal channel for ensuring that underinsured and uninsured patients referred for surgical care are connected to primary care services.

Post-operative care protocols will include discharge planning that reinforces the patient's connection to their primary care provider, ensuring continuity of care following any ambulatory surgical procedure performed at the Center.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Conclusion

The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a(3).

Financial Analysis

Total Project Cost and Financing

Total project cost, which is for new construction and the acquisition of moveable equipment, is estimated at $9,364,688, and further broken down as follows:

New Construction	$3,794,500
Design Contingency	$379,450
Construction Contingency	$189,725
Architect/Engineering Fees	$225,000
Construction Manager Fees	$60,000
Moveable Equipment	$4,662,800
CON Fee	$2,000
Additional Processing Fee	$51,213
Total Project Cost	$9,364,688

The applicant's financing plan appears as follows:

Equity	$1,201,888
Bank Loan (6.00% interest rate for an eight-year term)	$3,500,000
Equipment Lease (9.60% interest rate for an eight-year term)	$4,662,800
	$9,364,688

The applicant has provided letters of interest for both the bank loan and equipment lease.

Operating Budget

The applicant has submitted an operating budget, in 2026 dollars, for the first and third years of operation, summarized below:

	Year One		Year Three	
	Per Procedure	Total	Per Procedure	Total
Revenues				
Commercial FFS	$8,620	$5,085,800	$8,620	$6,154,680
Medicare Managed Care	$4,310	$2,542,900	$4,310	$3,077,340
Medicaid Managed Care	$2,075	$180,525	$2,075	$219,950
Other	$5,076	$2,202,984	$5,076	$2,664,900
Charity Care		($175,708)		($210,850)
Bad Debt Expense		($500,610)		($605,843)
Total		$9,335,891		$11,300,177
Expenses:				
Operating	$3,785	$6,571,001	$3,933	$8,263,875
Capital	$1,107	$1,921,168	$924	$1,941,151
Total Expenses	$4,892	$8,492,169	$4,857	$10,205,026
Net Income		$843,722		$1,105,151
Utilization: (Procedures)		1,736		2,101

The following is noted with respect to the submitted operating budget:

- The applicant projects 18 FTEs in Year One and 21 FTEs in Year Three. The average salary is $96,979 and $107,847 during Year One and Year Three.
- The number of registered nurse FTEs during Year One and Year Three are 7 and 8.5, respectively. The average salary for the nurses is $112,354 and $126,000 in Year One and Year Three.
- Revenues are based on current reimbursement methodologies for ambulatory surgery services. Commercial rates were derived from experience conducting direct payer contracting for FASCs in the NY metro markets. Medicare rates were derived using the publicly published CMS rates for the Center's geographical area. Medicaid rates were derived from contracted rates with Medicaid Managed Care plans and the NY Medicaid rates assigned to other facilities in the NY metro market.
- The primary population to be served by this proposed FASC will be the Suffolk County communities of Islandia, Ronkonkoma, Bohemia, Holbrook and Lake Grove.
- Hawkins ASC, LLC expects to perform 1,736 procedures in Year One and 2,101 procedures in Year Three of operation. Volume estimates are based on the physician applicant and additional physicians who have committed to perform procedures at the proposed center. In support of projected levels, the physicians have submitted letters indicating their projected annual procedures.
- The majority of the proposed center's patients will be referred to the center by the participating physicians as well as independent physicians practicing in the Suffolk County communities.

Utilization broken down by payor source, for the first and third years are as follows:

	Year One	Year Three
Commercial MC	33.99%	33.98%
Medicare Managed Care	33.99%	33.98%
Medicaid Managed Care	5.01%	5.05%
Workers Comp/No Fault	25.00%	24.99%
Charity Care	2.01%	2.00%
Total	100.00%	100.00%

Lease Rental Agreement

The applicant has submitted an executed lease rental agreement for the site that they will occupy, which is summarized below:

Premises	9,893 square feet located at 640 Hawkins Avenue, Ronkonkoma, New York
Lessor	New York Spine Medicine and Surgery, PLLC and Agility Management Services, LLC
Lessee	Hawkins ASC, LLC
Term	15 years with two additional renewable lease terms
Rental	Year One $494,650 annual rental ($50.00 per sq. ft.) with a 2% annual increase thereafter.
Provisions	The lessee shall be responsible for maintenance, utilities and real estate taxes.

The applicant has provided an affidavit that the lease will be a non-arm's length arrangement. The applicant has submitted two real estate letters attesting to the reasonableness of the per square foot rental.

Capability and Feasibility

The total project cost for this application is $9,364,688 and will be funded with a bank loan of $3,500,000 at an interest rate of 6.00% for an eight-year term, an equipment lease of $4,662,800 at an interest rate of 9.60% for an eight-year term, and equity of $1,201,888 to be provided from the sole members personal resources.

The working capital requirements are estimated at $1,683,683, equivalent to two months of third-year expenses. The sole member will provide equity from personal resources to meet these requirements. BFA Attachment A, Personal Net Worth Statement of Daniel Choi MD, shows the availability of sufficient funds for the equity contribution.

BFA Attachment B, Pro Forma Balance Sheet, shows a positive net asset position of $1,663,683 as of the first day of operations.

The submitted budget projects a net income of $843,722 in Year One and $1,105,151 in Year Three. Revenues are based on current reimbursement methodologies for ambulatory surgery services. The budget appears reasonable.

Conclusion

The applicant has demonstrated the capability to proceed in a financially feasible manner.

Attachments

BHFP Attachment	Map
BFA Attachment A	Personal Net Worth Statement - Daniel Choi MD
BFA Attachment B	Pro Forma Balance Sheet

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 24th day of June 2026, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish and construct a Multi-Specialty Ambulatory Surgery Center at 640 Hawkins Avenue, Ronkonkoma, and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:	FACILITY/APPLICANT:
261080 B	Hawkins ASC, LLC dba Vanguard Specialty Surgery Center

APPROVAL CONTINGENT UPON:

Approval with an expiration of the operating certificate five years from the date of its issuance, contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Architectural Design Development Drawings: Submission of architectural and life safety drawings, acceptable to the Department, as described in the Bureau of Architecture and Engineering Review Drawing Submission Guidelines DSG-1.0. [AER]
3. Engineering Design Development Drawings: Submission of mechanical, electrical, plumbing and fire protection drawings, acceptable to the Department, as described in the Bureau of Architecture and Engineering Review Drawing Submission Guidelines DSG-1.0. [AER]
4. Submission of an executed loan that is acceptable to the Department of Health. [BFA]
5. Submission of an executed working capital loan that is acceptable to the Department of Health. [BFA]
6. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
7. Submission by the governing body of the ambulatory surgery center of an Organizational Mission Statement which identifies, at a minimum, the populations and communities to be served by the center, including underserved populations (such as racial and ethnic minorities, women, and handicapped persons) and the centers commitment to meet the health care needs of the community, including the provision of services to those in need, regardless of ability to pay. The statement shall also include a commitment to the development of policies and procedures to ensure that charity care is available to those who cannot afford to pay. [RNR]
8. Submission of a signed agreement with an outside, independent entity satisfactory to the Department to provide annual reports to DOH. Reports are due no later than April 1st for the prior year and are to be based upon the calendar year. Submission of annual reports will begin after the first full or, if greater or equal to six months after the date of certification, partial year of operation. Reports should include:
   a. Data displaying actual utilization including procedures;
   b. Data displaying the breakdown of visits by payor source;
   c. Data displaying the number of patients who needed follow-up care in a hospital within seven days after ambulatory surgery;
   d. Data displaying the number of emergency transfers to a hospital;
   e. Data displaying the percentage of charity care provided;
   f. The number of nosocomial infections recorded during the year reported;
   g. A list of all efforts made to secure charity cases; and
   h. A description of the progress of contract negotiations with Medicaid managed care plans. [RNR]

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **December 1, 2027**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before **January 1, 2027**, and construction must be completed by **September 1, 2027**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date, this shall constitute abandonment of the approval. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
4. The staff of the facility must be separate and distinct from the staff of other entities; the signage must clearly denote that the facility is separate and distinct from other entities; the clinical space must be used exclusively for the approved purpose; and the entrance must not disrupt any other entity's clinical program space. [HSP]
5. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
   https://www.health.ny.gov/facilities/hospital/docs/hcs_access_form_new_clinics.pdf.
   Questions may be directed to the Division of Hospitals and Diagnostic &Treatment Centers at 518-402-1004 or email: hospinfo@health.ny.gov. [HSP]
6. The submission of annual reports to the Department as prescribed by the related contingency, each year, for the duration of the limited life approval of the facility. [RNR]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a complete response to each individual contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in the Contingencies Tab in NYSE-CON.

NEW YORK STATE OF OPPORTUNITY. Department of Health

Public Health and Health Planning Council

Project # 242277-B
Hyp+Care

Program: **Diagnostic and Treatment Center** ***County:*** **New York**
Purpose: **Establishment and Construction** ***Acknowledged:*** **December 16, 2024**

Executive Summary

Description
Hyp+Access, Inc. (the Center), an existing Delaware-based non-stock corporation that is certified to do business in New York as a non-profit organization, is seeking approval to establish and construct an Article 28 Diagnostic and Treatment Center (D&TC) on the fourth floor of a seven (7) story building at 111 West 24th Street, New York (New York County).

The eight (8) exam room clinic will be certified for Medical Services – Primary Care and Medical Services – Other Medical Specialties. Hyp+Access will specialize in serving patients who exhibit symptoms of connective tissue disorders, such as connective tissue diagnoses, autonomic dysfunction, allergy and immunological dysfunction, chronic pain and fatigue and rheumatic dysfunction, conditions that often defy effective diagnosis and treatment.

Susan Polizzi, MD will serve as the Medical Director. The Center will enter into a transfer and affiliation agreement with Northwell Greenwich Village Hospital, .7miles/7 minutes away.

OPCHSM Recommendation
Contingent approval with an expiration of the operating certificate two years from the date of its issuance.

Need Summary
The applicant projects 18,257 visits in Year One and 39,422 visits in Year Three with 28.96% Medicaid and 2% Charity.

Program Summary
The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a (3).

Financial Summary
Total project cost of $1,965,820 will be met with $1,187,708 in landlord equity and $778,112 in Hyp+Access, Inc. equity.

Budget:	Year One	Year Three
Revenues	$5,648,736	$13,731,046
Expenses	$5,757,687	$10,126,120
Excess Revenues	($108,951)	$3,604,926

Health Equity Impact Assessment
This project does not meet the requirements for a Health Equity Impact Assessment under Section 2802-B of the PHL.

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

Approval with an expiration of the operating certificate two years from the date of its issuance, contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]
3. Submission of Engineering (MEP) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]
4. Submission of an executed lease that is acceptable to the Department of Health. [BFA]
5. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]

Approval conditional upon:

1. This project must be completed by **June 1, 2027**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before **September 1, 2026**, and construction must be completed by **March 1, 2027**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date, this shall constitute abandonment of the approval. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
4. Hydration Infusion services shall be administered solely when deemed medically necessary by a licensed healthcare provider and the medication is approved by the US Food and Drug Administration (FDA). [HSP]
5. Submission of a report to the New York State Department of Health and the Public Health and Health Planning Council (PHHPC) on both quantitative and qualitative measures as approved by the Department after Year One and Year Two following the facility's opening. [HSP]
6. The staff of the facility must be separate and distinct from the staff of other entities; the signage must clearly denote that the facility is separate and distinct from other entities; the clinical space must be used exclusively for the approved purpose; and the entrance must not disrupt any other entity's clinical program space. [HSP]

7. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary: https://www.health.ny.gov/facilities/hospital/docs/hcs_access_form_new_clinics.pdf. Questions may be directed to the Division of Hospitals and Diagnostic &Treatment Centers at 518-402-1004 or email: hospinfo@health.ny.gov. [HSP]

Council Action Date
June 24, 2026

Need Analysis

Project Description

Hyp+Access, Inc. (Hyp+Care or the Center), an existing not-for-profit corporation, seeks approval to establish and construct an Article 28 diagnostic and treatment center, certified to provide primary medical care and other medical specialty services, including infusion services to patients who exhibit symptoms of connective tissue disorders such as connective tissue diagnosis, autonomic dysfunction, allergy and immunological dysfunction, chronic pain and fatigue and rheumatic dysfunction, which can cause a variety of physical, psychological and economic problems for those affected.

Background and Analysis

The primary service area (PSA) for this project is comprised of the New York City Region containing Bronx, Kings, New York, Richmond, and Queens Counties. The population of the region is projected to increase to 9,249,182, an 8.6% increase, by 2030 according to the Cornell Program on Applied Demographics. Demographics for the primary service area are noted below including a comparison with New York State.

Demographics	New York City Region	New York State
Total Population	8,516,202	19,872,319
Hispanic or Latino (of any race)	28.4%	19.6%
White (non-Hispanic)	31.3%	53.4%
Black or African American (non-Hispanic)	20.8%	13.6%
Asian (non-Hispanic)	14.5%	8.8%
Other (non-Hispanic)	5.0%	4.6%

Source: 2023 American Community Survey (5-Year Estimates Data Profiles)

In 2023, 93.6% of the population of the NYC Region and 95.7% of New York County had health coverage as follows

Health Plans	New York County	New York, NY (NYC Region)
Employer plans	52.4%	41.9%
Medicaid	19.3%	30.0%
Medicare	11.0%	9.57%
Non-group plans	12.8%	11.8%
Military or VA plans	0.284%	0.304%

Source: Data USA

The projected payor mix includes

Applicant Projected Payor Mix		
Payor	**Year One**	**Year Three**
Commercial	34.43%	34.43%
Medicare	34.61%	34.61%
Medicaid	28.96%	28.96%
Charity Care	2.00%	2.00%

Source: Applicant

The applicant has been providing case management and other non-medical services to this population for approximately five years. They project 18,257 visits in Year One and 39,422 visits in Year Three for the proposed facility.

According to the applicant, there is a significant and growing need for specialized care for individuals with connective tissue variance, as these conditions often go undiagnosed or misdiagnosed, leading to inadequate treatment and worsening health outcomes. As a result, individuals with these conditions often endure years of unnecessary medical expenses, psychological distress, and deteriorating health. Given the increasing recognition of these disorders and their complex interactions with other medical conditions, there is a pressing need for a dedicated center that provides interdisciplinary, specialized care to address the full spectrum of connective tissue variance. Hyp+Care would offer accessible, holistic treatment to improve patient outcomes and overall quality of life.

The Manhattan Lupus Surveillance Program, a population-based registry to determine the prevalence of systemic lupus erythematosus, an autoimmune disease classified as a connective tissue disorder, found the incidence from 2007 to 2009 among New York County residents, showing the age-standardized prevalence rate as 62.2 and incidence rate as 4.6 per 100,000 persons per year.

The Center will provide healthcare services during the following expected days/hours of operation upon opening: Monday through Friday (8:00 am-6:00 pm). Expanded hours will be provided as determined by demand. It is expected that most of the visits will be scheduled, but there will be capacity for unscheduled patients.

Prevention Quality Indicators (PQIs) are rates of admission to the hospital for conditions for which good outpatient care can potentially prevent the need for hospitalization, or for which early intervention can prevent complications or more severe disease. The table below provides information on PQI rates for 2024 related to this application.

Hospital Admissions per 10,000 Adults						
PQI Name	**Bronx County**	**Kings County**	**New York County**	**Richmond County**	**Queens County**	**New York State**
Diabetes Short-Term Complications	12	7	7	7	6	7
Diabetes Long-Term Complications	28	13	14	17	12	13
Chronic Obstructive Pulmonary Disease or Asthma	60	25	25	29	20	25
Hypertension	16	8	8	9	10	7
Heart Failure	62	38	37	40	34	36
Bacterial Pneumonia	15	8	9	11	7	12
Uncontrolled Diabetes	12	6	5	5	6	5
Prevention Quality Overall Composite	206	108	107	126	101	114

Source: NYSDOH, HCS, Data Hub
Crude Rates per 10,000

Conclusion

Approval of this project will provide comprehensive treatment for connective tissue disorders for residents of the New York City region.

Program Analysis

Project Proposal

Proposed Operator	Hyp+Access, Inc.
To Be Known As	Hyp+Care
Site Address	111 West 24th Street, 4th Floor New York, New York 10011 (New York County)
Specialties	Medical Services - Other Medical Specialties Medical Services - Primary Care
Hours of Operation	Monday through Friday, 8 am to 6 pm
Staffing (1st Year / 3rd Year)	32.5 FTEs / 48 FTEs
Medical Director(s)	Susan Polizzi, M.D.
Emergency, In-Patient and Backup Support Services Agreement and Distance	Northwell Greenwich Village Hospital 30 Seventh Avenue New York, New York 10011 Minutes away: 7 minutes Distance away: 0.7 miles away.

Hyp+Care will be certified for Primary Care and Medical Services – Other Medical Specialties, with a focus on cardiology, pain management, and hydration infusion therapy services.

The Center intends to serve patients with Hypermobility Spectrum Disorders, Postural Orthostatic Tachycardia Syndrome (POTS), Dysautonomia, Fibromyalgia, Mast Cell Activation Syndrome, Long-Covid, Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, common connective tissue disorders, hypermobile Ehlers-Danlos Syndrome, autonomic dysfunction, allergy and immunological dysfunction, chronic pain, and Rheumatic Dysfunction. These disorders often cause a lifelong variety of physical, psychological, and economic problems for those affected. Hyp+Care will offer accessible, clinical, and alternative holistic treatments to help improve patient outcomes and overall quality of life. The Center's mission is to improve and to initiate culturally appropriate medical and alternative care access for the vulnerable impacted by connective tissue variance and related disorders. Hyp+Care will focus on improving clinical outcomes through symptom management, comorbidity management and quality of life improvement techniques, and through usage of off-label FDA approved medications. The Center intends to treat dehydration symptoms with a variety of treatments which will include Saline infusion therapy with the goal to reduce unnecessary emergency room visits and to promote better preventative care for patients with connective disorders.

Hyp+Care contends that the inability to find and to access care for this population is due to lack of providers with expertise in diagnosis and treatment of connective tissue disorders and overlapping conditions. Many incoming patients will self-refer due to their inability to find and to access the specialized care they seek for treatment of connective tissue disorders and related conditions. Many physicians who comprehensively address connective tissue disorders and overlapping conditions do not take Medicaid and Medicare and are not actively accepting new patients due to the inability to add to their current patient loads.

Hyp+Care will also provide treatment for patients presenting with long-Covid symptoms (e.g., chronic fatigue, pain, breathlessness, brain fog, autonomic dysfunction, etc.). The agency will focus on improving clinical outcomes through symptom management and quality of life improvement, which will include use of off-label FDA approved meds. According to the applicant, medications and Saline infusion treatments are currently used by clinicians across the United State (e.g., low dose naltrexone, pyridostigmine and fludrocortisone) for treatment of long-Covid symptoms and are considered first-line of treatment.

Another diagnosis Hyp+Care may treat is Lyme disease. The applicant states Lyme disease and many connective tissue disorders co-exist, interact, and share overlapping symptoms, particularly joint pain, fatigue and other systemic issues like autonomic and gastrointestinal dysfunction, leading to complex interplay of symptoms. Hyp+Care believes overlapping symptoms and misdiagnosis highlights the importance of care evaluation and specialized testing for connective tissue disorders. Neurological evaluations will be referred out to other Article 28 providers or to other physicians who are known to work with the population Hyp+Care is proposing to serve.

Hyp+Acess, Inc. currently provides supportive care management services and other non-medical healthcare services to educate and to help better manage symptoms with members who attend their programs. The care management services at the clinic are provided on sliding scale and pro bono basis. The Center will work with a Regional Health Information Organization that serves the region that will help the Center to connect to the Statewide Health Information Network for New York (SHIN-NY).

The table below shows the FTEs in Year One and Year Three after completion of this project:

Positions	**Year One**	**Year Three**
Management & Supervision	3	3
Medical Technician	2	2
Registered Nurse	2	2
Physicians	3.5	5
Nurse Practitioner	3	4
Acupuncturist	0	1
Clerical, Administrative & Other (Community Health Workers, Medical Billers, PR etc)	19	31
Totals	**32.50**	**48.0**

Testing and Infusion IV Therapy will be provided by clinical staff and not by a physician provider or physician extender. The Center based physician and physician-extender visits on seeing twelve (12) patients per clinical day. The projected number of annual infusion treatments (4,899) are based on an average of 19-20 infusions per clinical 8-hour day across 7-infusion bays.

The infusion staff will include 2-Registered Nurses and 1-Nurse Practitioner. Infusion staff will be separate and distinct staff from the other outpatient services proposed by the Center.

The proposed Medical Director will be **Susan Polizzi, M.D**., who specializes in treating patients with connective tissue disorders and related cardiovascular manifestations. Dr. Polizzi will be full-time at the Center and provide direct patient care services.

Character and Competence

Susan Polizzi, MD is a licensed cardiologist with experience in immunology and with providing infusions with a focus on dysautonomia care. Dr. Polizza completed a Fellowship with a focus on cardiovascular disease at the University of Colorado Health Science Center in Denver, Colorado in June 2022; completed a Residency in Internal Medicine at the University of Texas at Southwestern Medical Center in Dallas, Texas in 1997; received a Doctor of Medicine degree from the Hahnemann University School of Medicine (now Drexel University) in Philadelphia, Pennsylvania in 1994; received a Bachelor of the Arts degree with a focus on Animal Physiology, Minor in Visual Arts at the University of California in La Jolla, California in 1989. Dr. Polizza is also Board Certified in Cardiovascular Disease (ABIM) and for Adult Echocardiography (ASE).

Currently, Dr. Polizza practices non-invasive cardiology at NYU Langone Medical Center since 2017; is a Cardiology Clinical Instructor and a member of the Long COVID Clinic at NYU Langone Medical Center since 2022; practiced as an invasive non-interventional Cardiologist at Aurora Denver Cardiology Associates, P.C located in Aurora, Colorado from 2008 to 2022; and practiced as a non-invasive Cardiologist at Murray Hill Medical Group / NYU Langone Medical Center from 2013 to 2016.

Audre E. Wirtanen
Audre Wirtanen is a hypermobile neuroscientist who focuses on practicing alternative physical care and alternative safety practices with hypermobile individuals; and co-developed a somatic practice therapy known as Hypermobile Accessible Proprioceptive Therapy (HAPT).

Audre Wirtanen received a Bachelor of Arts (BA) degree specializing in dance, neuroscience with a minor in chemistry at Bennington College located in Vermont in 2016; attended the Balance Arts Center in New York City in 2017 and completed a 1600-hour certification program at the American Society for the Alexander Technique in 2020; was a research assistant at the Integral Anatomy Productions Institute located in Colorado Springs, Colorado in 2023; and completed a fellowship at the New Yorkers For Culture and Arts in New York City in 2022.

Additionally, Audra Wirtanen is registered as a Somatic Movement Educator (RSME), Somatic Movement Therapist (RSMT), and as a Somatic Dance Educator (RSDE).

Currently, Audre Wirtanen is a co-founder and director of Hyp+Care since 2021; is a co-founder and co-director at Hyp+Access, Inc since 2019; is a co-developer and lead teacher of HAPT since 2017.

Laura Tuthall
Laura Tuthall is a co-partner with Hyp+Access, Inc, focusing across body-based fields utilizing somatic, dance, and science in service of hypermobility, specific to accessibility and injury prevention; and is a co-developer of a somatic practice Hypermobile Accessible Proprioceptive Therapy (HAPT). Laura Tuthall has a dance and disability-sensory-movement background; is a performer, a dancer and performance artist who tackles trauma and disability through dance and other artistic mediums; and is an advocate for other individuals with disabilities.

Laura Tuthall is anticipated to receive a Master of Arts in Disability Studies degree from CUNY School of Professional Studies located in New York City in 2026; completed a Bachelor's in Fine Arts (BFA) degree from Boston Conservatory at Berklee located in Massachusetts in 2015; is a member of the International Somatics Movement Educations and Therapy Association; is registered as a Somatic Movement Educator (RSME), as a Somatic Movement Therapist (RSMT), and as a Somatic Dance Educator (RSDE).

Since 2019, Laura Tuthall has been a co-founder and board member, a Worker Program Director and Head of Education in Community Healthcare with Hyp+Access since 2021. Also, Laura Tuthall is a HAPT co-developer and lead teacher since 2016 and Hyp-Improv co-developer and lead teacher since 2020. Laura Tuthall was the co-founder and the Director of Education & Programming at the Integrating Instability Balance Arts Center in New York City from 2016 to 2019.

Ciaran M. Cooper
Ciaran Cooper has over 30 years' experience in medical devices, pharmaceutical development, and clinical trial services development. Ciaran Cooper received a master's in fine arts (MFA) degree from Bennington College located in Vermont in 2004 and received a bachelor's in arts with a minor in writing in 1987 from Bennington College.

Since February 2025, Ciaran Cooper is the Chief Executive Officer of an ECG core lab that conducts cardiac safety studies for the pharmaceutical, medical device, and CRO industries, at HeartcoR Solutions, LLC located in Schaumburg, Illinois; was the Founder and CEO of Strategic Insight Consulting, located in Chicago, Illinois focusing on General Management, Strategic Planning, Business Development, Marketing Communications and Operations from 2024 to 2025; and was the president and general manager for BioTel Research located in Chicago. In this position, Ciaran Cooper was focusing on clinical trial service providers on cardiac safety monitoring and medical imaging solutions from 2022 to 2024; and was also the vice-president in global business development with BioTel Research from 2019 to 2022.

Ciaran Cooper also was employed as an industry consultant at Metrics Champion Consortium located in Chicago focusing on the development of standardized performance metrics to improve clinical trials from 2017 to 2019; and was the director of Operations at Astellas Pharmaceuticals, Inc in Northbrook, Illinois from 2016 to 2017.

Bree T. Ferrin
Bree Ferrin received a Master of Science in Nursing degree from Frontier Nursing University located in Kentucky in 2018; completed an associate in applied science in Nursing at Philips Beth Israel School of Nursing located in New York in 2009; and completed a Bachelor of Technology in Entertainment from NYC College of Technology in 2003.

Currently, Bree Ferrin is a Hyp+Access board member since 2022; is an Advanced Practice Clinician at Planned Parenthood Greater New York in New York City since 2018; was the charge nurse at Planned Parenthood NYC from 2015 to 2018; was an Ebola Treatment Unit Clinician for Partners in Health located in Port Loko, Sierra Leone from 2014 to 2015; and was a registered nurse with Prime Staffing located in New York City from 2013 to 2015.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Conclusion
The individual background review indicates the proposed members have met the standard for approval as set forth in Public Health Law §2801-a (3).

Financial Analysis

Total Project Cost and Financing

Total project cost of $1,965,820, which is for renovations and the acquisition of moveable equipment, is further broken down as follows

Renovation and Demolition	$986,748
Design Contingency	98,675
Construction Contingency	98,675
Planning Consultant Fees	62,000
Architect/Engineering Fees	100,000
Other Fees Consultant	43,610
Moveable Equipment	563,370
CON Fee	2,000
Additional Processing Fee	10,742
Total Project Cost	$1,965,820

The Department has determined that allowable project cost is $778,112.

The applicant's financing plan appears as follows

Equity (Landlord)	$1,187,708
Equity (Applicant)	778,112
Total	$1,965,820

Operating Budget

The applicant has submitted an operating budget, in 2025 dollars, for the first and third years, summarized below:

	Year One		Year Three	
	Per Visit	Total	Per Visit	Total
Revenues:				
Commercial FFS	$267.15	$1,679,559	$272.49	$3,699,336
Medicare FFS	$265.84	1,679,559	$271.15	$3,699,081
Medicaid Managed Care	$217.31	1,148,938	$221.66	$2,530,471
Care Management Services		1,140,680		$3,802,158
Total Revenues		$5,648,736		$13,731,046
Expenses:				
Operating	$292.01	$5,331,263	$245.66	$9,684,564
Capital	$23.36	426,424	$11.20	441,556
Total Expenses	$315.37	$5,757,687	$256.86	$10,126,120
Excess Revenues		($108,951)		$3,604,926
Utilization:				
Primary Care		9,880		21,334
Medical Specialties		8,377		18,088
Total Visits		18,257		39,422

The following is noted with respect to the submitted operating budget:

- Medical specialty services include cardiology, pain management and infusion therapy.
- The applicant is projecting a total growth in visits of 21,165 from Year One to Year Three. Growth is based on projected increase demand for the specialized medical care to be provided by the applicant.
- Revenues are based on current reimbursement methodologies for the type of services they provide.
- Expenses and utilization assumptions are based on the historical experience of other D&TCs in New York State in providing primary care and specialty care.

Utilization, broken down by payor source, during Year One and Year Three is as follows

	Year One	Year Three
Commercial FFS	34.43%	34.43%
Medicare FFS	34.61%	34.61%
Medicaid MC	28.96%	28.96%
Charity Care	2.00%	2.00%
Total	100.00%	100.00%

Lease Rental Agreement

The applicant has submitted a draft lease for the site that they will occupy, which is summarized below:

Premises	6,810 square feet at 111 West 24th Street, New York,
Lessor	Okada, Inc.
Lessee	Hyp+Access, Inc.
Term	10 years
Rental	Year One $340,500 annually ($50 per sq.ft.) and an approximately 3% increase each year thereafter.
Provisions	The lessee shall be responsible for utilities, maintenance and real estate taxes.

The applicant has submitted an affidavit attesting that the lease is an arms-length agreement. The applicant has provided two real estate letters attesting to the reasonableness of the rental payments.

Capability and Feasibility

The total project costs of $1,965,820 will be met with $1,187,708 in landlord equity and equity of $778,112 from Hyp+Access. Both the landlord and the applicant provided documentation showing the availability of sufficient funds for the equity contribution.

The working capital requirements are estimated $1,687,687, which is equivalent to two months of third year expenses, will be funded with Hype+Access equity of $177,934 and $1,500,000 from the Wirtanen Family Trust. Audre Wirtanen is a director and president of the not-for-profit operating entity.

BFA Attachment A, Pro Forma Balance Sheet, shows the operations will begin with $3,653,507 as of the first day of operations.

The submitted budget indicates an excess of revenues over expenses of ($108,951) and $3,604,926 during Year One and Year Three, respectively. Year One losses will be offset with working capital funds. Revenues are based on current reimbursement methodologies for primary medical care and infusion services. The submitted budget appears reasonable.

Conclusion

The applicant has demonstrated the capability to proceed in a financially feasible manner.

Attachments

BFA Attachment A	Pro Forma Balance Sheet

RESOLUTION

RESOLVED, that the Public Health and Health Planning Council, pursuant to the provisions of Section 2801-a of the Public Health Law, on this 24th day of June 2026, having considered any advice offered by the Regional Health Systems Agency, the staff of the New York State Department of Health, and the Establishment and Project Review Committee of this Council and after due deliberation, hereby proposes to approve the following application to establish and construct a new Diagnostic and Treatment Center to be constructed at 111 West 24th Street, New York to provide primary medical care and medical specialty services, to include saline hydration infusion services, for patients who exhibit symptoms of connective tissue disorders., and with the contingencies, if any, as set forth below and providing that each applicant fulfills the contingencies and conditions, if any, specified with reference to the application, and be it further

RESOLVED, that upon fulfillment by the applicant of the conditions and contingencies specified for the application in a manner satisfactory to the Public Health and Health Planning Council and the New York State Department of Health, the Secretary of the Council is hereby authorized to issue the approval of the Council of the application, and be it further

RESOLVED, that any approval of this application is not to be construed as in any manner releasing or relieving any transferor (of any interest in the facility that is the subject of the application) of responsibility and liability for any Medicaid (Medicaid Assistance Program -- Title XIX of the Social Security Act) or other State fund overpayments made to the facility covering the period during which any such transferor was an operator of the facility, regardless of whether the applicant or any other entity or individual is also responsible and liable for such overpayments, and the State of New York shall continue to hold any such transferor responsible and liable for any such overpayments, and be it further

RESOLVED, that upon the failure, neglect or refusal of the applicant to submit documentation or information in order to satisfy a contingency specified with reference to the application, within the stated time frame, the application will be deemed abandoned or withdrawn by the applicant without the need for further action by the Council, and be it further

RESOLVED, that upon submission of documentation or information to satisfy a contingency specified with reference to the application, within the stated time frame, which documentation or information is not deemed sufficient by Department of Health staff, to satisfy the contingency, the application shall be returned to the Council for whatever action the Council deems appropriate.

NUMBER:	FACILITY/APPLICANT:
242277 B	Hyp+Care

APPROVAL CONTINGENT UPON:

Approval with an expiration of the operating certificate two years from the date of its issuance, contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of State Hospital Code (SHC) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]
3. Submission of Engineering (MEP) Drawings, acceptable to the Department, as described in BAEFP Drawing Submission Guidelines DSG-01. [AER]
4. Submission of an executed lease that is acceptable to the Department of Health. [BFA]
5. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]

APPROVAL CONDITIONAL UPON:

1. This project must be completed by **June 1, 2027**, including all pre-opening processes, if applicable. Failure to complete the project by this date may constitute an abandonment of the project by the applicant and the expiration of the approval. It is the responsibility of the applicant to request prior approval for any extensions to the project approval expiration date. [PMU]
2. Construction must start on or before **September 1, 2026**, and construction must be completed by **March 1, 2027**, presuming the Department has issued a letter deeming all contingencies have been satisfied prior to commencement. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. In accordance with 10 NYCRR Section 710.10(a), if construction is not started on or before the approved start date, this shall constitute abandonment of the approval. [PMU]
3. The submission of Final Construction Documents, as described in BAER Drawing Submission Guidelines DSG-05, is required prior to the applicant's start of construction. [AER]
4. Hydration Infusion services shall be administered solely when deemed medically necessary by a licensed healthcare provider and the medication is approved by the US Food and Drug Administration (FDA). [HSP]
5. Submission of a report to the Department after Year One and Year Two following the facility's opening, including a summary of the first year of operations, services provided, payor mix, program outcomes, and key lessons learned. [HSP]
6. The staff of the facility must be separate and distinct from the staff of other entities; the signage must clearly denote that the facility is separate and distinct from other entities; the clinical space must be used exclusively for the approved purpose; and the entrance must not disrupt any other entity's clinical program space. [HSP]

7. The applicant must ensure registration for and training of facility staff on the Department's Health Commerce System (HCS). The HCS is the secure web-based means by which facilities must communicate with the Department and receive vital information. Upon receipt of the Operating Certificate, the Administrator/director that has day-to-day oversight of the facility's operations shall submit the HCS Access Form at the following link to begin the process to enroll for HCS access for the first time or update enrollment information as necessary:
   https://www.health.ny.gov/facilities/hospital/docs/hcs_access_form_new_clinics.pdf.
   Questions may be directed to the Division of Hospitals and Diagnostic &Treatment Centers at 518-402-1004 or email: hospinfo@health.ny.gov. [HSP]

Documentation submitted to satisfy the above-referenced contingencies shall be submitted within sixty (60) days. Enter a complete response to each individual contingency via the New York State Electronic Certificate of Need (NYSE-CON) system by the due date(s) reflected in the Contingencies Tab in NYSE-CON.