

NEW YORK STATE DEPARTMENT OF HEALTH
PUBLIC HEALTH AND HEALTH PLANNING COUNCIL
COMMITTEE ON CODES, REGULATIONS AND LEGISLATION MEETING
JUNE 24, 2026, 10:15 AM
ESP, CONCOURSE LEVEL, MEETING ROOM 6 ALBANY
TRANSCRIPT

Mr. Holt Good morning. My name is Tom Holt. I'm the Chair of the Committee on Codes, Regulations, and Legislation. I have the privilege to call to order the Codes Committee, and welcome members, participants, and observers. I'd like to remind council members, staff, and the audience that this meeting is subject to the Open Meeting Law and is broadcast over the internet. The webcasts are accessed at the Department of Health's website. The on-demand webcast will be available no later than seven days after the meeting, for a minimum of thirty days, and then a copy will be with the department for four months. We have some suggestions or ground rules to follow to make this meeting more successful. Because there is synchronized captioning, it's important that people do not talk over each other. Captioning cannot be done correctly with two people speaking at the same time. The first time that you speak, if you would state your name and briefly identify yourself as a council member or DOH staff. This will be of assistance to the broadcasting company who's recording this meeting. Please note that the microphones are hot mics, meaning that they pick up every sound. I ask that you avoid rustling papers next to the microphone and also be sensitive about personal conversations or sidebars as the microphones can pick up that chatter. As a reminder for our audience, there's a form that needs to be filled out before you enter the meeting room, which records your attendance at these meetings, which is required by the Commission on Ethics, Lobbying and Government in accordance with Executive Law Section 166. This form is also posted on the Department of Health's website under Certificate of Need. In the future, you can fill out the form prior to these council meetings, and we thank you for your cooperation with these duties as prescribed by the law. We have two codes for adoption this morning, and then two codes for information, just as a heads up to the members of the committee and the council, we may be suspending the meeting after we get through the first two motions for adoption to go to Amir and Commissioner McDonald for their presentations. It could be potentially a little bit fluid for us here. I just wanted to give you that heads up. We did not have anybody who had signed up to speak on any of the codes that are before us today. Again, we have four regulations on the agenda today. The first two for adoption, first being certificates of qualification for clinical laboratory directors.

Mr. Holt May I have a motion for recommendation of the adoption of this regulation to the full Public Health and Health Planning Council.

Mr. Holt Ms. Soffel.

Mr. Holt Dr. Watkins, thank you.

Mr. Holt Beverly and Alexa from the department are available and will provide us with information on this proposal.

Ms. Rauch Good morning. My name is Beverly Rauch. I'm with the division of Laboratory Quality Certification in the Department of Health.

Ms. Rauch I'm here to provide information about the adoption of the repeal of Part 19 of Title 10 of the New York State Code's Rules and Regulations and replacement of that part with Subpart 58.6. The reason for the change is to bring the requirements for certificate of qualification, which is a credential for laboratory directors to serve in that role at permitted clinical laboratories in New York and to bring those requirements into alignment with the federal regulations for laboratory directors under the federal code. The reason for the re-designation from Part 19 Sub Part 58 6 is because of the amendment to public health laws, February 2025, which removed the authority of the Public Health and Health Planning Council to review and advise on the qualifications of those directors.

Mr. Holt Thank you.

Mr. Holt Do we have questions from members of the committee?

Mr. Holt Dr. Watkins.

Dr. Watkins Kevin Watkins, member of the committee. I do have a question regarding this and these new certifications that you are requiring from the laboratory directors. And my question is, it looks like there are... You indicated in your report that there are about eighty-five current directors identified in New York state that will no longer meet these standards. I was a little concerned that where these eighty-five directors are located? Are they county laboratory directors or are they private physician laboratory directors? My other concern is what you have looked at the impact that this will impose on small counties who have county laboratory directors and the resources that are available in these rural communities that may not have these new certifications that you're requiring for laboratory directors.

Ms. Rauch As we've been investigating and managing the change in public health law, we've identified that there's fewer than eighty laboratories and some certificate qualification holders that are affected, because as these individuals are renewing their certificates, they are providing additional documentation that they may have board certification that they didn't provide to us previously. The number is less than eighty now. However, there are no local health departments impacted. There's no hospitals impacted. Primarily, these are independent laboratories that provide routine testing for potentially nursing homes and places like that. There's no hospitals directly impacted. Some of those independent laboratories are very niche testing, where they may be offering only one or two laboratory developed tests, very novel testing. The issue at hand and the reason why we're making this change is because our clinical laboratory evaluation program applies for what's known as a CLIA exemption from the federal

government every six years. During our last re-approval process, they identified that our requirements for the laboratory directors were less stringent than the federal code. They notified us that we needed to make those changes prior to our next re-exemption period, which ends, expires in March of 2027. The impact is on the more niche testing and more independent laboratories, not on hospitals and not necessarily on rural communities and local health departments. These individuals have been notified for, I've been performing outreach for several years now since we had this notification from the federal government that they would be, we are exempt from maybe in jeopardy if we don't make this change. There has been outreach and education and notification to those affected parties for quite some time.

Dr. Watkins Thank you.

Mr. Holt Thank you, Dr. Watkins.

Mr. Holt Any other questions from members of the committee or from the council?

Mr. Holt We did not have anybody from the public signed up to speak, so I will go ahead and just as a reminder, there are seven members of this committee now. Those voting now are just the seven members of the committee, myself, Dr Rugge, Dr Watkins, Dr Yang, Mr. Kraut, Dr Soffel and Dr. Friedman, so that's who this is in front of right now.

Mr. Holt All in favor?

All Aye.

Mr. Holt Any opposed?

Mr. Holt Abstentions?

Mr. Holt That motion carries. Thank you.

Mr. Holt The next is that we have ionizing radiation.

Mr. Holt May I have a motion for a recommendation of adoption of this regulation for the full Public Health and Health Planning Council?

Mr. Holt Dr. Watkins.

Mr. Holt Dr. Soffel, thank you.

Mr. Holt Mr. Charles Burns and Mr. William Sacks of the Department are available and will provide us with information on this proposal.

Mr. Burns Good morning. My name is Charles Burns. I'm the Director of the Bureau of Environmental Radiation Protection. Part 16 is being repealed and replaced with a brand-new Part 16 that makes many changes throughout the rule. Part 16 is composed of three major sections. The first is general radiation safety and administration. The second section covers radiation producing equipment that would be X-ray machines for diagnostic and therapeutic purposes. The quality assurance requirements for diagnostic imaging and radiation therapy have many changes as well, and most of them have previously been implemented through guidance and recommendations, but those are very difficult to enforce. They don't really have a regulatory hook so to speak. The third section of the code that is being changed covers radioactive materials licensing and use. Updates to the regulations are required to incorporate and reference changes to multiple sections of the federal code of regulations, including 10 CFR 37, the physical protection of Category One and Category Two, quantities of radioactive material, and we remove reference to the Department of Labor Regulations. That were transferred to the department in 2006. Department of Health received many comments in response to the 2024 publication of this proposed rule. Many of the comments were very helpful and resulted in a new regulation package, which we have here today. We let that package expire due to the number of comments that we received. This is the current package we intend to adopt.

Mr. Holt Great. Thank you very much.

Mr. Holt Any questions from the members of the committee or the council?

Mr. Holt Yes, Dr. Soffel.

Dr. Soffel Good morning. Denise Soffel, member of the committee and of the council. The phrase ionizing radiation, can you, that's not a term of art that I am used to. Can you sort of give us why these three fairly disparate pieces of practice are all under the same broad heading of ionizing and radiation?

Mr. Burns Well, we protect the members of the public and patients from ionizing radiation. There's all different types of radiation, like electromagnetic and ultraviolet. We focus on radiation that can cause electrons to be ejected from their orbits causing an ionization event. There are many uses for ionizing and radiation in medicine, research and industry.

Mr. Kraut We're going to have to pull out that old physics book.

All (Laughing)

Mr. Kraut I know. I know. I can see your face.

Dr. Soffel It's embarrassing to admit I have a PhD, and I never took Physics.

Dr. Soffel My husband is appalled.

Mr. Burns We don't regulate magnets. Very important.

Mr. Holt Thank you for the question and the follow-up.

Mr. Holt Any additional questions from the members of the committee or council?

Mr. Holt Again, we had nobody from the public who signed up to speak. I would call the motion then.

Mr. Holt All in favor?

All Aye.

Mr. Holt Opposed?

Mr. Holt Any abstentions?

Mr. Holt Thank you.

Mr. Holt The motion carries.

Mr. Holt This will go to the full council for adaptation. Hang on for just one second as I do a time check. So, at this point we're going to suspend the Codes Committee, and for that I need a motion and a second.

Mr. Holt We will suspend the council meeting. I'll turn the meeting over to Mr. Kraut.