

**New York State Department of Health
Bureau of Environmental Radiation Protection**

**Guide for Radiation Safety/Quality Assurance Program
Primary Diagnostic Monitors**

INTRODUCTION

A. Purpose

This guide describes the type and extent of information and standards by which the New York State Department of Health will evaluate a Primary Diagnostic Monitor (PDM) as part of the Radiation Safety/Quality Assurance Program at a facility.

This guide may be used by registrants to develop that part of a registrant's Quality Assurance manual that covers Primary Diagnostic Monitors. This guide is NOT a Quality Assurance manual rather it provides an outline of what a Quality Assurance manual should contain and it may list some standard policies that may be used.

The term "Primary Diagnostic Monitor" or PDM is used in this document to describe monitors that are used by practitioners to make primary diagnosis. Monitors that are used by teleradiology services for off hours interpretations are considered PDMs. Other monitors are frequently available for review of images by technologists ("technologist's monitors") and by other practitioners such as may be found in the ICU or OR ("clinical monitors"). Of primary importance is testing of PDMs. This guide would not have been possible without the express input of the medical physics community, in particular Dustin Gress, MS, DABR.

The Department of Health has implemented this program to reduce radiation exposure, optimize diagnostic image quality and foster facility involvement in the responsibility for Quality Assurance (QA). Facilities may substitute quality control tests if the tests are deemed equivalent by the Department prior to their implementation. Written request should be forwarded to the Bureau at 547 River Street, Room 530, Troy, N.Y. 12180-2216.

B. ALARA (As Low As Reasonable Achievable)

The regulations in Part 16 and this guide have been established on the ALARA principle to ensure that the benefits of the use of ionizing radiation exceed the risks to the individual and the public health and safety.

C. Limits and Standards

The control limits and standards used in this guide have been taken from Online Report #03 "Assessment of Display Performance for Medical Imaging Systems" published by the American Association of Physicists in Medicine and other references, including the American College of Radiology (ACR). Equipment problems should be corrected and documented expeditiously and shall be corrected with appropriate documentation within thirty (30) days of discovery.

D. Authority

The statutory authority for these rules and regulations is found in the New York State Public Health Law, Section 225. The Radiation Safety/Quality Assurance requirements are outlined in Sections 16.5 and 16.23 of Part 16 of Chapter 1 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations. It should be noted that this program is in addition to and does not replace other sections of Part 16, which pertain to each facility operation.

RADIATION SAFETY/QUALITY ASSURANCE PROGRAMS

A. Radiation Safety/Quality Assurance Responsibility

Responsibility for Primary Diagnostic Monitor Quality Assurance is a function of the size of the facility. Large facilities can absorb the responsibilities and structure for PDM quality assurance into their existing committee that is responsible for overseeing Quality Assurance activities in diagnostic imaging. In smaller facilities, QC program oversight is the responsibility of the Radiation Safety Officer. The responsibility for performing PDM equipment preventive Maintenance/testing falls upon several different groups. Medical physicists, radiologic technologists, in-house engineering, and manufacturer service representatives are responsible for various aspects of equipment evaluation and/or performance. In all facilities, the medical physicist should be consulted and maintain technical oversight of the QC program. The QA responsibilities for each party shall be defined as a manual item.

B. Records

1. Manual

Each facility will establish a manual that includes the following items:

- a) a list of tests to be performed and the frequency of performance;
- b) a list identifying which individual or group will be doing each test;
- c) a written description of the procedure that will be used for each test;
- d) a list of all the variables which comprise the operating conditions for each test procedure;
- e) the acceptability limits for each test;
- f) a list of the equipment to be used for testing; and
- g) sample records to be used for each test.

2. Equipment Records

Records shall be maintained for each monitor currently in operation and include:

- a. Initial test results (acceptance testing and other documentation as appropriate);
 - b. QC test results for the current year;
 - c. one set of QC test results from each intervening year to show changes over time.
- Records of repairs and other pertinent data shall also be available.

3. QC Records for Test Equipment

Records shall be maintained and available for review for QC test equipment that requires calibration. QC records may be maintained in either a hardcopy or softcopy format, but must be available for review during inspections and whenever else they are needed.

C. **Equipment Monitoring**

Each facility shall make or have made quality control tests to monitor equipment performance and maintain records of data collected. The tests performed will vary from manufacturer to manufacturer but must include those quality control checks specified by the manufacturer and be modeled after the program below. If, at the time of inspection, significant equipment malfunctions are found, the facility may be required to perform more frequent and/or more thorough testing to ensure good diagnostic image quality.

This guide describes a basic Radiation Safety/Quality Assurance Program and represents only a portion of the Quality Control tests your facility may choose to perform as part of an individualized program. Facilities with equipment under warranty or service contract with an Original Equipment Manufacturer (OEM) or an Independent Service Organization (ISO) must follow the testing and preventive maintenance schedule required by the OEM or ISO to keep the warranty or contract valid. The OEM or ISO testing and maintenance schedule must be included in the manual. Facilities with equipment not under warranty or service contract must follow the testing frequency stated in this guide. Facilities must perform all the QC tests which their manufacturer supplied phantom will allow.

Appropriate quality control testing must be conducted whenever major maintenance or a change in equipment operation (software change) occurs.

1. **Frequency – Bi-Weekly (Routine)**

- a. Using the software provided by your PACS/PDM vendor, display a SMPTE test pattern. Evaluate the SMPTE test pattern considering the following criteria:
 - Grayscale squares should be easily differentiated at each step, 0% through 100%.
 - High and low contrast resolution patterns should be of high integrity in the center and all four corners.
 - 95% - 100% and 0% - 5% patches should be easily visible.
 - Grid lines should be straight with no distortion.
- b. Each monitor must be thoroughly cleaned with an appropriate cleaning solution and cloth. Your PDM vendor should be able to provide recommendations for an appropriate cleaning solution and cloth.
- c. Display an all-white image, either using PACS/PDM software, or by using window width and window level adjustments to make a clinical image all-white. On visual inspection, brightness should appear uniform on each PDM. If two or more PDMs are grouped to form a PDM workstation, there should be no noticeable difference in brightness between individual PDMs in the workstation.
- d. Display an all-black image, either using PACS/PDM software, or by using window width and window level adjustments to make a clinical image all-black. On visual inspection, the black should appear uniform on each PDM, and each PDM should have the same color tone. If two or more PDMs are grouped to form a PDM workstation, there should be no noticeable difference in brightness between individual PDMs in the workstation.

- e. If the PDM is capable of displaying color, an appropriate test pattern must be displayed and evaluated for color trueness. The test pattern should contain objects of three colors, displaying shades of red, green, and blue. Objects should not be distorted.

2. **Frequency – Quarterly**

- a. If the workstation and PDM has software allowing *verification* of DICOM calibration of the Grayscale Standard Display Function (GSDF) to be performed, GSDF verification should be performed at quarterly intervals, with full GSDF calibrations recommended annually.
- b. If the PDM *does not* have software allowing verification of DICOM GSDF calibration, full GSDF calibrations should be performed quarterly.
- c. DICOM GSDF calibration verifications and calibrations will typically be made using the vendor-supplied photometer (often called a “puck” or inherent in the display device itself) and software resident on the workstation.
 - i. For PDMs not used for mammography, the maximum luminance output of each PDM must be no less than 171 cd/m², with a luminance ratio (defined as the ratio of maximum luminance to minimum luminance) no less than 170 (ref. ACR Technical Standard for Electronic Practice of Medical Imaging, 10/01/07; AAPM Task Group 18 OR-03). Maximum luminance of at least 200 cd/m² and a luminance ratio of 250 or greater are recommended.
 - ii. For PDMs used for mammography, the maximum luminance output of each PDM must be no less than 250 cd/m², with a luminance ratio no less than 250. Maximum luminance of 450 cd/m² and a luminance ratio of 500 or greater are recommended.

3. **Frequency – Annually**

To verify the accuracy of the vendor-provided photometer and software, PDMs should be evaluated annually by a Licensed Medical Physicist. Using an external calibrated photometer, the following represents the minimum set of tests to be performed:

- a. Perform a DICOM Grayscale Standard Display Function (GSDF) verification using a stand-alone photometer and compare with the results obtained using the vendor-supplied photometer.
- b. Review of all facility QC documentation and procedures for PDMs.
- c. Quantitative assessment of the brightness (luminance) uniformity of each PDM.
- d. Quantitative determination of the luminance ratio.
- e. Quantitative assessment of the viewing conditions.
- f. Analysis of all test results, including comparison with specifications provided by the vendor and applicable technical standards from professional societies.
- g. Document recommendations for quality improvement and corrective actions.