I. Overview

The New York City Health Department’s Office of Radiological Health (ORH) provides the regulated community with guidance on the quality assurance requirements in Article 175.07(b)(1)(i) of the New York City Health Code. That section of the code applies to primary diagnostic monitors (PDMs) used to make a final interpretation/diagnosis from images generated by radiological devices. The guidance includes an overview of the minimum actions that must be performed by facilities subject to a PDM quality assurance (PDM QA) program.

This document is intended for medical professionals with a registration from ORH, as well as the medical physics community that provides services to medical facilities.

Note: If a facility uses an off-site tele-radiography service, the registrant must be able to demonstrate that the tele-radiography services used comply with the PDM QA requirements.

II. Definitions

Acceptance Testing of Primary Diagnostic Monitor (PDM) Unit: The tests conducted to determine if the requirements of a monitor specification are met

Digital Imaging and Communications in Medicine (DICOM): A standard for handling, storing, printing and transmitting information in medical imaging

Documenting: Making written, electronic and/or photographic records of testing performance

External Photometer: A photometer that is not built into the monitor and requires calibration every two years
Note: PDM Quality Assurance (QA) guidelines require registrants to keep a copy of the calibration certificate on site.

Licensed Medical Physicist Annual Review: An annual review of the registrant’s PDM QA program, which must be conducted and documented by a medical physicist licensed in New York State or another state.

Notes: The licensed medical physicist must review the PDM QA program in its entirety, including bi-weekly testing, quarterly and annual testing conducted and documented during the review period. The report must include an assessment of each PDM, its location and its serial number. The medical physicist’s report must also include recommendations for improving the QA program, if applicable. If the facility does not comply with Health Department requirements for the PDM QA program, this must be specified in the report.

Luminance Ratio for a Primary Diagnostic Monitor: The contrast ratio of the brightest to darkest colors displayed on a PDM. The luminance ratio must be equal to or greater than 250:1.

Note: This ratio must be determined through annual quality control (QC) testing, using an external, calibrated photometer to measure the luminance ratio of the brightest and darkest steps of the test pattern displayed on the PDM.

Maximum Luminance: The maximum light emission from the PDM front surface as measured by a calibrated photometer in units of candela/m².

Medical Monitor: Any monitor that has both a built-in photometer and a QA software program allowing for routine QC tests to be performed.

Monitor: A display device that shows the results of a patient radiological image.

Off-site PDM: Any PDM not located at the registrant’s facility.

Note: In these instances, the tele-radiology service must establish a PDM QA program that conforms to Health Department guidelines.

Picture Archiving and Communication System (PACS): Imaging technology that offers storage of, and access to, medical images.

Primary Diagnostic Monitor (PDM): A monitor used to render a final diagnosis of a patient exam, including interpretations of patient mammograms.

Note: Monitors attached to digital units used as PDMs must have a QA program that complies with this guidance document, with the exception of monitors attached to bone densitometer units.
**PDM Annual Test:** A yearly test, required for all PDMs, to evaluate the GSDF calibration, quantitative assessment of brightness, uniformity, luminance ratio and qualitative assessment of the viewing conditions.

**PDM List:** A list of locations for all PDMs used on site and all locations of off-site PDMs, such as tele-radiology services.

*Note:* Registrants who use PDMs must keep this list on-site.

**PDM Maximum Luminance (PDM L\textsubscript{MAX}):** The standard that must apply to the primary diagnostic monitors used in New York City clinical facilities, as specified below:

- For hospitals, medical centers, imaging centers and radiologist offices, the L\textsubscript{MAX} for each PDM must be equal to or greater than 350 cd/m\textsuperscript{2}.
- For all other clinical sites, including chiropractic offices, medical doctor offices and orthopedic offices, the L\textsubscript{MAX} must be equal to or greater than 250 cd/m\textsuperscript{2}.
- For mammography facilities, the L\textsubscript{MAX} must be equal to or greater than 420 cd/m\textsuperscript{2} or the manufacturer’s standard, as specified in the current FDA Mammography Quality Standards Act regulations.

**Stereotactic monitors (which are used for surgical breast studies and the like) are not involved in patient diagnostic interpretations and therefore are not considered PDMs.**

*Note:* The standard for PDM L\textsubscript{MAX} is sourced from the ACR–AAPM–SIIM Technical Standard for Electronic Practice of Medical Imaging (Amended 2014) (Resolution 39) Chapter III Display Characteristics. The latest version of that standard, found on page 9, must be used.

**Preliminary reads:** (formerly referred to as “wet reads”): A type of monitor that is exempt from PDM guidelines.

*Note:* When images were developed from film, an x-ray could be read wet if the doctor ordering it couldn’t wait for the film to dry. Wet reads are not a final diagnostic report. Therefore, monitors used for wet reads, such as a monitor in a hospital emergency room used to make decisions about trauma patients, are not considered PDMs in the context of this guideline.

**Registrant:** The individual responsible for ensuring that a PDM QA program is implemented on site.

*Note:* This requirement still applies if the registrant contracts with an off-site service, for example tele-radiology service, for patient final diagnostic evaluations.
**Test Pattern:** For the purposes of PDM QA requirements, a pattern that is either a Society of Motion Picture and Television Engineers (SMPTE) test pattern, or the American Association of Medical Physicists (AAPM) Task Group (TG) #18 test pattern (TG 18 test pattern)

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**III. Acceptance Testing Requirements**

The minimum quality control (QC) testing and documenting required for an installed PDM before it can be clinically used are as follows:

1) Measurement of the Grayscale Standard Display Function (GSDF)
2) Quantitative assessment of the luminance uniformity
3) Quantitative determination of the luminance ratio
4) Qualitative assessment of the viewing conditions for the monitor location

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**IV. Bi-weekly PDM Testing**

Bi-weekly testing and documenting must include the following steps:

1) Display a test pattern and evaluate the test pattern using vendor-provided software according to the following criteria:
   a) Easily differentiated Grayscale squares at each step, 0% through 100%
   b) High- and low-contrast resolution patterns indicating high integrity in the center and in all four corners
   c) Easily visible 95% to 100% and 0% to 5% patches
   d) Straight, undistorted grid lines

2) Thoroughly clean PDM monitors. This must be done using the appropriate material and cleaning solution, in accordance with the manufacturer’s specifications.

3) Show an all-white clinical image display using PACS/PDM software or window-width and window-level adjustments. Brightness must be uniform on each PDM, including any grouped to form a workstation.

4) Show an all-black image display using PACS/PDM software or window-width and window-level adjustments. The black image must be uniform on each PDM, including any grouped to form a workstation.

5) For PDMs that can display color, show an appropriate test pattern to evaluate color trueness. The test pattern must contain objects of three colors, displaying shades of red, green and blue. The images must not be distorted.
V. Quarterly PDM Testing

The registrant must conduct and document quarterly PDM QC testing, choosing Method 1 or Method 2 below.

**Method 1:** If the registrant’s PDM has software allowing verification of the GSDF calibration, the registrant must run the verification software to determine compliance with the baseline GSDF. If the monitor is found to be out of compliance with the baseline GSDF standard, the registrant must contact a qualified service engineer to perform a GSDF re-calibration, and the resulting GSDF calibration graph must be made available during an inspection.

**Method 2:** Displaying the TG-18 CT test pattern on each of the registrant’s PDM(s), the registrant must verify that:

- Each density patch is distinctly visible from its adjacent density patch; and
- The half-moon density patches inside each density patch are distinctly visible from their background density.

If either action above fails, the registrant must contact a qualified service engineer to perform a GSDF re-calibration, and the resulting GSDF calibration graph must be made available during an inspection.

**Exception to the Quarterly PDM Testing Requirements**
Bone densitometer units are not included in the above requirement, since they are used for data determination rather than image analysis.

VI. Annual PDM Testing

Annual PDM testing can be performed and documented by trained personnel, but the annual review of the QA reports (including Bi-Weekly, Quarterly and Annual reports) must be specifically performed by a medical physicist. The following reports must be available at the time of inspection for review by the Health Department inspector.

Annual PDM testing includes these steps:

1) **Qualitative Assessment of Viewing Conditions**

   For each PDM, there must be a written assessment of the viewing conditions. This assessment must evaluate the PDM environment for excessive ambient light levels or shadows, or excessive glare reflecting onto PDM display surfaces. The written assessment must include recommended improvements, if any.
2) Quantitative Assessment of Luminance Ratio

The registrant must measure the lightest and darkest steps of the SMPTE or TG 18 test patterns as displayed on the PDM using a calibrated photometer. This information must be recorded in the annual report with PDM location and serial number, along with the analysis of the luminance ratio and indication of compliance with guideline limits.

3) Luminance Uniformity Assessment

The registrant must measure each PDM’s luminance uniformity, adhering to the manufacturer’s recommendations and standards, or if there is no manufacturer’s recommendation, the registrant must:

- Display a uniform white image on the PDM
- Measure the luminance in the center of each of the four quadrants and in the center of the PDM screen and record this information in the annual report
- Using the data indicated in the item directly above, apply the following standard to verify that the luminance at the center of each of the four quadrants doesn’t differ from that at the center of the PDM by more than 30% (“Assessment of Display Performance for Medical Imaging Systems”, AAPM On-Line Report No. 03, April 2005, Section 6: Quality Control of a Display System, Page 124 or its successor standard).

4) Quantitative Measurement of the Grayscale Standard Display Function (GSDF)

The registrant must measure each PDM’s GSDF using a calibrated external photometer for each monitor annual report. For PDMs with a QA software service, this measurement is actually GSDF verification that the internal monitor photometer is measuring the GSDF accurately within the manufacturer’s tolerances. For PDMs without a QA software service, this will be an actual GSDF measurement using an appropriate test pattern, plus a calibrated external photometer, to ascertain the GSDF. The resulting graph and all data must be available for Health Department inspection.

5) Licensed Medical Physicist Annual Review:

A Licensed Medical Physicist must provide each registrant a report of the Registrant’s compliance with this document. The report must include issues of non-compliance with this and any other recommendations to improve the facility’s PDM QA program. The document must be signed and dated by the licensed medical physicist.
VII. Inspection Requirements

Registrants must have these elements ready before inspection begins:

1) Monitor with test pattern displayed
2) Monitor-cleaning solutions
3) Access to an external calibrated photometer
4) Documents indicating proof of compliance with the following:
   a) Acceptance Testing Report conducted for each PDM
   b) Bi-weekly testing
   c) Quarterly quality control reports
   d) Annual quality control reports
   e) Annual review of PDM program (by licensed medical physicist)
   f) Calibration report for external photometer (even if not owned by registrant)

Resources

To read the New York City Health Code regulations on radiation control, visit nyc.gov/healthcode and select Article 175.

For more information, call 311 and ask for Radiation Equipment or call the New York City Health Department’s Office of Radiological Health at 347-396-6000.