



Minimum Quality Assurance Requirements For Healing Arts Radiography

This document is intended for facilities that use diagnostic X-ray equipment in the healing arts, most of which do not have the resources of consultant or in-house medical physics support to implement a Quality Assurance (QA) program. Its purpose is to address frequently asked questions regarding the department's regulation, 25 Pa. Code Section 221.11(l), which requires facilities to have a QA program. A list of resources may be found at www.depweb.state.pa.us, keyword: Radiation Control, then click on "Radiation Control & Procedures." The document is titled, "Quality Assurance Resources For Use In Healing Arts Radiography." Registrants may request that the department recognize QA programs developed by other sources. If you know of a program established by an organization or source not included on our list, and believe it should be added, please contact us.

The quality of radiographic procedures is fundamental to the proper diagnosis and treatment of patients. A QA program is a set of management tools (procedures and controls) organized to optimize the clinical value of radiographic images for timely patient diagnosis while taking radiation exposure and impact to the imaging facility into consideration. An effective QA program helps to ensure that radiation exposure to the patients and operators of X-ray equipment is as low as reasonably achievable while providing efficient, consistent, high-quality diagnostic results. Experience indicates that the implementation cost of a basic QA program may reduce down time, waste and major repairs. Many insurance providers recognize the benefits of having their subscribers maintain a QA program and are now requiring them to have a program in place. Most professional organizations (e.g., American Association of Physicists in Medicine, American College of Radiology, American Chiropractic College of Radiology, etc.) have come to provide model QA programs and generally agree on what aspects are necessary components of a QA program. Many also provide forms that will help in satisfying the documentation requirements of the QA regulation.

Registrants have the option of adopting a complete QA program that was promulgated by a professional organization recognized by the department, or using component parts and the provisions here to customize one of their own. This approach allows for flexibility, especially in areas where state-of-the-art equipment and procedures are used prior to the adoption by recognized professional organizations of related standard quality assurance protocols. Should a facility elect to develop its own QA program, it would be beneficial to review the resources and protocols currently approved by the department so that all the essential components are included in the QA program. For the time being, the equipment manufacturer or a consulting medical physicist may be the best resource for establishing QA measures for applications involving advanced imaging technologies like computed or digital radiography.

The regulations require that registrants maintain records of their QA program for three years. These records should be sufficiently detailed to enable the department to reconstruct all QA activities associated with X-ray operations. Inspections by the Bureau of Radiation Protection will include a full review of each facility's written QA program description and procedures, test results and actions.

Minimum QA Program Elements

There are a minimum number of program elements to address in a basic QA program. The first is documentation or records to demonstrate compliance. There must be a written description of the QA program. It will be helpful to organize a loose-leaf binder or electronic folder as a QA manual to record the program description as well as test results, observations and associated Quality Control (QC) activities. The manual should contain tables and checklists to identify when QC functions occur and to record the results. Next are the standards or action levels used to assess quality and trigger any necessary corrective action. The quality of images (clinical value) and patient safety are most important. Several aspects of the image and imaging media need to be evaluated. They include contrast, density, fog, artifacts and coverage of the clinical area. These aspects help identify problems associated with the image recording media, image processing or the X-ray operation. For safety, establish and adhere to optimum exposure technique settings. When these settings no longer yield clinical quality images, the cause must be investigated and resolved.

The regulations also specify certain areas that must be addressed in the QA program, which include the following:

Repeat Rate: Establish a system to record the occurrence of repeat X-rays and the reason why the X-rays had to be retaken. This may identify equipment, operator or technique problems.

Image Recording, Processing and Viewing: If X-ray film is used for imaging, develop it using the time/temperature recommended by the film or chemistry manufacturer. Improperly developed film reduces diagnostic quality and often results in higher radiation exposures as a result of underdevelopment. Instant developer or forced processing should be avoided except where minimal clinical quality is required. Follow a consistent processing protocol. Avoid varying development parameters to adjust image characteristics like density, contrast and latitude. Other means are available to adjust the image such as anatomy compensation filters, wide latitude film or varying kVp. Mix, store, replace and replenish processor chemistry as the manufacturer recommends. Adjust replenishment to compensate for oxidation, heat and unusually low or high film use. Periodically clean and maintain automatic processors and manual tanks. Keep the darkroom clean and light tight. Pay particular attention to the area around the door, wall, ceiling fixtures and panels. Check that the safelight has the filter, bulb wattage and mounting distance recommended by the film manufacturer and no white light leakage. (*Also refer to DEP's Fact Sheet "Darkroom Fog."*) Store film and loaded cassettes in a shielded area with temperature and humidity levels as recommended by the film manufacturer. Clean cassettes and screens periodically and evaluate for artifacts.

Check the image-viewing environment. Ambient light levels affect perceived contrast and reader fatigue. For film, use view boxes with uniform light of the correct color and intensity. Use opaque film mounts and mask unused areas of the view box to prevent peripheral glaring.

Maintenance and Modifications to the QA Program: The QA program needs to be reviewed at least annually and modified as needed. Equipment can be expected to perform as intended only if adequately maintained and supported. At a minimum, periodically check the X-ray beam collimation and positioning stability and perform maintenance recommended by the manufacturer. Remember that the program consists of human elements as well as equipment and procedures. Ensure that personnel are adequately trained and supported to perform the QA activities. Periodically evaluate operator performance and ensure that continuing education requirements are met.

Records of the QC activities conducted under the QA program should be filled out promptly and legibly. Any changes to the records should be made such that the original entry remains legible. The individual making changes to the records should also initial and date the change.

If you have questions regarding the quality assurance requirement, or other aspects of radiation safety, please contact the Radiation Control Program staff in your region.

Northwest Region

230 Chestnut St.
Meadville, PA 16335-3481
Main Telephone: 814-332-6945
24-Hour Emergency: 1-800-373-3398

Northcentral Region

208 W. Third St., Suite 101
Williamsport, PA 17701
Main Telephone: 570-327-3636
24-Hour Emergency: 570-327-3636

Northeast Region

2 Public Square
Wilkes-Barre, PA 18701-1915
Main Telephone: 570-826-2511
24-Hour Emergency: 570-826-2511

Southwest Region

400 Waterfront Drive
Pittsburgh, PA 15222-4745
Main Telephone: 412-442-4000
24-Hour Emergency: 412-442-4000

Southcentral Region

909 Elmerton Ave.
Harrisburg, PA 17110
Main Telephone: 717-705-4700
24-Hour Emergency: 1-877-333-1904

Southeast Region

2 E. Main St.
Norristown, PA 19401
Main Telephone: 484-250-5900
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For more information, visit www.depweb.state.pa.us, keyword: Radiation Protection.