pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

Minimum Quality Assurance Requirements for Healing Arts Radiography

This document is intended for facilities that use diagnostic X-ray equipment in the healing arts and for those which do not have the resources of a 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 of Environmental Protection's (DEP) regulation, 25 Pa. Code Section 221.11(l), which requires facilities to have a QA program.

The quality of radiographic procedures is fundamental to the proper diagnosis and treatment of patients. A QA program is a set of procedures and controls organized to optimize the clinical value of radiographic images for timely patient diagnosis. 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, and high-quality diagnostic results. Most professional organizations (e.g., American Association of Physicists in Medicine, American College of Radiology, American Chiropractic College of Radiology, etc.) provide model QA programs and generally agree on the necessary components of a QA program. Many also provide forms that will help in satisfying the documentation requirements of the QA regulation. The Conference of Radiation Control Program Directors (CRCPD) published Quality Control Recommendations for Diagnostic Radiography Volumes 1, 2, and 3. These three guides provide a model program and instruction for establishing and maintaining a QA program in dental, podiatry, and radiographic/fluoroscopic facilities other than mammography, respectively. For mammography, DEP recognized a QA program that meets the requirements of federal FDA regulations in 21 CFR Part 900 as being in compliance with 25 Pa Code Section 221.11(l).

Registrants have the option of adopting a complete QA program that was promulgated by a professional organization recognized by DEP or using component parts and identified provisions to customize one of their own. Should a facility elect to develop its own QA program, it would be beneficial to review the resources and protocols currently approved by DEP so that all the essential components are included in the QA program. 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 five years. These records should be sufficiently detailed to enable DEP 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 including description and procedures, test results, and actions.

A list of resources may be found at www.dep.pa.gov. Registrants may request that DEP recognize QA programs developed by other sources. If there is a program established by an organization or source not included on the list and justification can be provided for it to be added, please contact DEP.

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. Aspects of the image and imaging media to be evaluated 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.

Diagnostic Reference Level (DRL): An investigational level, set as a standard by a recognized body (for example, the American College of Radiology, the American Association of Physicists in Medicine, the National Council on Radiation Protection and Measurements or similar), used to identify unusually high radiation doses for common diagnostic medical X-ray imaging procedures. DRLs are suggested action levels above which a facility should review its methods and determine if acceptable image quality can be achieved at lower doses. DRLs should not be applied to an individual patient.

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. 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 kilovoltage (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.

Those facilities who acquire images using Computed Radiography (CR) or Digital Radiography (DR) equipment shall establish and follow an image QC program in accordance with the recommendations of a Qualified Medical Physicist (QMP), the system manufacturer, or a nationally recognized organization as per 25 Pa. Code § 221.50. When exposure indicators are available, the facility shall establish, document, and post an acceptable range for the exposure values for examinations routinely performed at the facility. The indicated exposure values for each image shall be compared to the established range. Consistent deviations from established ranges shall be investigated, corrective actions taken as necessary, and results documented. Evaluation of patient exposure and exposure index numbers from representative exams to avoid dose creep is important for patient exposure safety. CR facilities shall erase all CR cassettes, at a minimum, on a weekly basis. Facilities other than dental, podiatric, and veterinary shall complete phantom image evaluation using a phantom approved by a QMP, system manufacturer, or DEP. The evaluation shall be completed on a quarterly basis and include, at a minimum, all of the following: artifacts, spatial resolution, contrast/noise, workstation monitors, and exposure indicator constancy. The CRCPD Publication No. E-10-2, the American Association of Physicists in Medicine Report No. 93, and the New York State Department of Health Recommended Guidelines can be referenced to assist in the development of a QC program for a CR/DR system.

The regulations for Cone Beam Computed Tomography (CBCT) units can be found in Pa Code Title 25, Chapter 221.64: 25 Pa. Code § 221.64. CBCT (pacodeandbulletin.gov). The registrant shall document and implement QC guidelines in accordance with nationally recognized guidelines. A policy addressing deviations from established protocols shall be maintained. A performance evaluation shall be performed by or under the direct supervision of a QMP or Qualified Expert (QE). The evaluation shall be performed within 30 days of initial installation, at intervals not to exceed 14 months, and within 30 days after any change or replacement of components which could cause a change in the radiation output or image quality.

CBCT systems are exempt from Chapter 221.202(a) (relating to equipment requirements).

Computed Tomography (CT) systems used solely to calculate attenuation coefficients or for image reconstruction in nuclear medicine studies must meet the requirements as stated in Pa Code Title 25 Chapter 221.65. 25 Pa. Code § 221.65. X-ray attenuation systems. (pacodeandbulletin.gov).

Chapter 221.204 contains the regulations for CT performance evaluations, routine QC and surveys. 25 Pa. Code § 221.204. Performance evaluations, routine QC and surveys. (pacodeandbulletin.gov)

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, as well as perform manufacturer-recommended maintenance. 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, and records retained.

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.

For questions regarding the QA requirement or other aspects of radiation safety, please contact the responsible DEP Regional Office for your location.

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For more information, visit www.dep.pa.gov.