

Model Quality Assurance Program Guidelines for Dental, Diagnostic Radiology and Mammography

In January 2019, the Department of Environmental Protection (DEP) amended 25 Pa. Code Section 221.11(l), related to X-ray equipment registrant responsibilities, to require registrants to have a Quality Assurance (QA) program. The revised regulation states: *“The registrant shall have a quality assurance program. This quality assurance program shall be documented and be in accordance with guidelines established by the Department or by another appropriate organization recognized by the Department. At a minimum, the quality assurance program shall address repeat rate, DRLs, image recording, processing and viewing, image quality and artifacts, and maintenance and modifications to the quality assurance program. For CT, each study shall be checked. If an artifact is present, the registrant shall take corrective action as appropriate. Records shall be maintained by the registrant for inspection by the Department for 5 years. The Department’s guidelines and a list of recognized organizations will be maintained and made available on the Department’s website and on request.”*

A review of available Quality Control guidelines for developing QA programs in dental and medical facilities using dental and diagnostic X-ray equipment revealed that numerous professional organizations have published articles on the subject, and all generally agree on what tests are essential in a model QA program. Because of the broad consensus, DEP has selected the Conference of Radiation Control Program Directors’ (CRCPD) *Quality Control Recommendations for Diagnostic Radiography Volumes 1, 2, and 3* as acceptable reference documents for QA programs. 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.

To ensure compliance with the above-noted regulation, it is recommended that X-ray equipment registrants acquire the appropriate manual for their facility and review it for applicability to onsite X-ray equipment and image processing activities. This is particularly important for facilities that have not established and documented a QA program.

The CRCPD is a nonprofit professional organization whose primary membership is made up of radiation safety and control professionals in state and federal government who regulate the use of radiation sources such as dental and diagnostic X-ray equipment. Other members include individuals with an interest in radiation protection.

In cooperation with the Food and Drug Administration’s (FDA) Center for Devices and Radiological Health, the CRCPD developed the above-noted manuals. It is important to note that the manuals were peer-reviewed by representatives of the American Dental Association, American Podiatric Medical Association, American Association of Physicists in Medicine, American College of Radiology, and other individuals with expertise in the field of radiation protection, diagnostic radiology, and quality control and quality assurance.

DEP endorses the use of these manuals and would consider facilities that utilize them for their QA program as being in compliance with our regulatory requirements. For mammography, DEP recognizes 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).

Lastly, it is recognized that implementation of a QA program very often improves image quality and reduces patient radiation exposure. DEP’s approach during routine inspections is to initially provide compliance assistance when QA program deficiencies are observed. However, enforcement action may be pursued if fundamental deficiencies are not corrected.

A list of resources that includes the CRCPD documents listed previously may be found at www.dep.pa.gov. The FDA guidance and requirements for mammography may be accessed at www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/default.htm.

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

**For more information,
call the DEP regional office in your area or contact:**

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