Diagnostic X-Rays and Associated Imaging Systems in the Healing Arts

216-RICR-40-20-4

Benefit-Cost Analysis

January 2022

The Rhode Island Department of Health (RIDOH) is amending the regulations pertaining to Diagnostic X-Rays and Associated Imaging Systems in the Healing Arts (216-RICR-40-20-4) to adopt the most current revision to Part F of the Suggested State Regulations for the Control of Radiation, *Medical Diagnostic and Interventional X-Ray and Imaging Systems*, published by the Conference of Radiation Control Program Director's, Inc. The proposed changes include renaming 216-RICR-40-20-4 to *Medical Diagnostic and Interventional X-Ray and Imaging Systems* to better reflect the scope of the amended regulation.

Background

The various parts of the Suggested State Regulations for the Control of Radiation published by the Conference of Radiation Control Program Director's, Inc. are developed by teams which include members from various state radiation control programs, federal agencies, and representatives of various professional organizations with expertise in the subject matter (e.g., ABR, AAPM). The draft of a major revision is prepared on the basis of all available resources, including standards and experts in the field, and is sent out for review and comment to those groups indicated above. The comments are analyzed by the working group for that part and a revised draft is prepared on the basis of the analysis of comments. A Regulations Overview Committee (ROC), composed of representatives of CRCPD and the participating Federal agencies, conducts the final review of each of the revised parts and rationale and the analysis of comments. Each of the participating groups is then asked to concur in the final draft.

216-RICR-40-20-4 establishes requirements, for which a registrant is responsible, for use of diagnostic X-ray equipment and associated imaging systems in the healing arts or veterinary medicine. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of Subchapter 216-RICR-40-20. Although the regulations do establish technical specifications for the use of diagnostic X-ray in the healing arts, the fundamental purpose of these regulations is to ensure that patients do not receive exposure to ionizing radiation beyond what is medically necessary for diagnosis and treatment. The regulations also include requirements which are designed to minimize radiation exposure to medical personnel who are conducting radiographic imaging.

Status Quo

Other than the renumbering required by conversion to the RICR format in 2019, this Part has not been amended since 2013. However, during this period the technology associated with the use of diagnostic X-ray has evolved to include applications which were not anticipated under the current regulations and/or cannot be effectively regulated under the status quo.

Proposed Regulation

The extent of changes to 216-RICR-40-20-4 is described in the *Concise Statement of Proposed Non-Technical Amendments* document for this rulemaking. However, the areas which have the most significant impact are the addition of requirements for training, computed tomography (CT)/cone beam computed tomography (CBCT) units, interventional radiology, digital imaging, quality control programs, and the consolidation of all requirements for use of dental X-ray into a single section.

§ 4.3.3(C) & (D) specify the required training for individuals who will use, or supervise the use of, fluoroscopic equipment. The amended regulations provide more specificity than the current regulations with regard to required training but do not impose any substantial additional burden. Fluoroscopy training is primarily an issue in hospitals (because that is where the majority of the complex fluoroscopic procedures are performed). However, because of JCAHO and other requirements most hospitals already have some type of credentialing program in place for individuals performing fluoroscopy. The amended regulations will standardize all future training and minimize the need for additional cross training as individuals move from facility to facility. The requirement in § 4.3.3(E) that this training be provided by a Qualified Medical Physicist or another individual approved by the Agency should not impose any significant additional burden because the training is typically presented by a medical physicist or a company tech rep. However, the intent of this requirement was to make it clear that this is not the type of instruction to be conducted by a facility's "training officer" or other individuals without adequate qualifications.

§ 4.3.3(H) establishes a more specific requirement for training of individuals who will operate dental X-ray equipment. It replaces a more general requirement to provide training to individuals before allowing them to operate X-ray equipment. However, the extent and type of training varied significantly from facility to facility. This standardizes the content of the required training.

§ 4.3.7, which required the use of gonadal shielding, has been deleted. This change is consistent with the latest research in the field and is endorsed by all of the relevant professional groups (e.g., ABR, AAPM).

§ 4.3.10(E) establishes the requirements for X-ray film processing. However, the use of film (analog) for diagnostic imaging has been replaced by digital imaging for virtually all applications. This section is being amended and retained to cover those few legacy situations where film (analog) imaging is still being used. § 4.3.10(J) establishes comparable requirements for use of digital imaging and does not impose any significant additional burden in terms of "new" requirements.

§ 4.4 establishes general requirements for interventional X-ray systems. Interventional X-ray is an emerging technology that is not specifically addressed in the current regulations. Interventional X-ray is a subset of fluoroscopy and would be regulated as such under the current regulations. However, interventional X-ray is significantly distinct from traditional fluoroscopy and needs its own set of regulations. Therefore, there would be no "new" facilities regulated under these requirements. Most interventional X-ray facilities are hospital-based and are subject to facility credentialling requirements (already mandated by JCAHO and other credentialing organizations) which should not be significantly different from these proposed regulations.

§ 4.5.1(B) specifies that only image-intensified or direct-digital receptor fluoroscopic equipment shall be used for fluoroscopy. While this is new regulatory text, it does not impose any additional

regulatory burdens. Early generation fluoroscopes were direct read where all of the X-rays went through the patient to the individual viewing the fluoroscope. This often led to fairly high exposures for those involved in the procedure. All current generation fluoroscopes involve an indirect read via some type of screen or image capture device. This requirement essentially prohibits use of equipment that should only be found in a museum and not in regular clinical use.

§ 4.7.1(A)(1) requires all diagnostic CT X-ray equipment for human use shall be accredited by an accrediting organization recognized by the Agency unless otherwise authorized by the Agency. The Department does not believe this imposes any additional regulatory burden because CT equipment is also subject to CON regulations [216-RICR-40-10-22] and participation in an accreditation process is typically a condition of CON approval. Therefore, it is the Department's understanding that all facilities currently have the required certification. However, there is sufficient "wiggle room" in the requirement to address unusual situations on a case-by-case basis.

§ 4.7.5 requires the establishment of a Radiation Protocol Committee (RPC) for all CT facilities. While this is a new requirement in these regulations, the Department doesn't believe this constitutes an unreasonable additional regulatory burden because most facilities would already have a similar credentialing committee because of JCAHO or other accreditation requirements. Furthermore, §§ 4.7.5(A)(2), (A)(3) and (A)(4) provide options which can reduce duplication of effort with regard to the RPC.

§§ 4.7.4, 4.7.6 and 4.7.7 specify that CT systems used for treatment planning in radiation oncology, PET, and SPECT and veterinary applications are only subject to a limited subset of the requirements applicable to CT systems used in typical clinical applications. These specific exemptions are only available as an interpretation under the current regulations.

§ 4.7.8 establishes general requirements for cone beam computed tomography System (CBCT) X-ray systems. CBCT is an emerging technology that is not specifically addressed in the current regulations. CBCT X-ray is a subset of CT and would be regulated as such under the current regulations. However, CBCT X-ray is significantly distinct from traditional CT and needs its own set of regulations. Therefore, there would be no "new" facilities regulated under these requirements.

§ 4.10 currently establishes general requirements for quality control (QC)/quality assurance (QA) of X-ray systems. These requirements are a more detailed version of what exists under the current regulations. These requirements represent a "best practices" standard for the industry. In theory, most facilities should already have had their medical physicist (consultant or in-house) develop a QA program that incorporates most of these elements. These QA requirements are consistent with what is recommended by AAPM for an effective QA program. The incremental cost for compliance with these requirements would depend on exactly what QA programs have already been put in-place by their medical physicist. Consequently, it would be difficult to come up with a one size fits all answer. However, using some very "broad brush" assumptions, the total cost (not incremental cost due to new regulations) of implementing a QA/QC program can be calculated as follows:

- Recordkeeping and performing daily QA/QC tests: Radiologic Technologist – 0.25-0.5 hour/day @ $35.64/hour[1] [$2,300- $4,600/year].
- Medical physicist quarterly/annual audit: 4 hours/quarter @ $66.74/hour + additional 8 hours for annual report @ $66.74/hour [$1,600/year].

The numbers would be slightly different for dental facilities:

- Recordkeeping and performing daily QA/QC tests: Dental Assistant – 0.25-0.5 hour/day @ $23.24/hour [$1,450-$2,900/year].
- Facility QA/QC activity review by dentist: 2 hours/quarter @ $120.18/hour + additional 8 hours for annual report @ $120.18/hour [$ 1,200/year].

§ 4.14 establishes requirements for dental X-ray facilities. Prior to the 2013 amendments, the regulations contained a specific section for dental X-ray. When the current regulations were adopted in 2013, the requirements for dental X-ray were merged into the more general requirements. However, it was subsequently determined that dental X-ray should have its own section. § 4.14 consolidates all of the dental X-ray requirements. There are no significant changes from what is required under the current regulations. Specifically with regard to QA, the new regulations provide more specific detail compared with what is currently required.

Alternatives

Although there may be slight incremental costs associated with implementation of these proposed amendments, these costs are outweighed by the benefits of protecting patients, medical staff, and the public from the harmful effects of ionizing radiation. In addition, the Department believes that these proposed amendments do not pose an unreasonable regulatory burden on the regulated community. Therefore, the Department does not believe there are any viable alternatives to the proposed amendments to 216-RICR-40-20-4. By adopting the most current revision to Part F of the Suggested State Regulations for the Control of Radiation, *Medical Diagnostic and Interventional X-Ray and Imaging Systems*, published by the Conference of Radiation Control Program Director's, Inc., the Department will be implementing a national consensus "best practices" standard that has already been adopted by many other state radiation control programs. Furthermore, as noted previously, since these regulations were last amended in 2013, the technology associated with the use of diagnostic X-ray has evolved to include applications which were not anticipated under the current regulations and/or cannot be effectively regulated under the status quo.

Determination

Based on the above analysis, the Department has determined that the current proposed amendments to 216-RICR-40-20-4 provide the only viable regulatory solution to carry out its statutory mandate for the protection of the public health and safety by developing policies and programs for evaluation of hazards associated with the use of radiation sources and for their amelioration [RI Gen. Laws § 23-1.3-2(c)].

[1] All salary data based on Bureau of Labor Statistics (BLS) May 2020 Metropolitan and Nonmetropolitan Area Occupational Employment and Wage Estimates for Providence-Warwick, RI-MA, where available, otherwise based on best available BLS regional/national data. [https://www.bls.gov/oes/current/oes_77200.htm]