April 2, 2023

Trevor Squirrell
LCAR Committee Chair
Montpelier, VT

Re: rule No. 22-P42 Radiological Health Rule Part A

Dear Mr. Squirrell:

We are board certified diagnostic imaging medical physicists each with over 25 years of experience performing quality assurance on X-ray medical imaging equipment in Vermont as well as multiple other states at different stages in our careers. We believe we are the only two medical physicists living and working in Vermont whose primary job responsibilities are focused on quality assurance of medical imaging X-ray equipment. As such, we have particular insight on section of 8 of part A of the Radiological Health Rule and how it can be updated to provide better image quality for patients as well as reduce costs.

The current regulations are overdue for an update, and we were happy to be included in a number of preliminary discussions with the Dept. of Health regarding an earlier draft of the rules. We support the majority of the proposed draft now being considered. However, there are two small changes that will significantly improve the regulations, reduce cost and provide better/consistent image quality for patients.

It was our understanding from our discussions with the Dept. of Health that an "or" was going to be included at the end of 8.12.5.1.1. Note, that "and/or" is present in the line below it, which probably implies an "or" in the line above, but leaves it somewhat open to interpretation. Either way, "or" is appropriate and should be added at the end of 8.12.5.1.1. Doing so will eliminate confusion about if duplicative testing programs are required, i.e. the manufacturer's recommendations plus another comprehensive quality assurance program.

8.12.3.2.1 should be edited as in the attached document. The draft, as written, replaces universal standards that place the priority on patient care with a standard that will vary by machine based on the whims of the manufacturer. It is our strong belief that the standard practice for Quality Assurance for medical imaging equipment should remain patient focused with universal standards.

More specifically, the regulation, as currently written, requires searching for every X-ray unit through manuals that are typically hundreds of pages long for manufacturer recommendations. That will take time, and therefore add cost, for both the owners of the equipment and for the state in determining compliance with the regulation. This could be particularly time consuming for units for which the manufacturer hasn't made recommendations as it is typically more challenging to prove that something doesn't exist than to prove that it does.

However, the primary reason 8.12.3.2.1 should be changed is it is contrary to how quality assurance is done for medical imaging equipment. The professional practice is to set standards that all medical X-ray equipment must meet. It is the standard that is used throughout the country by medical physicists. It is the approach of all the major national radiological organizations use, including the American Association of Physicists in Medicine (AAPM), the American College of Radiology (ACR), the National Council of Radiation Protection and Measurements (NCRP), the Radiological Society of North America (RSNA) etc. Numerous books and publications advocate for this methodology, including NCRP 99, the ACR quality assurance manuals, "Quality Management in the Imaging Sciences" etc.

This approach is PATIENT FOCUSED. It aims to assure good image quality at a reasonable dose for all patients for all equipment. The quality of the exam a patient receives shouldn't be dependent upon the machine they happen to have assigned to them to take their images. What matters is the quality and quantity of X-rays used to form the image, not which manufacturer's machine produced the X-rays.

The proposed regulation, as currently written, instead focuses on the equipment itself. Manufacturers have financial incentives that may or may not always be aligned with optimal patient care. The regulation, as currently written, forces the manufacturer's recommendation to become the standard that must be used. It allows for different standards for X-ray rooms performing the very same function. Manufacturers are experts at what they do, i.e. making X-ray equipment. However, they are not necessarily experts in patient care and image quality. Hospitals and the qualified medical physicists they employ, on the other hand, are experts in these areas.

We hope that you will make the two adjustments that we have suggested so Vermonters can continue to benefit from them being the primary focus of the quality assurance programs of their medical X-ray exams. If not, we recommend the proposed rule be shelved this year so that there can be more time to address these concerns and the fundamental approach used. A change of this fundamental and significant should not be done without overwhelming justification, none of which exists or has been provided.

Sincerely,

Dan Beideck

Dan Beideck, M.S., DABMP

Arthur J. Savard, PhD, DABMP

Cardinal Medical Physics Services

Radiological Health Rule

8.12. Special Requirements for General Purpose Radiographic Equipment

8.12.1. Administrative Controls

8.12.1.1. In addition to the provisions of Sections 8.2 through 8.11, the requirements of this Section apply to all x-ray imaging equipment and associated facilities other than:

8.12.1.1.1. Fluoroscopy (in Section 8.13);

8.12.1.1.2. Dental (in Section 8.14);

8.12.1.1.3. Handheld Diagnostic (in Section 8.15)

8.12.1.1.4. Veterinary (in Section 8.16);

8.12.1.1.5. Computed tomography (in Section 8.17);

8.12.1.1.6. Mammography (in Section 8.18)

8.12.1.1.7. Bone densitometry (in Section 8.19)

8.12.2. For each general purpose stationary, mobile, and/or portable x-ray imaging system subject to the requirements of this Section, the useful beam shall be limited to the area of clinical interest.

8.12.3. Radiation Exposure Control Devices

8.12.3.1. X-ray Control

8.12.3.1.1. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:

8.12.3.1.1.1. Exposure of one-half second or less, or

8.12.3.1.1.2. During serial radiography when a means shall be provided to permit completion of any single exposure of the series in process.

8.12.3.1.2. Except for a bone densitometry system, each x-ray control shall be located in such a way as to meet the following requirements:

8.12.3.1.2.1. For stationary x-ray systems, the x-ray control shall be permanently mounted in a

separated area behind a whole body protective barrier, as described in shielding plan, where the operator is required to remain during the entire exposure. If no barrier is described in the shielding plan, then not less than 0.25 millimeter lead equivalent shall be used.

8.12.3.1.2.2. Mobile and portable x-ray systems shall be required to have an exposure switch so arranged that the operator can stand at least 2 meters (more than 6 feet) from the patient, the x-ray tube, and the useful beam, or behind a whole body protective barrier (of not less than 0.25 millimeter lead equivalent) where the operator is required to remain during the entire exposure.

8.12.3.1.3. The settings to be used during an exposure shall be indicated before the exposure begins.

8.12.3.1.3.1. When automatic exposure controls are used, the exposure settings that are set prior to the exposure shall be indicated.

8.12.3.1.3.2. On equipment having fixed exposure settings, permanent markings visible from the operator's position are acceptable.

8.12.3.2. Accuracy for a Diagnostic X-ray System with Any Certified Component

~~8.12.3.2.1. If manufacturer recommendations regarding~~

8.12.3.2.1. ~~exposure settings are available, those shall be followed.~~

8.12.3.2.2. ~~If manufacturer recommendations are not available,~~ the following minimum criteria shall be used:

8.12.3.2.2.1. The kVp shall not deviate from indicated values by more than 7%.

8.12.3.2.2.2. The timer accuracy shall not deviate from indicated values by more than:

8.12.3.2.2.2.1. Ten percent for an indicated time of greater than 20 milliseconds; or

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8.12.3.2.2.2.2. Fifty percent for an indicated time of 20 milliseconds or less, or 1 pulse, whichever is greater.

~~8.12.3.2.2.2.2.~~8.12.3.2.3. For new technology or in unique applications of existing technology, manufacturer recommended criteria may be followed if the preceding criteria is inappropriate in the view of the Qualified Medical Physicist.

8.12.4. For each general-purpose x-ray imaging system, the registrant shall ensure that manufacturer maintenance recommendations are followed.

8.12.5. For each general-use diagnostic radiographic x-ray system, the registrant shall ensure that written quality control and quality assurance procedures are available and in use, including for facility operations and emergencies.

8.12.5.1. The quality control and quality assurance procedures shall be consistent with Section 8.10 and shall follow:

8.12.5.1.1. Recommendations of the manufacturer; or

8.12.5.1.2. Recommendations of a Qualified Medical Physicist; ~~and~~/or

8.12.5.1.3. Standards of one of the following nationally recognized organizations:

8.12.5.1.3.1. The American College of Radiology; or

8.12.5.1.3.2. The American Association of Physicists in Medicine; or

8.12.5.1.3.3. NCRP; or

8.12.5.1.3.4. The Joint Commission

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