April 24, 2023

Trevor Squirrell
LCAR Committee Chair
Montpelier, VT

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

Dear Mr. Squirrell:

We've copied below the email that we sent to the Dept of Health offering further information and compromises following the LCAR meeting on April 13, 2023. As you can see, we offered to drop one of the two objections we raised. We also offered an alternative option for the other concern that we hoped would be acceptable to the state.

Several references from nationally recognized expert organizations and textbooks were presented that backed up the approach in current use by board-certified medical physicists throughout the United States that use universal standards as the appropriate standard of patient care. We also sent copies of the pertinent pages from those sources with relevant information highlighted at the Dept of Health's request. Unfortunately, it appears the Dept of Health has decided to reject either of the options suggested and instead has proposed one that makes no meaningful change.

Sincerely,

Dan Beideck, M.S., DABMP

Arthur J. Savard, PhD, DABMP
Cardinal Medical Physics Services

----------Email sent to Dept of Health----------

The Dept of Health has indicated that it believes MQSA provides justification for requiring manufacturer recommendations to be used as QC requirements. However, MQSA requires kVp accuracy to be within 5% for all manufacturers models that were in use at the time MQSA was passed. That was regardless of any possible separate manufacturer recommendations (21 CFR 900.12.e.5.ii). The dept has noted that MQSA does say that manufacturer recommendations/QC shall be followed at some point. However, that only applied to new mammography modalities, e.g. digital mammography, which had not yet been

fully developed or approved by the FDA for use yet. The FDA couldn't put QC requirements on something that didn't yet exist. So, they included manufacturer's recommendations knowing that manufacturers would have to submit their equipment to the FDA for approval. The FDA also required manufacturers to submit their recommendations/QC program along with their application. Thus, the FDA had oversight and the ability to approve or reject any recommendations beforehand. I believe the kVp accuracy requirement remains at 5% for all digital mammography machines the FDA has approved.

The edit that I have proposed for 8.12.3.2 follows the MQSA model. It uses the criteria suggested by the state, e.g. kVp accuracy within 7%. However, it also provides the ability to use manufacturer's recommendations for new technology or if the universal criteria is for some other reason inappropriate in the view of the QMP.

The above discussion is for mammography. However, the proposed state regulations in question apply to "general purpose radiographic equipment", which does not include mammography. The FDA, for its part, has no QC requirements for this equipment. Those requirements apply only to mammography. As such, manufacturers don't need to submit QC recommendations as part of the approval process. Unlike mammography, manufacturers are free to recommend what they like without outside oversight.

The practice by QMPs and expert national organizations is to use universal criteria. The fact that this is the standard for annual quality assurance by experts in the field for X-ray equipment should be taken as evidence that this is an appropriate approach unless there is overwhelming evidence to suggest otherwise. I don't believe that evidence exists. Here are a few examples in published works that support the approach of using universal criteria:

- "Quality Control in Diagnostic Imaging" page 106.
- "Quality Management in the Imaging Sciences" p 86.
- "Radiologic Physics, Equipment and Quality Control" p246.
- AAPM "Acceptance Testing of Radiological Imaging Equipment" table III, p123
- NCRP report No. 99 "Quality Assurance for Diagnostic Imaging" table A.2, p195
- ACR "Mammography Quality Control Manual" p272

I believe the current dept of health personnel when they say they will be flexible interpreting the regs. However, the proposed regs are very likely to outlive all of us in our current positions and what we are left with is what's in the regs. 8.15.3.2.1 says "If manufacturer recommendations regarding exposure settings are available, those shall be followed." The word "shall" is pretty clear. Future readers of this reg aren't going to know the history of our conversations, and I suspect are likely to have a much less flexible interpretation, e.g shall = must. Let's make sure the regs have the necessary flexibility built into them.

I believe the edits I have submitted for 8.12.3.2 achieve the end result that both of us desire. I will offer a second alternative that might also work. Add "or" to the end of 8.12.3.2.1 and strike "If manufacturer recommendations are not available" from 8.12.3.2.2 so that it reads as follows:

8.12.3.2.1 If manufacturer recommendations regarding exposure settings are available, those shall be followed **OR**

8.12.3.2.2 The following minimum criteria shall be used:

The bottom line for me is that QMPs should be able to unambiguously and clearly within the regulations be able to continue the practice of applying universal criteria for general practice radiographic equipment in the state as they currently do and other QMPs do throughout the country. This approach has a long history and has been established by decades of experience and recommendations by experts in the field. This is not possible the way the current regulations are worded without a very flexible interpretation that I fear will not stand up over time. I believe the first edit I suggested is the best option. However, I could also accept the second alternative suggested in this email if the dept prefers that one.

I understand the Dept of Health interprets 8.12.5.1.1 to have an implied “or” at the end. I think it would remove any ambiguity to have an actual “or” included but will drop my objects if the dept wishes to keep it as is.

Please let me know if you are amenable to the suggestions I have put forth.