VERMONT
DEPARTMENT OF HEALTH

To: Representative Trevor Squirrell, Chair of the Legislative Committee on Administrative Rules

From: Brendan Atwood, Public Health Policy Advisor for the Vermont Department of Health

Re: Radiological Health Rule

Date: April 21, 2023

In accordance with the recommendation from the Legislative Committee on Administrative Rules (LCAR) to work with Mr. Dan Beideck, a Diagnostic Medical Imaging Physicist, to clarify within section 8.12.3.2 of the Rule that the flexibility exists for a practitioner to utilize the criteria that is the most protective of patient health, the Department of Health (Department) offers the proposed amendment included below.

The following language in section 8.12.3.2.3 of the rule clarifies that the use of criteria that is more protective of patient health than those identified in the proceeding sections is permissible:

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

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

8.12.3.2.2. If manufacturer recommendations are not available, the following 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

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

8.12.3.2.3. <u>Criteria that is more protective of patient health than the criteria identified in section 8.12.3.2 may be utilized</u>.

Adoption of this rule will unambiguously enhance the protections for Vermont workers and the public with regards to the use of x-ray machines compared to the status quo. As noted by the Medical Physics Network Chief and the Radiation Safety Officer at the University of Vermont

Health Network in their letter of support for this proposed Rule, "*The use of electronically produced, non-radioactive, sources of ionizing radiation are by and large unregulated by the federal government and until now largely unregulated in Vermont. The amendments proposed to Part A of the Radiological Health Rule are a step in the right direction to ensure the safe and efficacious use of radiation for the treatment and diagnosis of disease.*"

The Department shares this perspective.

Attached please find the email correspondence between the Department and Mr. Beideck regarding this amendment, demonstrating the Department's good faith effort to work with Mr. Beideck to address his specific request to make the flexibility to utilize criteria that are more protective to patient health explicit in the Rule.

From: Beideck, Daniel
To: Atwood, Brendan
Subject: Re: reg followup
Date: Friday, April 21, 2023 1:37:15 PM

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I thought I responded in the last email. I don't believe the addition you proposed changes the substance of the issue. Since it doesn't address my concerns, I'm not in support of it.

Dan

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From: Atwood, Brendan <Brendan.Atwood@vermont.gov>
Sent: Friday, April 21, 2023 12:29:31 PM
To: Beideck, Daniel <Dan.Beideck@uvmhealth.org>
Cc: Mann, Littia (she/her) <Littia.Mann@vermont.gov>; Englander, David <David.Englander@vermont.gov>; Deeley, Matthew <Matthew.Deeley@uvmhealth.org>; Clements, Jessica <Jessica.Clements@uvmhealth.org>; Williams, Jason W. <Jason.Williams@uvmhealth.org>
Subject: RE: reg followup

Hi Dan,

I just wanted to provide one final opportunity for you to weigh in on whether you support or object to the proposed language included below. I will note for the record that this is the fourth time this request for your perspective has been made.

As a courtesy to you, and to make sure you are aware, this afternoon I plan to submit the amendment to LCAR along with this correspondence below so the committee understands the context of our engagement on this matter.

Best,
Brendan

From: Atwood, Brendan
Sent: Friday, April 21, 2023 8:36 AM
To: Beideck, Daniel <Dan.Beideck@uvmhealth.org>
Cc: Mann, Littia (she/her) <Littia.Mann@vermont.gov>; Englander, David <David.Englander@vermont.gov>; Deeley, Matthew <Matthew.Deeley@uvmhealth.org>; Clements, Jessica <Jessica.Clements@uvmhealth.org>; Williams, Jason <Jason.Williams@uvmhealth.org>
Subject: RE: reg followup

Hi Dan,

As we stated at LCAR, we share the perspective that the rule currently allows for the use of criteria that is more protective of patient health. The request from LCAR and from your email below was to

make that flexibility more explicit. We feel this language does that. Please let us know by noon today whether you intend to offer a clear opinion on whether you support this language, as I intend to file this amendment by COB today.

Best,
Brendan

From: Beideck, Daniel <Dan.Beideck@uvmhealth.org>
Sent: Friday, April 21, 2023 8:28 AM
To: Atwood, Brendan <Brendan.Atwood@vermont.gov>
Subject: Re: reg followup

Brendan

I'm not sure the added language effectively changes things. Most people realize that they can use stricter criteria than what's in the regs if they choose.

Dan

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From: Atwood, Brendan <Brendan.Atwood@vermont.gov>
Sent: Thursday, April 20, 2023 5:03:29 PM
To: Beideck, Daniel <Dan.Beideck@uvmhealth.org>
Cc: Mann, Littia (she/her) <Littia.Mann@vermont.gov>; Englander, David <David.Englander@vermont.gov>; Deeley, Matthew <Matthew.Deeley@uvmhealth.org>; Clements, Jessica <Jessica.Clements@uvmhealth.org>; Williams, Jason W. <Jason.Williams@uvmhealth.org>
Subject: RE: reg followup

Hi Dan:

We feel that this language most effectively ensures a prioritization of patient health. Please let us know if you agree and whether you can support this language.

Best,
Brendan

From: Beideck, Daniel <Dan.Beideck@uvmhealth.org>
Sent: Thursday, April 20, 2023 3:47 PM
To: Atwood, Brendan <Brendan.Atwood@vermont.gov>
Subject: RE: reg followup

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Brendan

I gather you don't like either of the two edits I proposed. Can you tell me what your objections are? Or to the methodology currently being used to test X-ray machines?

Thanks
Dan

From: Atwood, Brendan <Brendan.Atwood@vermont.gov>
Sent: Thursday, April 20, 2023 12:00 PM
To: Beideck, Daniel <Dan.Beideck@uvmhealth.org>
Cc: Mann, Littia (she/her) <Littia.Mann@vermont.gov>; Englander, David <David.Englander@vermont.gov>; Deeley, Matthew <Matthew.Deeley@uvmhealth.org>; Clements, Jessica <Jessica.Clements@uvmhealth.org>; Williams, Jason W. <Jason.Williams@uvmhealth.org>
Subject: RE: reg followup

Hi Dan,

Thanks for sharing these resources and your proposed language. After a careful review by myself and my colleagues, we are willing to propose the following amendment to the rule in order to clarify that patient safety is the priority. Please let me know by noon tomorrow whether you can support this language, as we are required to provide any proposed changes to the rule to LCAR by noon on Monday, and I will need to draft some documents prior to then.

Best,
Brendan

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8.12.3.1.

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

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

8.12.3.2.2. If manufacturer recommendations are not available, the following 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

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

8.12.3.2.3. Criteria that is more protective of patient health than the criteria identified in section 8.12.3.2 may be utilized.

From: Beideck, Daniel <Dan.Beideck@uvmhealth.org>
Sent: Monday, April 17, 2023 8:13 AM
To: Atwood, Brendan <Brendan.Atwood@vermont.gov>
Subject: reg followup

Brendan

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.

Dan