X-ray Industrial Focus Group Meeting

MEETING MINUTES

Date: December 5, 2017

Location: Orville Freeman Building
645 Robert St. N.
Saint Paul, MN 55155

Attendees: Brad Hoium (Medtronic), Brett Muehlhauser (North Star Imaging, Service Provider), David Paulu (University of Minnesota), Michael Lewandowski (3M).

Via Conference Call: Wade Padrnos (Ridgewater University).

MDH: Bevin Beaver, Craig Verke, Jacquie Cavanagh, Kelly Medellin, Mary Navara, Teresa Purrington.

Acronyms and Terms

21 CFR – Title 21 of the Code of Federal Regulations

IFGM – Industrial Focus Group member

MDH – Minnesota Department of Health

Revisor – Office of the Revisor of Statutes

SSRCR – State Suggested Regulations for Control of Radiation

Welcome and Introductions

Mary Navara, Indoor Environments and Radiation Manager

Navara welcomed everyone.

Teresa Purrington, X-ray Program Supervisor

Purrington welcomed everyone, and introduced herself and MDH staff. Gave details regarding the rule writing research process, including looking at other state regulations and SSRCR. Asked the committee to introduce themselves. Explained how to submit comments on the Request for Comments webpage at http://www.health.state.mn.us/divs/eh/radiation/xray/rules/xrayrulerequest.html.

Rulemaking Update

Jacquie Cavanagh, Section Policy and Rules Analyst

Went through the Rulemaking Progress Chart. MDH published Request for Comments, and we are currently developing rules and SONAR as part of the process. Hoping to propose the rules in about a year. Reiterated the focus group role in the rulemaking process is not a decision making group; comments are taken under advisement. Will go through rule drafts at this meeting. The definitions document is a guide that will be reviewed by the Advisory Committee.

Teresa Purrington, X-ray Unit Supervisor

Referred to the Industrial Rule Revision hand-out outlining each system type that will be reviewed with the Focus Group and stated that today we will be focusing on Analytical and Cabinet X-ray Systems. She asked the focus group to let MDH know if any system types are missing from the hand-out.

Review of Non-Medical Analytical X-ray Rule Draft

Jacquie Cavanagh, Section Policy and Rules Analyst
Teresa Purrington, X-ray Unit Supervisor

Subp. 1. Applicability.

Michael Lewandowski (IFGM) asked about the rule organization, and questioned if it was based on usage. Cavanagh stated yes.

Subp. 2(b). Safety device.

Lewandowski stated that all we need is subitem (2), (subitem 1) seems redundant.

Subp. 3. Warning lights.

Purrington asked the group to distinguish between warning lights and warning devices. Lewandowski stated that warning lights is a switch next to the device. He stated that using the words "lights" or "devices" doesn't seem very useful. Brett Muehlhauser (IFGM) suggested using the wording "warning indicator".

Subp. 4. Warning devices.

Lewandowski stated this wording seems outdated, instead include "or words with similar meaning". Manufacturers from other countries use different wording. Group commented that each state has a differing date for compliance and this might be based on adoption of the state rules regarding fail-safe design.

Subp. 5. Beam ports.

Lewandowski stated that "port" is the part of the process where the beam is not intended. This definition seems the same as aperture, seems redundant. He suggested we should address the different language from the cabinet drafts and their definitions. Muehlhauser stated he read that differently. He suggested that it needs to be simplified, beam port versus chamber port. Keep the term Port, and have Beam Port and Enclosure Port under that definition.

Lewandowski pointed out that "radiation producing housing should be "radiation source housing".

Subp. 8. Labeling.

Lewandowski questioned the difference between subpart 8a and subpart 3a. Muehlhauser stated labeling is an indication of what's going to happen. Lewandowski stated there should be an inclusion of 3a in 8a. Not all equipment has that wording.

Subp. 9. Safety device evaluation.

Lewandowski questioned how to test the required emergency shut-off switches. Craig Verke (MDH) stated there should be some way to verify that it's functioning properly. Lewandowski stated that we would need some clarity as to how to perform this test. Muehlhauser stated that usually a stick or other non-biological sample is used to perform these types of tests. The manufacturer should be providing the means to perform this test. Verke stated we could ask registrants to establish administrative controls to prevent humans from crossing the beam. Purrington said that MDH will research this issue by contacting other states. David Paulu (IFGM) questioned subpart 9e. Muehlhauser stated that he confirms if the bulb is working, versus the whole 6 month check. Lewandowski stated that he thought subpart E was an extension of subpart D. It would make sense to do an evaluation if something needed to be prepared. Paulu doesn't have an issue if the evaluation was based on something that needed to be prepared, but doesn't agree with the 6 months.

Subp. 10. Radiation emission limit.

Purrington asked the focus group how MDH should refer to this part, radiation levels or radiation emission limit. Lewandowski stated that using radiation levels would suffice. He also questioned the wording for "maximum tube rating". He stated it should say "maximum operating parameters". Purrington stated this should be a definition, asked the focus group where we can find this definition. Muehlhauser (IFGM) stated that tube rating terminology is set by the manufacturer, and agrees with operating parameters. Brad Houim (IFGM) asked where 10a 2.5 mrem comes from. Purrington stated that this is consistent with other states and SSRCR. He stated that it could just say apply ALARA, or replace the wording "dose rate".

Subp. 13. Safety procedures.

Lewandowski questioned the wording of "must include" when SSRCR states "may include". He also stated the list of items in this subpart isn't necessary. These items are relatively obvious and there isn't an opportunity for unsafe conditions. He suggested that written procedures must be maintained. Paulu stated that bypassing is not allowed by the manufacturer, so it doesn’t need to be included. Lewandowski stated that lock out/tag out is regulated by OSHA and doesn't need to be noted here.

Purrington asked the focus group if it is a good idea to delegate radiation safety officer responsibilities to someone else onsite. Muehlhauser stated there should be something in their procedures for onsite responsibilities.

Subp. 14. Posting.

Paulu questioned the purpose of posting and what we're trying to convey. Muehlhauser asked if it would be sufficient to have a label on the control.

Subp. 15. Bypassing a safety device.

Muehlhauser asked when MDH is addressing training for each equipment type. Purrington stated MDH is just looking at the use of the equipment right now. The records and training will be at the end with the Advisory Committee. Paulu questioned "safety systems not working", should be "safety system has been bypassed". Lewandowski stated that the reference to subpart 12 is incorrect. Verke stated it should be subpart 13. Muehlhauser asked if this language is similar in other state regulations. Bevin Beaver (MDH) stated that ours is more detailed. Muehlhauser stated it should include the wording "authorized trained personnel". Lewandowski suggested that MDH remove many of the specifications and be similar to other states. He disagrees with too much specificity in the rules. Purrington stated MDH is getting feedback from registrants that they want more specificity. Lewandowski stated that this information could be provided in a guidance document, and not in the rule. Muehlhauser has suggested language. He stated that safety accidents occur when they bypass the safety device. Lewandowski stated that the rule should state to not do this, unless under certain circumstances. Cavanagh stated that the word "may" is often unclear in rulemaking, and the word "must" is generally preferable. She also stated that MDH cannot cite a registrant for information contained only in a guidance document.

Subp. 16. Repair or modification.

Purrington asked if this should be located in these draft rules or in cabinet draft rules. Lewandowski stated that most of these systems do not require a qualified service provider to install, because they are just plugged in. Some repairs also do not require a qualified service provider. There should be some flexibility for the registrant. Muehlhauser stated he can see both sides of this, as there is a potential for a different output. He also suggested that wording could be added that if the repair or modification affects radiation emission, then the level of radiation emission would determine if a qualified service provider needs to perform the action. Lewandowski agrees to limit repair modification to those who are trained, either provided by the manufacturer or a qualified service provider. Purrington stated she agrees, and MDH will take this under advisement.

Review of Non-Medical Cabinet X-ray Rule Draft

Jacquie Cavanagh, Section Policy and Rules Analyst

Teresa Purrington, X-ray Unit Supervisor

Purrington stated that MDH's research didn't uncover a lot of information from SSRCR. Focused on 21 CFR and other states when writing this rule draft, which is clear and understandable to the registrant. She asked the focus group if this should be a subpart of the Analytical rules. Because Cabinet mostly references 21 CFR, could place in Analytical and reference 21 CFR. MDH wants to be transparent and help registrants to find the rule parts they need to comply with.

Lewandowski suggested that MDH could separate by macroscopic and microscopic applications, or by closed beam and open beam. The distinction between what is a cabinet can be confusing for registrants. Could organize analytical by all rules, and an additional piece for open beam. Muehlhauser agrees with having separate sections for Analytical and Cabinet. He questioned where a vault system comes into place. Lewandowski suggested that MDH could organize by unshielded or shielded room. Muehlhauser stated he would like to see cabinet or enclosure based radiography rules separate than open air equipment. He doesn't agree with cabinet systems having to comply with industrial radiography exams and rules.

Purrington ended the meeting and announced that the focus group will continue with cabinet draft rules at the next meeting. She asked the focus group to provide feedback for cabinet draft rules before next meeting.

Public Comments

There were no comments from the public.

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