X-ray Industrial Focus Group Meeting

MEETING MINUTES

Date: January 4, 2018

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).

Absent: 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. Encouraged the public to provide comments, either at the meeting or through MDH's online comment form. Next meeting is scheduled for February 9 and the agenda includes Non-Medical Gauging, Non-Medical Hand-held and Non-Medical Bomb Detection. Rule drafts will be sent to the focus group before the next meeting.

Review of Non-Medical Cabinet X-ray Rule Draft

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

Begin review of Non-Medical Cabinet X-ray Rule Draft, v1.0

Subp. 5. Controls and indicators.

Purrington asked the focus group if safety switch makes sense as used in this subpart. Brett Muehlhauser (IFGM) stated that there's a key, not necessarily a safety switch. Michael Lewandowski (IFGM) stated that the key/switch provides power to the system and it's not operable otherwise. Both agreed that MDH should remove the wording "key-actuated" from item A. Muehlhauser stated that it should be clear that this is for certified cabinet x-ray systems only.

Purrington also asked the focus group if they could clarify item C (taken from Code of Federal Regulations). Lewandowski stated that he has suggested wording and will provide it to MDH.

Purrington asked the group about item D. Lewandowski stated that he has suggested wording and will provide it to MDH.

Subp. 6. Safety Interlocks.

Muehlhauser questioned the second sentence and stated it should be reworded. Lewandowski stated to make sure it's clear and the wording "but not both" should not be removed.

Subp. 9. Labeling.

Muehlhauser stated that item A doesn't apply to all equipment, and suggested using item A or B, but not both. Lewandowski responded that both are not consistent, and suggested using "x-rays" and not "ionizing radiation", and adding "or other words with similar effect".

Subp. 10. Safety device evaluation.

Muehlhauser stated that there is wording regarding "daily checks" that he's familiar with and he will send it to MDH. Lewandowski stated that there should be some clarification as to what the safety device evaluation applies to. Purrington replied that MDH will clarify the definition of "safety device". Muehlhauser suggested including a complete list. David Paulu (IFGM) stated he needed clarification on the intent of item B, and that the word "it" should be defined. Muehlhauser stated it should say "system" and the focus group agreed. Paulu questioned why the evaluation is not after the repair in item E.

Subp. 12. Additional controls and indicators for cabinet x-ray systems designed to admit humans.

Lewandowski stated there are larger cabinets where it is possible for an individual to get in front of the beam. Lewandowski questions item E and stated item E(2) makes it sound like it's a light. Muehlhauser stated the verbiage is illuminated. Lewandowski stated that's true for certified cabinets, but not for those not certified, and they shouldn't have the same requirements. Purrington stated that MDH will review the differences between certified and

non-certified systems. Lewandowski also questioned item G and the wording "test daily". This implies that there is a record keeping requirement to document these tests, and this would be excessive. Bevin Beaver (MDH) stated that the intent is to not record these tests. Muehlhauser agreed that they do not need to be logged and there should be language that specifically exempts this provision from record keeping. Lewandowski stated that if MDH is not requiring documentation, then it shouldn't be in there for inspection purposes. Beaver stated this is consistent with CFR and Arkansas. Purrington stated that MDH will revisit this provision. Brad Hoium (IFGM) stated that item G should reference subpart 10, not subpart 9.

Subp. 13. Additional requirements for x-ray cabinet inspection systems.

Purrington asked the group about MDH's comment about "industrial quality control". Lewandowski stated that he thinks this wording is fine. He questioned item A and said it is inconsistent with the definition of "port" in the proposed rules. Muehlhauser suggested there should be something regarding the flap shielding/drapes to be viewed daily, and that he is curious as to what other states' rules indicate. Lewandowski suggested that MDH could look at manufacturer recommendations. Purrington stated that MDH used similar wording in the dental x-ray rule provisions, but there is a concern that the manufacturer may not include this in their specifications. Lewandowski stated that most cabinet machines do not need these quality control measures because it is not possible to produce an x-ray when something is not working and there is no leakage in conveyer belt systems. Muehlhauser stated that it is up to the registrant to talk to their manufacturer to make sure they have in place what they're supposed to have. Craig Verke (MDH) stated that some cabinets that have the drapes already in place and some do not. There are also non-certified cabinet x-ray systems that may not have manufacturer recommendations.

Subp. 14. Radiation survey.

Muehlhauser stated that this subpart should be modified to address the issues with baggage systems. If the system is moved, it's not considered a new installation. Item B could be modified to include the baggage systems, including anything that may alter integrity of the radiation shielding. He also questioned item E, that the safety interlocks should never be bypassed. Need to add the word "detects" to item F. Hoium stated the item A should be more flexible with the not to exceed 12 months. Purrington stated MDH will take this into consideration and compared with other states. Paulu recommended subpart 14 be moved to subpart 12. Radiation survey placed after Radiation emission limit provided better flow to the rule.

Subp. 15. Safety Procedures.

Purrington asked the focus group if subitems 2 and 3 are needed. Lewandowski stated he doesn't think there's a need to have any of the six subitems. Purrington stated this is taken from normal operating procedures definition in SSRCR. Paulu suggested adding "written or electronic" to be consistent with other sections.

Subp. 16. Bypassing a safety system.

Purrington stated that some of the wording has been updated to reflect review from last meeting and will be available after the comments from this meeting. Lewandowski stated that item A should be rewritten, and he will send that to MDH as well. Muehlhauser stated there

shouldn't be protocols for bypassing safety systems. Lewandowski stated if we are allowing this, we need to make sure the appropriate controls are in place to maintain safety. Verke asked the focus group if they would need to bypass the safety system for maintenance. Muehlhauser stated that there could be a bypass during maintenance, but a safety meter would be used at that time.

Subp. 17. Repair or modification.

Lewandowski suggested using the words “power source” rather than “power switch”. He also questioned that some installations may not require a qualified service provider, and the instructions are included in the manual. May need to separate this item. Muehlhauser suggested using “qualified personnel”, who have been trained, instead of “qualified service provider”. Purrington asked Lewandowski to send MDH the suggested wording.

Review of Non-Medical Particle Accelerator X-ray Rule Draft

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

Lewandowski questioned why the rules are less for particle accelerators when the exposure could be higher. He also added that there needs to be a precise definition for particle accelerators. Muehlhauser stated that the market for using particle accelerators for imaging is growing in the U.S. Purrington stated that MDH will look into this, but has reservations about putting equipment type and uses in the rule because they could be antiquated in the future. Muehlhauser suggested that there could be some verbiage in the rule regarding electron beams. Purrington stated MDH could develop guidance to help registrants understand what type of equipment would be regulated by each subpart. The focus group was unclear as to what types of industrial equipment fall into the industrial rule categories currently under review. Purrington stated that these are good questions and that MDH will need to be review all types of industrial equipment types. Muehlhauser stated that MDH shouldn't shy away from setting a precedent that is different than other states, and that we may need to include all the different types of industrial equipment. Paulu stated that X-ray should be dropped from the Non-Medical Particle Accelerator rule draft title and the rest of the document.

Subp. 2. Controls and safety interlocks.

Purrington asked the focus group if there is a better word than instrumentation. Lewandowski stated that the word is accurate but added that "read-outs" is redundant. Muehlhauser asked for the reason for not having common language with this and the cabinet x-ray rule drafts. Beaver stated that her research of other states suggests that the verbiage was different. Lewandowski questioned the safety locks in item C. Purrington asked the focus group if item I belongs in shielding. Lewandowski stated he thinks its fine where it is. Lewandowski questioned dose rates in a high radiation area, could have monitoring for when people access the area. If the dose rates are high, continuous monitoring could burn-out the radiation detectors. Muehlhauser stated that he's fine with this verbiage, but it needs to include monitoring all the time or before an individual enters the radiation are to verify particle accelerator is off. He also questioned item I(3) and doesn't think there needs to be a calibration when the equipment is

always monitored. Lewandowski suggested a source check rather than calibration. Muehlhauser stated that the calibration could be the monitoring/check. Purrington stated that MDH will review this with the accelerator rules for consistency.

Subp. 3. Warning lights and devices.

Lewandowski stated that the warning system needs to be on long enough before the accelerator turns on, and this should be consistent throughout the rule. Muehlhauser stated the size of the area that a person has to travel should be addressed as well. Paulu stated that the wording “high radiation area” shouldn't be used in this subpart. The wording could be “very high radiation area” and depends on equipment.

Subp. 4. Safety device evaluation; requirements; frequency.

Purrington asked the focus group if tags are needed in this area. Lewandowski stated that tags can be removed.

Subp. 6. Radiation monitoring.

Lewandowski asked about the term “qualified service provider”, and stated that people operating this equipment would be qualified to maintain it. Muehlhauser suggested using “qualified personnel”. Muehlhauser stated that we may need to differentiate between certified and non-certified systems. Muehlhauser stated we could refer to it as an enclosure survey. Paulu stated that some accelerators are so large that an accelerator (or the building that houses the accelerator) is enclosed with a fence and it would be cumbersome to perform a daily survey. Paulu stated that occupancy should be in shielding, and not in this part. Muehlhauser stated that a qualified service provider should be “qualified personnel”. Purrington stated that MDH needs to differentiate between a radiation protection survey and an area survey.

Subp. 7. Safety Procedures.

Lewandowski stated item A is the first time we see a requirement for unauthorized use, and this shouldn't be required with a procedure. There's a statement from SSRCR that's not in procedure, and that should be used. Purrington stated MDH will review this provision and suggestion.

Subp. 8. Bypassing a safety device.

Purrington asked the focus group what they thought about bypassing a safety device as soon as possible. Lewandowski stated that this should be considered in all parts of the rule, not specific to this part. Paulu stated that this fits best under subpart C(2). Hoium stated that item A has the incorrect subpart reference. Paulu stated that subpart E(7) should read post bypass survey.

Public Comments

- Jeff Brunette: Commented that MDH should get rid of 90 days reference, because some months have more days than others. In dental, MDH added an extra 30 days, and should do so for industrial as well. Lewandowski agreed, and suggested the 30-day grace period should be for everything. Purrington stated national recognized guidelines and states allows for a grace period for equipment performance testing only.

- Michael Bergeson: Commented that he thinks it should be to the end of the month, without the extra 30-day grace period. Purrington stated that Texas added the 30 days and they do not deviate from exactly 30 days. Muehlhauser stated if 12 months is interpreted different ways, it should be clear in the rule.
- Linda Laman: Before Minnesota was an agreement state, NRC allowed a 5 day grace period.
- Kelly Daigle: MQSA references frequency in regulations and provides wording for a grace period. Purrington responded MDH research only showed equipment performance evaluation and could not find any specific to quality control. Purrington stated she valued any language she might find and to provide it to MDH for review.

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