

X-ray Industrial Focus Group Meeting

MEETING MINUTES

Date: February 9, 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).
Conference Call: Wade Padrnos (Ridgewater University).
Guest: Sergeant Jeff Keller (St. Paul Police Bomb Squad).
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

Teresa Purrington, X-ray Program Supervisor

Purrington welcomed everyone. Stated that MDH will take public comments during the last 15 minutes of the meeting. Reminded the public that they can subscribe to the GovDelivery email list for rule updates. Comments on the rule can be submitted on the Request for Comments webpage. Talked about the industrial buckets, or industrial rule categories that will be discussed with the focus group. MDH will wait to develop Non-Medical X-ray Systems rules until after the Medical rules have been reviewed and updated.

Brett Muehlhauser (IFGM) stated that there could be some overlap between industrial and research. Michael Lewandowski (IFGM) responded that some sites could use the same device for both applications making it difficult to separate the two. Lewandowski, suggested using

human-use and non-human use distinction. Purrington stated MDH would take that into consideration. David Paulu (IFGM) stated he is fine with them together in the rule.

Purrington stated that the Industrial Focus Group is wrapping up, and should be finished after the next group meeting on March 1. The Advisory Committee will discuss the drafts.

Purrington welcomed a special guest on the focus group, Sergeant Jeff Keller from the St. Paul Police Bomb Squad, and Sergeant Tom Subject from the Minneapolis Bomb Squad who is attending today's meeting.

Review of Bomb Detection X-ray Systems

Jacquie Cavanagh, Section Policy and Rules Analyst

Teresa Purrington, X-ray Unit Supervisor

Began review of Bomb Detection X-ray Systems Rule Draft, v1.0.

Subp. 1. Applicability.

Sergeant Jeff Keller (IFGM Guest) stated the rule name should be changed from bomb detection to suspected hazards. Technically, the x-ray machines do not detect bombs, they detect hazardous materials or substances that may be part of a bomb. Purrington stated they have talked about renaming the area and the applicability. Keller stated he has a manual that he can provide to MDH that includes the nomenclature. Purrington stated that they have been relying on the SSRCR for the nomenclature, but would appreciate looking at the manual. Muehlhauser agreed that the differentiation between human use and non-human use could be important. Muehlhauser stated it would be okay to be redundant, for the sake of the user.

Subp. 3. Warning lights and devices.

Keller stated that the device does not necessarily say, "x-ray on". Muehlhauser stated the words could be next to the light or in the manual, that states when the light is on, the x-rays are on.

Subp. 4 and 5. Beam Ports. Shutters.

Lewandowski stated that subparts four and five are not applicable for these devices. He suggested removing these subparts. Muehlhauser and Keller both agreed.

Subp. 7. Safety device evaluation.

Lewandowski questioned the word "installation" in item A. Purrington stated there is a definition for installation in the rule. Lewandowski suggested using "initial use" instead. He also stated that using days, instead of months, does not make sense in item B. Keller stated that these devices work either correctly, or not at all. He stated that keeping a log is redundant, because there would be a service request and receipts if the system were not working.

Subp. 8. Radiation emission limit.

Lewandowski questioned the dose limits in this subpart. He questioned what the expectation would be for sites and access control to prevent exposure. He stated a defined exclusion might

be practical in this situation. Brad Hoium (IFGM) asked Keller if they do surveys, and Keller stated that they do not.

Subp. 10. Area survey.

David Paulu (IFGM) suggested the wording “follow the current FBI process”, if everyone has to follow the same process. Keller stated the 300 feet is not always feasible. Lewandowski stated that the dose of these devices is low and considering the potential outcome of not using the device, and suggested exempting these devices from this subpart. Muehlhauser reinforced that the way the rule is currently drafted protects the public, but it also has to be feasible for a registrant to follow. Paulu stated that these devices are also used for training, and believes there needs to be rule parts specifically for training.

Subp. 11. Safety procedures.

Lewandowski stated he believes this subpart should not be “locked out and tagged”, because it is a past action. Should be lock out and tag out. Paulu stated that these devices could only be locked out by removing the battery. Hoium stated the wording should be “locked out and removed from service”.

Subp. 12. Temporary job site.

Sergeant Adamek stated that the word “detection” should be removed from the title, as these devices are used to analyze. He also stated that having a certificate on hand is not necessarily applicable, and it makes more sense for the paperwork to be in the office. Lewandowski stated that an inspection would not necessarily take place at a temporary job site of this nature. Purrington asked the bomb squad members what they do if there is a problem with the device. Sergeant Subject stated that if the device is not functioning, there procedure is to get another one, not to repair it themselves.

Subp. 13. Utilization data.

Sergeant Adamek stated that they do write a report, but do not include this information in the report. Subject said that they do calibrate the equipment and the data are kept with the vendor. Hoium stated then maybe it is best to remove utilization data.

Subp. 15. Additional requirements for handheld bomb detection x-ray systems.

Paulu stated that 15 E does not make sense for hand-held devices. Lewandowski stated that the beam is forward directional and there is no radiation dose for the operator. Keller stated that the language should state that registrants “maintain the distance set forth by the FBI”. Muehlhauser stated the wording could state to “follow the manufacturer recommendations”, as well as the dose requirements, rather than the actual distance. Subject stated that he believes the whole subpart should be removed. There are many times that they cannot follow these rules, because of the nature of their jobs. He also stated there is no “dead-man” type switch on their devices. Purrington stated there are some hand-held devices in the industry that have this and this part is only referencing handheld devices. Sergeant Adamek stated they should be separated from the industry. Sergeant Subject stated they all go through specific training on x-ray procedures for their specific x-ray system. The local bomb squads would not purchase another type of system, as they have to purchase certain systems. Purrington asked if

they hold the portable device in their hands. Sergeant Adamek stated that there are times that they have to hold the device. Lewandowski stated that it might be worthwhile to have rules that apply during non-emergency use for this registrant type, and a provision for newer technology and not include emergencies.

Purrington thanked the focus group guests for taking time to collaborate with MDH in putting together bomb detection/suspected hazards rules.

Review of Non-Medical Hand-held X-ray Systems Rule Draft

Jacquie Cavanagh, Section Policy and Rules Analyst

Teresa Purrington, X-ray Unit Supervisor

Began review of Non-Medical Hand-held X-ray Systems Rule Draft, v1.0.

Subp. 4 and 5. Beam ports. Shutters.

Lewandowski stated that these subparts are not applicable in this situation.

Subp. 7. Safety device evaluation.

Purrington stated that there is confusion as to what a safety device is, and MDH has outlined what a safety device is in this rule part.

Subp. 9. Area survey.

Lewandowski questioned this part, because this section refers to hand-held x-ray systems. Craig Verke (MDH) stated there is nothing in the rule that states a registrant cannot service a device, so that is why this was included. Lewandowski responded he suggests either taking it out, or leaving it in with the caveat that some sites could have engineers on site who could service a device.

Subp. 10. Safety procedures.

Lewandowski questioned item B(2) doing a daily check before each use seems excessive. He stated that if the devices do not work, then the x-ray does not work. Bevin Beaver (MDH) stated that by turning it on, this would be the self-check for certain types of equipment. Muehlhauser stated he does not know if these types of equipment have the same standards as CFR, and feels it is a good check. Purrington stated that MDH would address this.

Subp. 12. Storage and security; notification in event of theft or loss.

Lewandowski suggested eliminating item A(1). Purrington stated this wording is from the 2017 law governing dental hand-held x-ray systems, and MDH wants to be consistent with those requirements. Lewandowski questioned the word "facility". Beaver provided the definition of a facility. Lewandowski questioned, "locked area". Suggested that we define what is considered a "locked area", as it could be the case it is carried in, and not a locked room. Verke stated that the intent of this section is to prevent theft of the device.

Subp. 13. Operator protection.

Lewandowski questioned items D and E, as they do not apply to XRF (describe what this is). Purrington agreed, and stated this needs to be reviewed. Paulu stated that the order of items D and E should be switched. Muehlhauser suggested not using the actual distance in subpart E instead of the manufacturer recommendations. Paulu suggested changing “operator” to “individual”.

Review of Gauging X-ray Systems Rule Draft

Jacquie Cavanagh, Section Policy and Rules Analyst

Teresa Purrington, X-ray Unit Supervisor

Subp. 1. Applicability.

Lewandowski asked for a definition of gauging. Muehlhauser questioned where the definitions would be contained in the rule. Purrington stated that all the industrial definitions will be in the industrial definitions part, not in each subpart, and that there is no current definition for “gauging”.

Subp. 3. Warning lights and devices.

Purrington asked if shutters apply to gauging. Lewandowski stated that they do.

Subp. 4 and 5. Beam ports. Shutters.

Lewandowski suggested removing subparts four and five.

Subp. 6. Labeling.

Lewandowski suggested removing item B. Purrington stated that some states use the wording “jaws of the gauge”. Lewandowski stated that this wording is not necessary, and refers to a specific type of gauge. Lewandowski offered the wording, “Do not place hands in gap”. Muehlhauser suggested looking at the manufacturer’s recommendations. Verke asked the group if the comment (in the margin) under item B would be more appropriate than the current wording. Lewandowski stated that would also work.

Subp. 7. Safety device evaluation.

Purrington asked the group if there are emergency shut-off switches. Lewandowski stated that a gauge is controlled by a software package, and someone is responsible for starting that process. Muehlhauser stated there is an emergency shut-off to stop the manufacturing line, which shuts off the gauge, but not an independent emergency shut-off switch for the gauge itself.

Subp. 10. Area survey.

Purrington asked the focus group if shielding and beam attenuation should be included here. Verke stated that this comment refers to taking the gauging system apart, and how this might affect the shielding. Lewandowski stated that if the shielding was taken apart, MDH should require a survey. Muehlhauser suggested the wording changed to “output” or “shielding”.

Subp. 11. Safety procedures.

Lewandowski questioned whether item B(1) should be in this rule part. Purrington stated that all of item B(1) will be removed.

Subp. 12. Repair and modification.

Lewandowski questioned “routine shutdown” in item A. Beaver responded that MDH was considering removing “routine” in this part. Hoium stated it would not be locked out and tagged out when the device is on.

Public Comments

- Barb Hodge: Questioned the definition of “qualified personnel”. Muehlhauser stated that a service provider is not always necessary and qualified personnel could service the equipment.
- Barb Hodge: Questioned the utilization log for bomb detection devices, and did not see that in the hand-held. Muehlhauser stated we should consider intent of the hand-held. Beaver stated that this was taken into consideration if they were out in the field. Hodge stated that they are also out in the field for research work. Lewandowski stated this does not add any value to health and safety to add it in rule.
- Barb Hodge: Questioned backscatter and putting a unit on a tube stand. Purrington stated they will take that into consideration, and MDH should include this for consistency purposes. Verke stated that a registrant might need to make an exposure by holding the device. Lewandowski stated that the rule should allow for the type of devices that include automatic exposure, no longer hand-held, enclosed in a shielded enclosure.
- Linda Laman: Questioned subpart 15 for the bomb detection rule draft and not being able to put something in the police report. Suggested including this in the annual audit.
- Jeffrey Brunette: Emailed a comment to Lewandowski for the hand-held rules. In subpart 7, item B, he suggested wording to be six consistent calendar months.

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