X-ray Advisory Committee Meeting

MEETING MINUTES, 10/16/19

Date: October 16, 2019

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

Attendees: Beth Schueler (Medical Physicist), Brian Hall (Service Provider), Dan Lind (Service Provider), Frank Zink (Medical Physicist), Julie Sabo (MN Nursing Board), Karyn Warnert (Minnesota Veterinary Associates), Michael Lewandowski (Health Physicist/CHP), Ronnell Hanson (MN Radiological Society), Scott Haglund (St. Catherine University), Vinton Albers (MN Chiropractic Association).

Conference Call: David Eastman (Medical Physicist), Richard Geise (Medical Physicist/PhD), Tony Murphy (Medical Physicist).

Absent: Bridgett Anderson (MN Dental Board), Jon Wohlhuter (MN Association of Nurse Anesthetists), Louis Saeger (MN Medical Association).

MDH: Bevin Beaver, Craig Verke, Jacquie Cavanagh, Kelly Medellin, Teresa Purrington, Tosin Lediju.

Acronyms and Terms

ACM – Advisory committee member

CRCPD – Council of Radiation Control Program Directors

CBCT – Cone beam computed tomography

CT – Computed tomography

FDA – Federal Drug Administration

IAC - Intersocietal Accreditation Commission

MDH – Minnesota Department of Health

NCRP – National Council on Radiation Protection and Measurements

QMP – Qualified medical physicist

Revisor – Office of the Revisor of Statutes

SSRCR – State Suggested Regulations for Control of Radiation, published by CRCPD

Welcome and Introductions

Teresa Purrington, X-ray Unit Supervisor

Purrington welcomed everyone to the meeting. She introduced MDH staff and new Advisory Committee members, David Eastman, Scott Haglund, and Karyn Warnert. She also reported that William Duppler has resigned from the committee.

Purrington gave an update on the rule revision process, stating that there are 16 rule parts left to discuss and three or four Advisory Committee meetings left. The next Advisory Committee meeting would be November 13.

Review of Training Course Approval

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

Subp. 1. Applicability.

Michael Lewandowski (Advisory Committee Group – ACG) asked what training courses would need to be approved by the commissioner. Purrington stated the courses include limited scope x-ray operator (LMXO) and fluoroscopy training. Beth Schueler (ACG) asked about fluoroscopy training and institutions that provide their own training. Purrington stated they would also need approval. Scott Haglund (ACG) asked how many this would be. Purrington stated this would only be for those who start training after the rule is adopted and so she does not know the answer to that question.

Subp. 2. Application; initial.

Purrington stated this language is consistent with another MDH program's rules for training courses.

Subp. 9. Training course examination.

Haglund asked why the passing rate of 70 percent is so low. Purrington stated this is for those individuals who will take initial training prior to sitting for the LMXO exam, not the LMXO exam offered through ARRT. Frank Zink (ACG) stated this seems overly prescriptive. Brian Hall (ACG) asked if MDH will look at the credentials of those providing training. Purrington stated we currently don't have that in here as a rule part, just the training. Bevin Beaver (MDH) stated this approach is consistent with other states. She also stated that not all states offer this type of training online and MDH intends to do so. Haglund stated instructors should be trained in the discipline they are teaching. Zink stated that we should review the credentials for those providing training. Zink stated this does not need to be so specific, such as number of questions. He suggested adding the author of the exam and recommended that the exam be reviewed by a medical physicist for fluoroscopy. Hall stated that this approach is pushing this into a college environment only. Zink stated that the content needs to be authored by qualified

individuals. Julie Sabo (ACG) stated that the Board of Nursing requires that the person providing the training must have experience in the areas in which they are teaching.

Subp. 10. Required records; retention period.

Haglund stated that there are professional societies that approve courses and maintain Continuing Education Unit's. He suggested MDH consider one of those organizations to maintain LMXO records.

Review of Shielding and Shielding Plans

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

Subp. 1. Applicability.

Zink stated the wording is inconsistent in item B. Jacquie Cavanagh (MDH) explained the intent in this part is to not repeat the language throughout this rule but to include a longer description in the applicability part.

Zink questioned the service technician wording. Purrington stated that service provider is the main category, and service technician is one of those categories under that umbrella topic. Zink asked if the signature is required under this part and others. Purrington stated they are required under all parts.

Richard Geise (ACG) questioned rooms that are exempt and stated that mammography is not listed. Rich mentioned a door might possibly be needed for tomosynthesis. Craig Verke (MDH) responded that MDH is researching tomosynthesis imaging. Purrington stated MDH could consider that.

Beth Schueler (ACG) questioned items C(4) and D(1) and the number of days. Purrington stated the number of days should be consistent and MDH looked at Colorado rules. Beaver stated MDH was trying to remove the word “continuously” and this may be an oversight. Purrington stated this oversight would be corrected. Schueler stated this would be difficult to document when a radiographic portable unit is moved frequently. She also stated that D(2) doesn't make sense because an operator cannot be 9 feet away from a mobile c-arm. Purrington stated that not all of the requirements must be followed because in the list because it contains an "or".

Zink stated we should not include language on a particular x-ray system, but make it specific to the room. Purrington stated this is consistent with SSRCR. Zink stated that we are concerned about the room, not the equipment. David Eastman (ACG) agreed that this would be difficult in an ER setting with mobile equipment. He also stated that the amount of fluoroscopic time should be considered. Eastman asked if mobile CT or O-arms are considered mobile and portable. Purrington stated these are mobile. Lewandowski agreed with Zink that this should be specific to the space and that item D seems to be in the wrong place, as it does not really apply to shielding. Geise stated the wording does focus on the room and noted that item C refers to item D. He also stated the word “continuously” is confusing, and suggested using mA minutes

or mAs. Verke stated this was mostly about protection of the operator, not shielding. Lind suggested using “workload”. Schueler asked where 9 feet came from, when it used to be 6 feet. Purrington stated this was from SSRCR, and MDH would review. Eastman stated that there is an "or" in the part as well.

Subp. 2. Shielding plan evaluation prior to construction.

Purrington stated that two parts have been removed from the current rule: 1) a placard is no longer needed, and 2) shielding plans do not have to be submitted to MDH. Lewandowski questioned if this is under all dose parts or only occupational. Purrington stated this came from Colorado, and MDH placed the dose limits listed in comments only as a reference. Geise suggested adding the phrase "as appropriate" to the terminology. Zink questioned what the shielding plan evaluation title meant in the headnote. Verke stated this is what the registrant needs to provide. Zink stated it makes it sound like there is something else registrants (QMPs/QEs) need to do. Purrington stated she understands Zink’s confusion to the title and MDH will review.

Subp. 3. Shielding plan requirements.

Schueler questioned item B(14) and stated that the report referenced is based on workloads and so it does not seem relevant. Zink suggested removing the components that may become outdated and simply reference NCRP #147. Purrington stated that if these components are not in the rule, then the registrant is not fully aware of their responsibilities. Zink stated that not all items in this section are relevant for all rooms. Purrington stated that there are some service providers not providing this information to the registrant and NCRP #147 is a cost. Registrants need the information to ask the questions. Zink responded that facilities do not always know what type of equipment they will have in their room(s). Eastman responded that facilities often provide the maximum amount of shielding to be on the safe side. Cavanagh stated that MDH can only incorporate a reference if it is readily available and noted that NCRP #147 must be purchased. Lewandowski stated that the qualified expert would have this report. Cavanagh responded the registrant would not have the report and MDH’s goal in this rulemaking is to increase transparency. Verke stated MDH inspectors also need this information to make a determination at an inspection. Verke asked if removing items B(14) and B(15) would make sense, as items B(4) and B(5) would cover those areas. Geise responded that the registrant might not be able to provide this information if they have not purchased the equipment. Eastman responded that the qualified expert does ask questions to get some idea of what type of equipment will be in the room. He agrees with removing items B(14) and B(15). Verke stated that MDH needs to know what was evaluated and the registrant needs the minimum amount of information. Zink stated that NCRP #147 gives guidance on the report and he will send an email to MDH for review to this rule part.

Subp. 6. Post-construction evaluation.

Eastman questioned if MDH would be looking for measure scatter results in this rule part. Purrington stated it would involve comparing the new construction shielding plan with the remodel shielding plan. Eastman responded they would rather work with the site and the install

engineer with a sign-off form to ensure limits are below what they should be. He asked if this would be appropriate from the MDH perspective. Purrington stated that the qualified expert would sign off on the post-construction evaluation. Tony Murphy (ACG) stated that it is difficult to see inconsistencies until they do measurements, and suggested that this is more than a physical inspection. Geise agreed.

Subp. 7. Any changes after operations.

Lewandowski questioned item 7(A)(6) as it references item F, but he can't find it. Purrington stated MDH would review.

Subp. 8. Shielding plan retention.

Purrington stated MDH's intent is to have only one rule part for record retention. This subpart will be moved to that area. Lind suggested that registrants should retain their shielding plans. Purrington stated that registrants have to keep the shielding plan. Haglund stated he agrees this is important for new ownership. Purrington stated this would be included in guidance.

Review of Caution Signs, Posting and Labeling

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

Subp. 4. Labeling x-ray systems.

Lewandowski questioned labeling research equipment with a sign, since this is usually near the switch. He questioned if the intent is to post in an area, or by a device. Purrington stated this is specifically for the area, not the device. Verke agreed this is separate from the device warning. Purrington stated MDH is trying to make this consistent with industrial rule provisions and may have changed it to mean something else. MDH will review for clarity. Ronnell Hanson (ACG) asked about medical equipment. Verke stated this is a federal requirement and our current rule does not include signage. He also stated that MDH is in discussions to include this in our proposed rule.

Review of Report of Theft or Loss of X-ray System

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

Subp. 2. Immediate notification required.

Lewandowski questioned the wording "become known". Purrington asked what his facility currently does. Lewandowski responded that they look for it first before submitting a notification. Cavanagh suggested using the word "unrecoverable" to take into consideration looking for the lost or missing equipment before submitting a notification of theft or loss.

Subp. 3. Theft or loss report; report contents.

Lewandowski stated that there is a typo at item A, should be “theft or loss”. He also stated that MDH should look at item B and the word “known”.

Review of Medical Event; Notification and Report

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

Subp. 2. Notification within 24 hours.

Schueler stated that a 24-hour notification period could be difficult if a medical event is discovered on a Friday. Purrington stated MDH will review this. Geise agreed with Schueler. Schuler also asked why the radiation safety committee was removed from this part since she currently reports to her facility’s radiation safety committee for review. Purrington stated that both need to be done and this is what other states are doing. She also stated that the radiation safety committee is included in the CT and Fluoroscopy sections of the rule. Schueler responded that it might be clearer if it was included here.

Subp. 3. Medical event; patient intervention.

Eastman asked if this would be true if a woman does not state they are pregnant and the fetus receives a high dose. Purrington stated that this would be an unintended dose. Schueler questioned the word ‘unintended’ because every exam could result in an unintended dose. Geise stated this is reporting unintended doses to the patient. Purrington stated MDH will review this. Eastman stated that ‘unintended’ happens when you irradiate the wrong patient or malfunction of equipment.

Schueler asked if this rule part replaces the over 6 Gray reporting. Purrington confirmed. Verke stated MDH’s intent is to be consistent with SSRCR and the H-38 workgroup on medical event reporting. He also stated this is self-reporting. Eastman stated this makes sense for those registrants that adhere to joint commission and must report that a patient has information as to why they received a high dose. Schueler asked about item B and (the facility's established protocol) and how would an operator know if they exceeded an organ or effective dose. Purrington asked if it is confusing to have this specifically be about CT and fluoroscopy. Lewandowski stated that items A and B are confusing because the rule is referencing skin dose, organs, and effective dose. Purrington stated she would review H-38 workgroup information and do some further research.

Schueler also questioned item D and the dose limit. Purrington stated this would only apply to CT or fluoroscopy. Schueler asked if this would be any dose. Purrington stated this is currently the case but will do further research. She also stated that there would be guidance for registrants. Haglund asked about equipment malfunction and scope of practice, if these should be added.

Subp. 4. Notice to affected patient and referring qualified practitioner by a registrant.

Lewandowski asked about the word “electronically”. Purrington stated electronic can be email. Lewandowski stated the word “must” should be removed, as this could be provided in writing and the registrant may want a record. Lind suggested using the wording “documented notification”. Verke stated the intent was electronic, as they need to be notified within 24 hours. Purrington stated MDH will review this.

Schueler questioned item B and stated this cannot be done before notifying the patient. Purrington stated MDH will review this.

Subp. 5. Medical event reports; contents.

Lewandowski asked if item A(5) could be a qualified medical physicist or qualified expert. Purrington stated MDH will review this.

Review of Notification of Occupational Levels Exceeded

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

Subp. 4. Reports of planned special exposures; contents.

Purrington asked about special exposures and whether rules on this topic is necessary. She prefers to keep this but asked the committee for their opinion. Geise stated there could be a disastrous situation that occurs where an occupational worker could be overexposed. Lewandowski stated there could be something outside the metro area where there are limited individuals at a facility, or a medical event where many people could be affected at the same time. He stated it should stay in the rule. Eastman stated the previous examples are confusing to him since they are technically emergencies and are not planned. Geise stated it would not hurt to leave it in and it might help.

Public Comments

- Jeffrey Brunette: Suggested looking at NRC guidelines for dose to pregnant patient. Purrington suggested sending this information to the designated email address for this rulemaking.
- Mike Freels: Asked about security screening shielding. Purrington stated MDH would be talking about security screening at the December 18 meeting.
- Mary Ellen Jafari: Asked about medical events and if the practitioner needs to be the referring practitioner. Purrington stated MDH will review this.
- Kelly Daigle: Questioned lead protective barriers and the inconsistencies with the barrier measurements. Purrington stated MDH will review this. She also asked about signage and veterinary medicine. Purrington stated MDH is developing a plan for veterinary and forensic science. These areas may be in a separate rule part.

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