X-ray Advisory Committee Meeting

MEETING MINUTES

Date: June 26, 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), Jon Wohlhuter (MN Association of Nurse Anesthetists), Julie Sabo (MN Nursing Board), Michael Lewandowski (Health Physicist/CHP), Ronnell Hanson (MN Radiological Society), Tony Murphy (Medical Physicist).

Absent: Bridgett Anderson (MN Dental Board), Louis Saeger (MN Medical Association), Richard Geise (Medical Physicist/PhD), Vinton Albers (Chiropractic Association), William Duppler (Medical Physicist).

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

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 Program Supervisor

Purrington welcomed everyone to the meeting and introduced MDH staff. She stated that MDH staff have been researching, discussing and reviewing the rule draft for the last six months. She also stated that MDH staff will be reviewing draft rules and add onto each draft for review at the meetings.

Legislative Updates

Jacquie Cavanagh, Section Policy and Rules Analyst

Cavanagh reported that two bills, which were enacted, recently affected the x-ray Statute. She described the two bills for CVT and Security Screening. She stated that security screening has its own rulemaking authority. MDH must propose security screening rules by November 2020. Because of this timeline, MDH intends to propose all x-ray rules and security screening rules at the same time. Stakeholders in this area will be invited to join the Advisory Committee.

Review of Registration

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

Subp. 2. Out-of-state x-ray systems.

Zink questioned why we need an out-of-state section. Purrington stated out-of-state is reciprocity and this is usually mobile vehicles. Michael Lewandowski (ACG) stated this is also useful for industrial registrants.

Subp. 3. Application; pre-registration.

Purrington stated that MDH currently receives shielding plans. MDH is removing the requirement for registrants to send shielding plans to MDH from the new rule, and instead of developing a pre-registration process. She stated facilities will be assigned a registration number, but in a pending status. Zink stated that this makes sense, but it is confusing for registrants who are just adding equipment.

Tony Murphy (ACG) stated the distinction between applicant and registrant is important. Cavanagh responded that person is defined as the entity and the applicant is defined as not registered. Purrington stated MDH would be able to help registrants through the process by having a pre-registration. Lewandowski asked about equipment that does not require shielding plans, if they are exempt from pre-registration. Purrington stated there would be a separate rule part for shielding plans that discerns it that one part is applicable or not. He also asked about a time frame. Purrington stated some facilities would not be able to follow a prescribed time frame.

Subp. 4. Registration; initial.

Lewandowski asked about item 4(B) and the definition of registration. Purrington stated that it must be confirmed and approved by MDH. This will be electronic and automatic.

Subp. 7. Registration; annual renewal.

Beth Schueler (ACG) questioned if this is a renewal of registration or just the equipment. Purrington stated it is both the equipment and the facility. Ronnell Hanson (ACG) asked about MDH turnaround time for denials and approvals. Purrington stated denials, revocations and suspensions are under the authority of the Health Enforcement Consolidation Act (HECA). These would be immediate. Dan Lind (ACG) asked for an example reason for a denial. Purrington stated that falsification of data would be a reason for revocation. Cavanagh stated that HECA governs enforcement for the X-ray program.

Subp. 11. Registration; additional x-ray system.

Zink questioned what the wording “confirmation of an IRB” means. Purrington stated this is referencing Subpart 22 and this should be added. Zink asked when registrants give this information. Purrington stated if it does not already exist on the record, it should be added when a piece of equipment falls into this category.

Lewandowski asked about item 11(C) and which items are applicable for industrial facilities. He also asked what would be considered “additional information”. Purrington stated that the registrant would not have to guess what this would be, as the online system would prompt for additional information, if needed.

Subp. 12. Short-term use of x-ray systems.

Lewandowski questioned how short-term use differs from out-of-state. Purrington stated that short-term use is temporary use of equipment at a facility and needs to be registered. Out-of-state use are registrants from out of state using equipment in Minnesota. Lewandowski responded that it seems redundant. Purrington responded that MDH receives many questions about this and it needs to clear for stakeholders. Schueler asked about equipment that is on-site for one day and the manufacturer owns it. Purrington stated that is a good point and MDH would review that. Murphy said he supports this, as patients for one day deserve the same treatment. Purrington stated that there has been equipment that is used for demonstration, but kept on-site and not registered. Lewandowski stated that other states allow 30 days to register, so if equipment has not been used within 30 days, it does not need to be registered. He also stated that registrants might want to test several pieces of equipment. Lind stated that sometimes there are more than one piece of equipment as well. Purrington stated MDH would look at the statute regarding this subject.

Lind asked about registration and loaning out just tubes. Purrington stated this only applies to the equipment, not just tubes.

Subp. 14. Disposition of x-ray systems.

Lewandowski stated the wording “change of disposition” should just be “disposition”. Cavanagh agreed. He also asked about items 7(A) and 7(B). He stated that A should fall under B.

Purrington stated she would review these part. Schueler questioned if the disposition will be electronic as well. Purrington stated that is the intent.

Lewandowski asked about item C(4) and the definition of a receipt, as industrial does not give a receipt for non-radioactive material. Craig Verke (MDH) responded that this is in response to have some verification that equipment has been disposed of. Purrington stated MDH would review this with Colorado regulations. Murphy stated he does not feel there is any value in the receipt. Purrington stated the registrant would need some type of documentation. Lewandowski stated the registrant should be able to provide the documentation, and not have a service provider report. Purrington asked how MDH would regulate this. Lewandowski responded that this could not be one size fits all, as industrial equipment is different. Lind stated that an electrician could disconnect the power. Lewandowski stated this would work for industrial registrants. Purrington stated MDH would review and take this discussion into consideration.

Review of Registrant Responsibilities

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

Subp. 16 and 17. Registrant responsibilities for a service company or service provider. Checklist contents and requirements.

Zink stated that subparts 16 and 17 show that we are holding registrants responsible for documentation. He also stated that item B talks about the checklist, but there is not an actual checklist. Zink stated there should be an explicit checklist if MDH is going to refer to this in rule, and include guidance. Purrington stated that this same checklist is in the service provider responsibilities as well. She continued that registrants manage the checklist and have their service provider sign off on it. Murphy stated that he does not think the checklist will work for new construction and should not be a paper checklist when everything else is electronic.

Zink stated that item 17(D) seems to be in error and does not include the wording "or". Purrington stated these are the exact same in the proposed CT and Fluoroscopy rules that the advisory committee already reviewed. Lewandowski stated that item 17(D) should not apply to non-medical/industrial use and non-certified cabinets. Purrington stated she would look into this for industrial equipment.

Subp. 18. Designation of radiation safety officer.

Murphy asked about item 18(B) and what the wording "through the radiation safety officer" means. Purrington stated that this is the delegation of authority. Jon Wohlhuter (ACG) stated he interprets this as the registrant is responsible for the Radiation Safety Officer (RSO). Purrington stated that is the registrant’s responsibility to appoint an RSO and delegate responsibilities to the RSO. Murphy stated that this needs to be clearer. Zink stated that responsibility is still on the registrant.

Subp. 20. Personal protective equipment.

Schueler questioned item B and if all three evaluations have to be completed. Purrington stated yes. Lind asked about saving fluoroscopic images. Purrington stated item C(4) says to store images if applicable. Zink stated that most registrants do not save images. Schueler stated that the Mayo's PAC system does not allow storing of images from the CT units. Purrington stated MDH would review this.

Zink asked about item A and labeling lead equivalence. He stated there are manufacturers that do not provide labeling for thyroid shields. Schueler asked about item C and if there should be a list of each apron. She stated that they have a tag on each garment that shows they been inspected, by who and the date. Purrington stated that MDH would look at this and consider exploring other avenues. Zink stated there should be a standard for pass/fail in rule or guidance. Hanson stated that if a garment is known to be damaged, it should be removed and not wait 24 months.

Subp. 21. Annual quality assurance program audit.

Lewandowski asked about Quality Assurance (QA) requirements for non-medical facilities. Purrington stated that this will be the next topic the committee discusses and most of the industrial rule parts list the procedures. Lewandowski asked about item B and an onsite audit. Purrington stated MDH needs to look at the larger prospective. Lewandowski responded that one size does not fit all and this could be done remotely, rather than onsite. Zink stated that the elements of the audit should be defined. Purrington stated that the RSO could delegate this to the sites, and verify the information is accurate. Zink stated that the RSO should be able to remotely check accuracy. Murphy stated he agrees.

Subp. 22. Living human research; institutional review board.

Schueler referenced the Institutional Review Board (IRB) comment in the margin. She stated that the wording could be "the IRB as defined by FDA". Zink stated it should just state they must follow federal requirements.

Review of Limited Scope X-ray Operators

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

Purrington stated that MDH has tracked the failure rates of Limited Scope X-ray Operators, with 42% failing the core module and one region of anatomy the first time. The exam cannot be changed as all states follow the same standards. Zink asked about the grandfathered-in x-ray operators and if they are in statute. Purrington stated they are but there will be continuing education requirements in the new rule.

Subp. 4. Limited scope x-ray operator practice.

Zink asked about other states passing standards. Purrington stated that Minnesota's passing standard is 70%, but other states are higher.

Subp. 7. Educational course content.

Zink stated this seems too prescriptive as well, specifically the number of hours per topic. Purrington stated that other states require these hours as well, and most states hours are higher than 120. Brian Hall (ACG) stated that the problem is applicants aren't studying, not that they don't have enough training. Purrington stated this does not have to be classroom training, it could be online. Hall stated the rule should require training, not hours of training. Purrington asked the committee if MDH should require clinical training after passing examination. Lewandowski stated there should be documentation of training, but the hours could include, study, observation, and participation. Zink suggested focusing on those who have passed and are undertrained. Purrington stated this is good discussion and would like to hear from education programs. Lewandowski stated that establishing hours by topic does not seem necessary, as the rule should focus on the topics. Purrington stated that MDH could look at the overall number of hours to not include the hours by topic. Schueler suggested referencing the ARRT exam and not the actual topic areas in the exam. Hanson stated he thinks 120 hours seems reasonable and a broad base of knowledge is beneficial and should be consistent with established programs. He also agrees to remove the number of hours by topic, unless there is a standard already in place. Lind asked about internships. Purrington stated this would fall under personal supervision. Julie Sabo (ACG) stated that there should be a requirement for practicum and it would be difficult to find clinical sites for these individuals. Lewandowski stated that some states list high-level topics, and break the topics down in guidance.

Public Comments

- Jeffrey Brunette: Asked about the number of times Limited Scope X-ray Operators try to pass the exam. Suggested referring to ARRT passing regulations.
- Linda Laman: Asked about the spine and lower extremities. The femur is the distal femurs, and the spine does not cover the pelvis or SI. Purrington stated that MDH is aware of that. She also asked about continuing education. Purrington stated they would require a 24 hours of CE within 24 months.
- Barb Lutterman: Asked about the checklist with new facilities and the registration number. Purrington stated this would be covered under pre-registration, as they will be assigned at that time. She also stated that she agrees with the committee that audits could be completed remotely.
- Barb Hodge: Asked about registrants who are moving addresses or a new construction. Purrington stated that would not require pre-registration. She also asked about lead testing and dental facilities. Purrington stated this is in item 3.
- Kelly Daigle: Asked about in transit and who is responsible for the equipment. If the manufacturer is demoing the unit onsite, who should register it. Purrington stated MDH would consider this when reviewing the rules.

  Kelly Daigle: Asked about the failure rates for the Limited Scope exam and if they are failing the Core or the Modules. Purrington stated MDH does not have that information available.

Kelly Daigle: Asked if there would be new educational programs available to help applicants. Purrington stated there are currently two educational programs in Minnesota, but there is many online training opportunities.

Kelly Daigle: Asked how the public knows the final decision of items that require an additional MDH review. Purrington stated MDH reviews and discusses all the comments, and they would be included in the next revision. Cavanagh responded that the Advisory Committee is appointed to give the Commissioner advice and has the power of persuasion, as does the public. MDH has to justify what we do and have a rational base, and the X-ray Unit has been more transparent than they have to be with this process. Lewandowski asked if all the comments would be addressed when the rule is finalized. Cavanaugh stated when the rules are proposed, there is a 30-day comment period. OAH hosts the comments. Lewandowski stated this gives MDH the chance to close the loop with comments. Cavanagh also stated there are a summary of changes in each revision on the first page of each draft.

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06/26/2019
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