

X-ray Advisory Committee Meeting

MEETING MINUTES

Date: April 10, 2017

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), Louis Saeger (MN Medical Association), Michael Lewandowski (Health Physicist/CHP), Richard Giese (Medical Physicist/PhD), Ronnell Hanson (MN Radiological Society), Tony Murphy (Medical Physicist), Vinton Albers (Chiropractic Association), William Duppler (Medical Physicist).

Via conference call: Kathryn White (MN Association of Nurse Anesthetists)

Absent: Bridgett Anderson (MN Dental Board), Dan Lind (NXC Imaging)

MDH: Craig Verke, Jacquie Cavanagh, John Olson, Kelly Medellin, Mary Navara, Teresa Purrington

Welcome and Introductions

Mary Navara, Indoor Environments and Radiation Manager

Mary welcomed everyone and relayed the rules of the meeting.

Updates

Jacquie Cavanagh, Section Policy and Rules Analyst

- Proposed monthly meeting dates through December 2017 were sent by email to advisory committee members
- Plan to get through letter "K" of the definitions today
- Once the advisory committee completes its review of the Definitions, MDH will place proposed rule changes from the focus groups on the agenda for advisory committee review

Teresa Purrington, X-ray Program Supervisor

- Stated that some from this committee might be asked to join upcoming focus groups.
- Dental focus group has completed their review. MDH intends to post dental rule provision and meeting minutes on the X-ray rule revision website by the end of April.
- Referred to posted document listing the X-ray rule revision webpage address, rule comments webpage and email address, and rule chapters referenced during this meeting.
- Public comments will be at the last 15 minutes.

- Asked the committee to respond with their availability regarding the proposed advisory committee meeting dates.

Definitions

Jacque Cavanagh, Section Policy and Rules Analyst

Cavanagh went through Preface of Definitions 4732.0110 v3. Asked for any comments or concerns with Definitions starting with “A”.

Subp. 9. Annual.

Michael Lewandowski (Advisory Committee Member, ACM) questioned the amendment to the definition of “annual”. He doesn't agree with adding “or 365 days”. Purrington explained that MDH intends to specify in the rule chapter when a registrant must meet the annual definition of 365 days plus 30 days to comply with an annual requirement. Cavanagh stated that once we go through the rule, we might find that it’s always plus 30 days, and change the definition at that time.

Subp. 22. Bone densitometry system.

Amend. Richard Giese (ACM) questioned why MDH added “gamma rays” to the definition of bone densitometry system, and asked if it should be removed from this rule. Purrington stated she will refer to Suggested State Regulations for Control of Radiation (SSRCR) from the Conference of Radiation Control Program Directors (CRCPD).

Subp. 25. Calibration.

Amend. Cavanagh asked the committee about the option to align with SSRCR, or create a new EPE (equipment performance evaluation) definition. Tony Murphy (ACM) stated that he supports creating a separate definition for EPE since EPE and calibration are often confusing for the regulated party. Frank Zink (ACM) agreed, as well as other committee members. Purrington asked the committee to review this topic and send comments.

Subp. 36. Computed radiography.

Repeal. Beth Schueler (ACM) asked if CR will be included at some point in the rule. Purrington stated CR will be defined in the digital radiography definition rule part, but it’s possible that MDH could opt to redefine in Definitions.

Subp. 37. Computed tomography or CT.

Purrington stated it's important to delineate the difference between CT and CBCT. Zink stated the definition of CT covers all types of CT systems. Cavanagh stated we could include examples of CT systems, or include this as a group such as the FDA describes groups. Lewandowski stated we shouldn't group all types of CT together. Purrington stated the CRCPD is currently working on a guidance document on this topic for dental CBCT. Zink stated this should be flagged for the Medical Focus Group and recommends that the FDA’s device classification for medical devices be recognized in the rule as advancements come out after the rule is approved.

Subp. 50. X-ray imaging system.

Amend. Zink asked if therapy planning systems will go under X-ray Imaging System definition. Purrington stated this would need its own definition or be exempt. Murphy stated we shouldn't assume that we're excluding OBI imaging from 4732 and will be cited in 4733, we should verify

that it is or include wording of this in 4732. Purrington stated MDH will verify that these points will be conveyed for those reviewing 4733. Cavanagh stated there is a draft rule document and John Olson (MDH) will be taking the lead on 4733. Giese proposed the wording “exempt therapeutic imaging system” within the definition.

Subp. 51. Digital radiography.

Amend. Asked committee to comment. Schueler stated this is a bad definition. Giese stated that it should be referred to as direct or indirect. Schueler stated that if CR and DR will be separated in the rule, they should have separate definitions. Purrington stated she'll have the Medical Focus Group look at this definition.

Subp. 52. Direct supervision.

Repeal. Murphy stated he doesn't agree with the definition for “Personal supervision”, and likes the “Direct supervision” definition. Zink stated he agrees with this. Murphy also stated this might need to be tabled until the committee's discussion on “Personal supervision”.

Subp. 64. Facility.

Amend. Schueler questioned the need for adding “complex” to the definition. Purrington gave examples such as Mayo and U of M campuses that have buildings on the same site. Zink questioned whether we need to clarify this in rule. Lewandowski stated that this might be common sense and not need to be in the definition. Purrington stated that MDH will take the committee's thoughts and suggestions, and review this definition.

Subp. 68a. Fluoroscopically-guided interventional procedure or FGI.

Amend. Schueler asked about the intention to use this definition in rule. Purrington stated a radiation safety committee with higher energy equipment will be reviewed for safety culture in a focus group. A definition for radiation safety committee is proposed in the rule changes.

Subp. 76. Healing Arts.

Amend. Julie Sabo (ACM) stated if there are changes to the definition of “licensed practitioner of the healing arts”, then this definition would need to be amended as well. Lewandowski asked about the difference between healing arts and healing arts screening, and non-human use. Purrington stated that if you don't have a written order from your clinician, registrants can submit an application to MDH for review for computed tomography lung, cardiac or colon examinations.

Subp. 78a. Image.

Amend. Giese offered that the word “image”, which could include a photograph, and may be too vague. Purrington stated we can differentiate between the definitions in the rule parts. Ronnell Hanson (ACM) mentioned that many of the types of images in the definition cannot be maintained for storage purposes.

Subp. 84. Individual monitoring devices.

Amend. Conforming to 4731 definition. Lewandowski questioned what we are monitoring, dose of record or monitoring devices? Purrington stated we could put a flag on this definition for when it's discussed in rule. William Duppler (ACM) added that there are many types of OSL (optically stimulated luminescence) devices not included in this rule definition.

Subp. 91a. Install or installed.

Amend. Verke stated that equipment can be drop-shipped, purchased online and delivered to a facility. These x-ray systems are received ready for use and are not physically assembled once received by the registrant. The definition is meant to encompass all x-ray systems that are deemed by the distributor or assembler ready for use by a registrant. Purrington stated that this definition needs some work, and asked the committee to provide comments. We'll flag this definition as well.

Subp. 101. Licensed practitioner of the healing arts.

Amend. Still receiving comments on this definition, will come back to this at our next meeting.

Subp. 102. Light field.

Amend. Murphy stated he doesn't agree with the amendments to this definition and would like to review. Purrington requested to submit suggestions to MDH for review.

Public Comments

Teresa Purrington, X-ray Unit Supervisor

Purrington asked for any public comments.

- Linda Laman, subp. 37a. Reconstruction algorithms not an option in CBCT, maybe a terminology change? Definition is potentially confusing. Committee agreed that this definition may need to be reviewed at a later date.
- Barb Hodge, referencing public comment, suggested changing to generate images "in" a desired plane.

Adjournment

Teresa Purrington, X-ray Unit Supervisor

Teresa stated that the committee's work and collaboration are important, and asked them to continue to provide comments and suggested language. Cavanagh asked the committee how much time they need to review documentation and provide comments before the next meeting. The committee agreed 10-14 days is sufficient. Cavanagh requested comments in the next two to three weeks to allow time to incorporate comments.