

X-ray Advisory Committee Meeting

MEETING MINUTES

Date: January 9, 2019

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

Attendees: Beth Schueler (Medical Physicist), Frank Zink (Medical Physicist), Jon Wohlhuter (MN Association of Nurse Anesthetists), Julie Sabo (MN Nursing Board), Ronnell Hanson (MN Radiological Society), Tony Murphy (Medical Physicist).

Conference Call: William Duppler (Medical Physicist).

Absent: Bridgett Anderson (MN Dental Board), Brian Hall (Service Provider), Dan Lind (Service Provider), Louis Saeger (MN Medical Association), Michael Lewandowski (Health Physicist/CHP), Richard Geise (Medical Physicist/PhD), Vinton Albers (Chiropractic Association).

MDH: Bevin Beaver, Craig Verke, Jacquie Cavanagh, Kelly Medellin, Mary Navara, Paul Germann, 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

Mary Navara, Indoor Environments and Radiation Manager

Teresa Purrington, X-ray Program Supervisor

Purrington welcomed the Advisory Committee and the public, and introduced MDH staff. She stated that the Advisory Committee may not be meeting until June or July, and MDH staff will take that time to prepare several rule drafts to present to the committee at that time.

Purrington asked the committee for comments on a potential definition for "operating". MDH researched this extensively and other states really do not define operating. MDH is considering including the definition from a suggestion at the last committee meeting. Frank Zink (Advisory Committee Group – ACG) questioned item D and stated that the patient table needs more clarification, as it could be moved for a number of reasons. Tony Murphy (ACG) stated item C should state at the beginning "setting or manipulating". Zink asked if the definition is consistent with the information notice sent out by MDH, and Purrington stated that it is.

Review of CT or Medical CBCT X-ray System Requirements

Teresa Purrington, X-ray Unit Supervisor

Jacquie Cavanagh, Section Policy and Rules Analyst

Subp. 1. Applicability.

Purrington stated that MDH looked at Colorado's draft rules as a reference. Beth Schueler (ACG) asked for a definition of CBCT and what type of equipment it includes. Purrington stated it is the FDA 21 CFR classification of CT, which includes CBCT. She also stated the "medical" and "dental" wording would be added before CBCT in the separate rule parts for clarity. Schueler asked if fluoroscopy is exempt from this whole section, or just the sections that state the exemption. Purrington stated that they are only exempt from the sections that specifically exempt fluoroscopy. Zink asked if O-arm has an FDA classification that includes cone beam. Purrington stated it is classified as fluoroscopic. Zink stated that this system should not be included in this rule part at all because it is not a CT system. Schueler asked about radiation therapy. Purrington stated it would be included in the radiation therapy rule. Purrington stated that might need to be clarified in the rule. Zink questioned item 1(B) and if we should be restating a statutory requirement. Purrington stated MDH thought it was important to include because it is not a statute that the X-ray program administers. Zink questioned including PET CT. Purrington stated that since MDH regulates this type of equipment, it should be held to the same standards.

Subp. 2. Radiation exposure control.

Schueler questioned what MDH intends with this subpart. Craig Verke (MDH) stated that it is referencing the federal regulations at 21 CFR. Zink questioned why this needs to be included in the rule and it might change. Purrington stated MDH considers it important to include these, as do other states that are including this in their new rules. If the FDA decides to adopt other standards, the applicability states or successor requirement to 21 CFR.

Subp. 3. Tomographic plane indication and alignment.

Schueler questioned whether to keep item A, as the single tomogram system is outdated. Purrington stated MDH would review it. Verke stated that 21 CFR was updated in 2015.

Subp. 4. Safety devices.

Zink asked if item 4(B) is a 21 CFR reference. Bevin Beaver (MDH) stated it is from SSRRCR. Zink stated we have no control over this and as technology evolves, this could change. He also stated that whatever we decide, it should be well grounded before making it a requirement. Purrington stated MDH would research this further.

Subp. 5. Additional requirements applicable to CT or medical CBCT x-ray systems containing a gantry manufactured after September 3, 1985.

Schueler questioned item C and stated that 1 millimeter is rather restrictive. She asked if this should be 2 millimeters as this is the requirement from ACR. Purrington stated this is consistent with 21 CFR federal regulations.

Subp. 6. Indication of CT conditions of operation.

Purrington asked the committee if operators could visualize the CT conditions of operations at all scan initiation positions. Zink stated that it makes sense and asked if it is in 21 CFR. Schueler asked if item C is meant for CT and not CBCT systems classified by FDA as a CT. Beaver stated that this is intended to include CBCT. Purrington stated that item D will go into the definitions part. Schueler stated the CT conditions of operations definition would only be for CT, not CBCT. Ronnell Hanson (ACG) stated the technique factors are not always visible. Purrington asked Hanson to look at his CT scanners and let MDH know where the technique factors are located. Zink stated he is concerned about including anything that the FDA does not define. Purrington stated that this is supposed to be followed now, and requires more discussion. Hanson stated the CT operator needs to know all these factors and that should be considered.

Subp. 7. CT x-ray system patient communication.

Zink questioned if there are viewing systems with no window that are electronic. Purrington stated this is in our current rule but we are not aware of any. Tony Murphy (ACG) stated that this might be true in radiation therapy and knows of a PET/CT system that currently does have an electronic viewing system. Purrington stated MDH would make sure the radiation therapy rules are consistent with the x-ray rules regarding patient viewing systems.

Review of CT or Medical CBCT X-ray System Equipment Testing

Teresa Purrington, X-ray Unit Supervisor

Jacquie Cavanagh, Section Policy and Rules Analyst

Subp. 8. Equipment performance evaluation; testing requirements; frequency.

Purrington stated that this provision represents a shift from our current rule but it is what SSRRCR recommends. Zink stated we need to add, "*as determined by a qualified medical*

physicist" to item B. Zink also stated that item C should include wording for those systems without national recognized tolerances. Purrington asked where that language would be. Zink stated he would provide MDH with the language. Zink questioned if a qualified medical physicist should sign off on all testing, even if it goes over the 14 days. Jon Wohlhuter (ACG) stated this is similar to the conversations the committee had for fluoroscopic equipment. He stated that a qualified medical physicist should sign off on all work. Zink stated wording could include "*the confirmation testing needs to be signed off by a qualified medical physicist*", and this could be done remotely. Murphy stated there should be some clarification on what causes a change in output. Purrington stated the American College of Radiology (ACR) has a document that clarifies this and maybe MDH should develop a guidance document as well. Murphy stated you could use the wording "*potentially cause harm*". Purrington asked where this would be added. Murphy stated whenever the word "*cause*" is used. Zink stated that because this is a gray area, it should be tested by a qualified medical physicist. Murphy stated maybe wording that includes "*service*" should be included. Schueler questioned the 14-day limit because the use is already being restricted. Purrington stated MDH would consider that. Hanson stated he agrees with the 14-day time limit because this would be safest in this scenario.

Purrington displayed the ACR Computed Tomography Quality Control Manual that was referenced. It includes a table that describes when a qualified medical physicist oversight is recommended. Zink stated this would be good guidance but do not include it in rule. Murphy stated he does have concerns about continuity, as there are many gray areas. Schueler questioned item E and whether the qualified medical physicist retains the documentation or the facility. Purrington stated it that it is the facility.

Subp. 9 and 10. Equipment performance evaluation; CT x-ray system. Equipment performance evaluation; medical CBCT x-ray system.

Zink asked where these standards came from. Purrington stated MDH researched this and the CT standards are from SSRCR and are consistent with ACR. There are no other set standards for CBCT in SSRCR, we are using IAC standards and reviewed how physicists are testing these systems. Murphy asked if qualified medical physicist guidelines would be acceptable if there are no other standards. Verke stated that was the intent of this rule part, but this may need to be clarified. Zink stated that not all the items are applicable, and including the wording "if applicable" for items A and B would suffice.

Subp. 11. Quality assurance.

Purrington asked the committee about the suggested language in the comment. Zink questioned why we would need the comment, as its worded correctly in 21 CFR. Zink also suggested to reference 21 CFR, and remove the wording "*under 21 CFR*". Schueler stated that the fluoroscopic systems would not have a phantom, and should be exempt. Zink stated that item A needs more clarification and is missing some text. Murphy pulled up 21 CFR to provide the wording, "*shall provide the following*". Zink stated that item C is referencing something in 21 CFR and we need to make it our own, as it does not make sense. Zink questioned item D(2) and if we intended for the quality control to be stored in PACS or the system. He suggests storing it in PACS. Purrington stated MDH would look into that.

Subp. 12. Routine quality control; development and requirements.

Schueler questioned item C and stated that fluoroscopy systems should be exempt. Zink questioned sites that have an x-ray technologist and an RT. Verke stated the CT operator must be someone that is qualified. Purrington stated each rule part would reference a qualified operator for that particular rule part. Zink stated the wording for item C should be 1 and 2, and 3. Cavanagh stated that the intent was the way it was written. William Duppler (ACG) stated his concern for the 24-hour timeframe. Schueler questioned item E and stated a qualified medical physicist could do this as well.

Subp. 13. Shielding plan.

Schueler questioned O-arms stating there is no barrier provided, and the operator needs to be next to it. She suggested exempting it. Zink agreed, and stated O-arms should be exempt from many of these provisions. Purrington stated MDH would review this.

Subp. 15. Radiation protection surveys; CT or medical CBCT x-ray systems.

Purrington asked the committee for their input on the comment for this subpart. Zink stated adding "*in the judgement of the qualified medical expert*" would suffice, and to use language from NCRP 147. Zink questioned item C and if we have a definition of when a mobile system becomes stationary. Purrington stated we do not have a definition for this but we have included this as a suggestion in the comment. Schueler stated that in item D, a written report should be required, but could be electronic.

Subp. 16. CT fluoroscopic x-ray system examination.

Purrington stated this language has not changed and it is in our current rule and in SSRCR. Zink stated the concept of fluoroscopy in a CT setting should be defined for interventional CT. Schueler questioned personnel monitors and if everyone needs to be badged. Zink stated personal monitoring should not automatically be required unless occupational dose meets 10% of the annual requirement. Purrington stated we have not gotten to those rule parts and the x-ray rules will be consistent with radioactive material rules. MDH will come back to this to clarify.

Review of Training for CT or Medical CBCT X-ray Systems

Teresa Purrington, X-ray Unit Supervisor

Jacquie Cavanagh, Section Policy and Rules Analyst

Subp. 17. CT qualified operator qualifications.

Hanson questioned item A(3) and stated their scope of practice should be specific to radiation and may want to consider supervision. Purrington stated MDH would look back on the discussions the committee had with fluoroscopy. Zink stated there is some concern about who should operate PET and SPECT CT systems and the concern to extend to allow a nuclear medicine technologist to do this. He offered to research this. Purrington stated we would need to refer to the statute to verify authority.

Public Comments

- Linda Laman: Questioned qualified operators under subpart 17, and stated they can go through ARRT and NMTCB. A nuclear medicine technologist without the qualifications would not be qualified. She would like to see the NMTCB registry accepted in this rule part.
- Sue McClanahan: Stated she is concerned about the operator list of training for fluoroscopy and CT that only a QMP could provide this training. Purrington stated MDH would review the training.
- Jeff Brunette: Asked if the rule parts we did not get to today will be discussed later. Purrington stated the public can send comments, and the rest of these rules will be discussed at the next meeting. He also stated not every facility defines their committee as a Radiation Safety Committee. Purrington stated the committee discussed this and it was determined to be consistent with radioactive materials. Many registrants already do this within their current committee. He also stated the definition of shielding for stationary and mobile is unclear.
- Lifeng Yu: Questioned CT protocol review and stated if the Radiation Safety Committee takes on that role, the RSO should be included in the committee. He also questioned why we define the tolerance under Subpart 5. Purrington stated this is something we have to follow because it is a requirement of 21 CFR. He also stated that 21 CFR is outdated, and that they are considering adopting IEC standards. Purrington stated that MDH is aware of IAC standards and the FDA changes, and will include successor requirements whenever possible.

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