X-ray Advisory Committee Meeting

MEETING MINUTES

Date: September 21, 2018

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

Attendees: Beth Schueler (Medical Physicist), Brian Hall (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).

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

Absent: Bridgett Anderson (MN Dental Board), Dan Lind (Service Provider), Louis Saeger (MN Medical Association), 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

CFR – Code of Federal Regulations (typically referencing 20 CFR 1020.30 to 1040.40)

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

Welcome and Introductions

Teresa Purrington, X-ray Program Supervisor

Purrington welcomed the Advisory Committee. Cavanagh explained that soon MDH would send some of the x-ray rule drafts to the Revisor's Office. Agencies are required to send their draft rules to the Revisor's Office so that they are in the proper form for publication. Purrington stated that the committee would discuss other fluoroscopy topics at the next meeting on October 26.

Review of Fluoroscopy X-ray System Equipment Specifications

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

Subp. 1. Applicability.

Purrington asked the committee for their opinion on adding a rule part regarding unauthorized hand-held fluoroscopic equipment for human use. Frank Zink (Advisory Committee Group – ACG) stated that MDH should include hand-held fluoroscopic equipment if FDA allows it and if they do not now, wait until they do. Purrington responded that FDA currently has no approved hand-held fluoroscopic equipment. MDH anticipates revising the rule every two years, and that a variance to the prohibition could be requested until the rules are amended to allow for this use. But, to obtain a variance, there must be a rule provision to vary. Craig Verke (MDH) stated that hand-held use came around 2005, and FDA has not changed their code of regulations for hand-held fluoroscopic equipment.

Beth Schueler (ACG) asked why it is necessary to duplicate the CFR requirements in the rules, rather than referring to it. Purrington responded that any paraphrasing of CFR requirements are intended to be consistent with CFR and any deviation from CFR is unintentional. Purrington stated FDA is looking to use IEC standards or allow to use 21 CFR. IEC standards are not for public viewing and comes with a cost. FDA is working with organizations to make IEC standards available with a crosswalk to 21 CFR, this process is unclear at this point. Richard Geise (ACG) stated he is concerned about everyone having access to IEC standards and including the IEC equivalent in the rules. Purrington responded that until MDH has more information, this is how we are going to move forward. Zink stated that the current draft is not readable to stakeholders, and suggested adding section headings that acknowledge meeting the CFR in this section. Purrington responded that this is a similar framework that is based on a review of other states' rules. Purrington stated MDH would reach out to the other states that include CFR in their rules to see if there are issues or concerns with interpretation.

Subp. 3. Measuring compliance; primary protective barrier.

Zink asked if anyone has used this CFR rule part to make the public safe. Geise asked if this is also in CFR. Purrington stated that is the case, and would like to focus on other discussion for the rest of the meeting. Zink asked if MDH is requiring registrants to do an actual measurement under subpart 3, item D. Verke stated this test was performed by MDH for Level 2 FDA initial compliance testing. Zink stated the rule should state if you measure it, this is how you do it.

Subp. 4. Field limitation; x-ray systems manufactured on or after February 25, 1978.

Purrington asked the committee about uncertified x-ray equipment for human use. Michael Lewandowski (ACG) asked if there is equipment that is more than 40 years old being used in the state. Purrington stated she could not answer the question because MDH's data system has not historically tracked the date or age of equipment. Geise suggested removing this part, and requiring registrants that have uncertified equipment apply for a variance.

Schueler asked if items G-I are referring to spot film devices, and stated if they are, they should be listed as subparts under item F. Lewandowski questioned items I and if 1 and 2, and stated they are repeated under item 3. Purrington stated MDH would look at that.

Subp. 6. Exposure rates; x-ray systems manufactured before May 19, 1995.

Purrington asked the committee if the wording "excluding last image hold" should be added. Texas has this language in its rules but it is not in CFR. Schueler stated she thinks it is fine to keep it.

Subp. 9. Exposure rate; measuring compliance.

Zink asked if mini C-arms are included, and Purrington confirmed that they are.

Subp. 13. Source-to-skin distance.

Schueler asked if adding the phrase "in a sterile field" is also referring to catheter and needle-based services. Suggested "or in a sterile field" for procedures where a spacer cone is not practical to use. She stated any procedure where there is a table that you need to go under, a spacer cone cannot be used. Zink suggested that the rules could allow the RSO to define all the procedures where the use of a spacer cone is exempted. Purrington stated MDH would take that under advisement. Purrington asked if the definition of sterile field needs to be added to the rules. Zink stated anything surgical is sterile. Purrington stated CRCPD has the wording "surgical procedure or sterile field". Ronnell Hanson (ACG) stated there are procedures that are clean procedures too. Verke stated the FDA/CFR refers to "sterile settings", but the term is not defined. Hanson stated that surgeons try to limit the Image Intensifier distance to the patients and the portable units cannot be altered to be closer to the patient. Purrington stated MDH would review all the suggestions.

Purrington asked about the wording "for extremity use only" in item C(2) for mini C-arms. Schueler stated that the language "for extremity use only" is required for FDA and is acceptable. Zink stated if item C is referencing a mini c-arm, we should make that clearer.

Subp. 15. Displays of values of exposure rate and cumulative exposure.

Purrington asked if air kerma should be added to this part. Zink stated there is value in adding AKR and cumulative air kerma because both CFR and Joint Commission use it. Zink cautioned that some systems display the AKR, however do not store the information as it only dates back to 2006 for certain equipment. Hanson asked how MDH is going to use these systems with the Joint Commission standards. The Joint Commission standards require AKR information to be in

a retrievable format, like EMR. Purrington accessed the Prepublication Requirements for Fluoroscopy on the Joint Commission website for the committee to review.

Review of Fluoroscopy X-ray System Equipment Testing

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

Subp. 16. Equipment performance evaluation; testing requirements; frequency.

Purrington asked the committee for their thoughts on equipment performance evaluations. She stated there is a current restraint now regarding EPE prior to first use for greater Minnesota. Tony Murphy (ACG) stated this is a rule of convenience, the 30 days. Zink agreed with Murphy. Zink stated this is a tough one to justify and inconsistent if we required everything in the past before first clinical use. Zink stated if MDH went to the 30-day window, this would be inconsistent with installation in rules. Murphy stated if it is worth testing at installation, or changing a component, it is worth it for every patient. Geise stated he is not in favor of the 30 days, but there is a difference between this and what we do now. He stated in the past, the service provider made some measurements to make sure it is working properly before first use. He questioned if something needs to be done immediately, could it be done by someone other than a qualified medical physicist. Murphy stated he agrees with Geise, and that someone has to check it immediately. Zink stated he agrees it should be tested, but we have not resolved who will do the testing. Schueler stated if a manufacturer repairs something, we trust them to repair properly. She also stated MQSA rules are so stringent, and we do not have to do this. Zink stated in MQSA it is done by service intervention from a physicist. He stated there are fluoroscopy service providers that do not measure dose and they are not equipped to measure maximum dose rates. Geise stated that if we say it has to be measured or certain tests have to be performed, then the registrant should get a physicist to perform the tests. He stated we should work around that to include someone other than a medical physicist or someone under their direction, or the QMP must come in within a certain amount of time to ensure it was done. Zink stated even if we do the 30 days, we do not want to release the service provider to make sure they do it right. He stated we need to be careful to not put the registrant in the position to make sure the service provider is qualified. Jon Wohlhuter (ACG) stated that this committee's job is to ensure public safety and the bottom line is that if we do not have a mechanism for testing then we are putting patients at risk. He stated it has to be tested and we need to make sure it is. Purrington asked the committee about greater Minnesota and if their equipment goes down, they cannot effectively manage care. Wohlhuter stated there could be something in the rule that says if it has not been tested, but there is an emergency, then go ahead and do it. He also stated this gets to be a gray area. Zink stated if you are going to have something repaired, have a QMP sign off in the post survey results. Purrington stated this is good communication and conversations we are having. Michael Lewandowski (ACG) stated that if repairs are made, there should be testing. He stated service providers could provide the testing, but have a QMP review it. He also stated we need to be careful between appropriate testing of a repair and a complete equipment performance evaluation, to keep the distinction between the two, as it is reasonable to test the repair, but not require all the things required in an equipment performance evaluation. Verke stated that we are finding out that many of the

service providers that work for the manufacturers do not do a complete evaluation and everything is done by software that evaluates everything. He stated they are not doing an actual external evaluation of the system and many of these manufacturers have physicist on staff. Purrington thanked the committee for their time, and all points will be discussed internally.

Schueler questioned item C. She questioned if this is necessary for mini c-arms with low output. Geise stated that a mobile c-arm would have factory testing and questioned if there would be a physicist there to monitor that. Zink stated there is room to have a QMP to sign off on a low output tube. He stated he has never had a manufacturer change for state regulations. Brian Hall (ACG) stated that does not make it right. Hanson asked if it is possible to run the test again and stated if it is abnormal, then call in qualified personnel. Zink stated we have a mechanism for a tiered system at the state level and should use it, as the manufacturers are not going to follow each individual state regulations.

Purrington summarized the committee's comments and asked if she captured everything, including excluding mini c-arms. Zink stated that she did and stated that if nationally we are using FGI, he does not have a problem with using that. Lewandowski stated that no one is saying that mini c-arms should not be tested, but who should do the testing. For those devices that have a higher risk, we need individuals with higher qualifications. Geise stated the committee discussed as the last meeting if they should include mobile c-arm and stated that you can do damage with very low power devices. Verke stated facilities are using fluoroscopy in different ways than they have in the past. Zink stated that joint commission standards require annual supervision of testing, not repairs. Purrington asked the committee to put something together and submit to our x-ray rules inbox. Zink stated he is willing to write something up that allows the repair person to do as much as they can, and if they can't, then have someone qualified do it.

Public Comments

- Shane McCotter: Questioned the 35% for air kerma. Stated there are some systems with calculated values higher than this that cannot be adjusted. Verke stated MDH would confer with the FDA.
- Shane McCotter: Suggested for subpart 16 that everything be tested after install and repair. If a service technician can test it, and if a medical physicist could review it that would suffice.
- Sue McClanahan: Stated MDH should go back and look at the qualifications that were already discussed in the rule as we have added more responsibilities to the service provider and non-qualified medical physicists.

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