X-ray Advisory Committee Meeting

MEETING MINUTES

Date: October 26, 2018

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), Matt Thorson for Louis Saeger (MN Medical Association), Richard Geise (Medical Physicist/PhD), Ronnell Hanson (MN Radiological Society), Vinton Albers (Chiropractic Association), William Duppler (Medical Physicist).

Conference Call: Tony Murphy (Medical Physicist).

Absent: Bridgett Anderson (MN Dental Board), Michael Lewandowski (Health Physicist/CHP).

MDH: Bevin Beaver, Craig Verke, Jacquie Cavanagh, Kelly Medellin, Mary Navara, Stephanie Welvaert, 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

Navara welcomed the Advisory Committee and the public. She introduced Jacquie Cavanagh and Teresa Purrington, as well as other MDH staff present at the meeting, Patricia Winget and Melissa Finnegan.

Purrington introduced the X-ray Unit rulemaking team. She stated there will be 30 minutes at the end of the meeting for public comments. She introduced Matt Thorson, M.D., representing Minnesota Medical Association for Louis Saeger. The committee introduced themselves to Matt Thorson.

Review of Fluoroscopy X-ray System Equipment Testing

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

Subp. 17. Equipment performance evaluation; exposure rates.

Frank Zink (Advisory Committee Group – ACG) questioned items B and C. He asked if there was difference among items one, two and three. Purrington stated we could be missing a header and MDH will review.

Subp. 18. Equipment performance evaluation; display exposure rate.

Rich Geise (ACG) suggested the wording “systems that provide displays”. Tony Murphy (ACG) asked if there would be criteria for item F (measurement evaluation). William Duppler (ACG) stated this is consistent with the FDA.

Subp. 19. Equipment performance evaluation; filtration (half-value layer) test.

Beth Schueler (ACG) questioned item G. Item G should state the “minimum”, not when everything is within the beam.

Zink asked where the rule states what needs to be tested and at how many kVps the half value is measured. Purrington stated the half-value layer it is in the beginning of this subpart. Purrington stated MDH discussed defining clinical range. Zink stated this could be misinterpreted without some guiding language.

Subp. 20. Equipment performance evaluation; beam size test.

Zink questioned the wording “spot film size”.

Subp. 22. Equipment performance evaluation; image resolution test.

Zink questioned item C(2) and stated the specification of the requirement is missing. Schueler stated that a manufacturer does not usually specify and it is usually a theoretical value. She

suggested not using the manufacturer specification for spatial resolution. Verke stated if the manufacturer does not have it then there is no standard for resolution. Zink stated he is not aware of any issues of and suggested we could put language for “either” or “the following”.

Subp. 23. Equipment performance evaluation; safety controls.

Purrington stated this requirement comes from SSRCR and asked the committee for feedback. Zink stated it looks fine.

Subp. 24. Shielding requirements.

Geise questioned occupational dose limits. Verke stated these would be the occupational and public dose limits.

Subp. 25. Shielding plan.

Purrington asked about mobile equipment. Geise stated this should be equipment being routinely used in one location. This would be the shielding of the room within the mobile unit. Schueler stated that Wisconsin rule applies only to radiographic units, not fluoroscopic. Purrington stated she would follow up with Wisconsin to verify. Geise stated you need to determine if shielding is needed in those situations. Zink responded that it should require a shielding plan. Schueler stated it does not seem necessary to include a shielding plan for a mobile c-arm, in an OR setting in a hospital. She suggested including a minimum workload. Purrington stated she wanted to gauge the input of the committee regarding shielding, as MDH will be working on shielding rules later. Zink stated that we should look at NCRP Report No. 147 for the wording.

Review of Fluoroscopy Supervision and Qualified Operators

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

Subp. 26. Supervision of fluoroscopy.

Julie Sabo (ACG) questioned item B(2) and asked if there should be components included in the number of hours for clinical experience supervised. Sabo stated MDH should reference subpart 28 listing. Bevin Beaver (MDH) stated B(2) is from SSRCR. Sabo stated it might be important to clarify what the didactic training is in B(3). She also asked if this would be reviewed by the radiation safety committee and MDH. Purrington stated MDH would review during inspection.

Zink questioned the 40-hour and the 8-hour training requirement. He believes the 8 hours would be exempt for Radiologists and others who receive training. Zink also stated MDH should differentiate between FGI and non-FGI procedures. Zink stated this would be expensive for larger sites to provide this training. Purrington stated sites could create their own 8-hour course.

Geise questioned item B(3) and gave the definition of didactic. He stated this definition would mean everything listed is didactic training. Purrington stated we could define didactic training in

the rule. Zink stated it should be specific, clinical versus non-clinical training. Geise also asked what type of supervision by a qualified practitioner, general or direct.

Ronnell Hanson (ACG) stated that the 40 hours should state 40 hours of *fluoroscopic* procedures. He also stated there should be competency testing at certain intervals and that there is free training online through Image Gently and other online resources. Geise stated that physicians should be excluded as they receive extensive training.

Purrington stated the intent of this rule part is that physicians would be excluded through education, and would only need to provide documentation. Schueler stated ACR standard from management of use of radiation refers to ancillary physicians only, PA's and APRN's.

Sabo stated that a registrant could validate that they have that training. Zink stated that physicians might not be able to provide proof of this specific training.

Jon Wohlhuter (ACG) stated that intent of this would be that the person supervises fluoroscopy would be responsible for ensuring safety in the room.

Purrington asked the committee to comment if residents need supervision in fluoroscopy. Matt Thorson (ACG for Louis Saeger) stated that residents would need to have direct supervision during their residency. He also stated that the wording should state that physicians are exempt from the 40-hour training requirement.

Brian Hall (ACG) stated that not all physicians have had fluoroscopy training.

Thorson stated that didactic training should be defined better.

Sabo stated that subitems A and B should not be under item 3. Geise questioned if the list should be in a guidance document and not specified in rule. Purrington stated that MDH would review the list.

Geise stated he agrees with Zink, but is concerned about physicians who have been practicing for a long time.

Wohlhuter suggested removing supervise in subpart 28 and removing subpart 3(A) and state we need 8 hours of training in addition to training in subpart 28.

Subp. 27. Qualified operator qualifications.

Schueler suggested adding the word "fellow" with "resident" and stated this should be clarified until they reach qualified practitioner status.

Zink questioned item A(1) and asked if there is a proposed change in the physician assistant (P.A.) delegation agreement. Purrington stated that MDH is removing our in 4732 requirement to have P.A. agreement onsite for review.

Zink also questioned item E and stated x-ray operators should not be grandfathered in and removed. Purrington stated this could not be removed because it is in statute. She also stated there would be a separate part where MDH would require continuing education. Zink stated this should be in this rule part.

Review of Fluoroscopy X-ray System

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

Subp. 28. Training requirements; fluoroscopic x-ray systems.

Wohlhuter questioned the 8 hours of training for supervisors. He stated this is the only training a qualified physician [ie – qualified practitioner] would need to take. He also questioned the amount of time and if it should say 40 hours of clinical time during a fluoroscopic case.

Purrington asked the committee to respond to the comment in item D.

Zink stated that he would allow either. Zink also had a comment on item B and referred to it a mini-application training. He stated that a surgeon does not need to know the application piece. He suggested limiting this to operators and differentiating between operation and supervision. Ronnell Hanson stated the VA requires training for physicians on each piece of equipment.

Geise asked if the training in item C could be the manufacturer or the person supervising them. Purrington stated MDH would look at that. Geise stated is initial training, and questioned if it is initial before you use that particular equipment.

Schueler asked if items B and C are required by other states. Purrington stated there are some states that require this. Zink stated the intent should be a one-time demonstration of principles. Geise stated a medical physicist would need to provide that training. Wohlhuter stated the exam from the operators training course would cover training and suggested removing item C. Purrington stated item C is the demonstration of the specific equipment.

Subp. 29. Ongoing training required.

Geise questioned the training requirements provided in eight hours, now shortened into a two-hour training. Purrington stated this would be a refresher training. Hanson stated this is already common practice. Geise suggested that “abbreviated training” be included. Sabo suggested a baseline minimum not just two hours.

Review of Radiation Safety Committee

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

Subp. 30. Conditions of operation.

Zink questioned item A and asked what is intended by the work interpreted. Purrington stated they would be in the exam and interpreting the images. Zink asked if the qualified practitioner has to watch what is going on. Hanson stated this would be someone would have enough knowledge of the examination and irradiating the right part for the right reason. Geise suggested using the word “evaluated”.

Subp. 31. Radiation safety committee; fluoroscopy.

Zink stated this could be onerous for a facility that does not do FGI procedures. He also asked if the RSO could also be the qualified medical physicist. He suggests only requiring this for FGI procedures. Purrington stated this was discussed with definition of radiation safety committee to include fluoroscopic equipment by the advisory committee. Schueler questioned if every registrant had a radiation safety committee, or if facilities under one organization could share a committee. She suggested that facilities under one organization should only have to have one committee. Wohlhuter agreed and stated that item F should be moved to item A or B. Hanson stated that maybe there should be some sort of limit to how many facilities one committee supervises, and this should be looked at on a case-by-case basis.

Subp. 32. Radiation safety committee; responsibilities.

A (1) Geise questioned the wording “radiation dose to the skin”. He suggested the wording that NRCP recommends “radiation dose level”. Schueler asked about the intention of this part. Verke stated this is only for those who have fluoro-time only. Beaver stated this was included after discussions from the last meeting regarding older fluoroscopic equipment. Geise stated that current regulations do not require a notification to the commissioner, and he suggests we keep it that way. A (3)(b)Geise stated this is specific to a medical event. Zink stated the radiation safety committee has very broad responsibilities for training, and it is already an institutional responsibility. He stated the committee responsibility should provide oversight to the RSO. He suggested changing the delegation of authority requirements to reflect this. Geise questioned item C and suggested adding the requirements for the QMP and QE has proper training/credentials as well. Schueler asked if the“6 gray” notification in the current rule would be removed from the proposed rule. Purrington stated that this is the case. Schueler suggested referencing what the new standard is in the rule. She asked who sets the SRDL and the rules should be specific.

Subp. 33. Radiation safety committee; document review.

Geise stated the QMP training should be included here as well. Thorson questioned item A(2) and asked if a qualified practitioner is supposed to evaluate themselves for smaller facilities. Purrington stated the radiation safety committee would be verifying scope of practice. Geise stated this is out of the realm of radiation safety. Wohlhuter stated when someone is credentialed the credentialing body is responsible for scope of practice. Frank stated that the organizations themselves verify scope of practice of the qualified practitioners before hired.

Subp. 35. Ordering of fluoroscopic examination.

Geise stated the word “order” should be “request”. Hanson questioned if this referring to a formal physician order and this is EMR required. Zink stated this is usually a formal order.

Subp. 36. Utilization data.

Zink questioned item B(5) and requiring the first and last name of all individuals in the room. He stated it might be required in procedure documentation to reference who is in the room, but not in the utilization log. Purrington stated the Advisory Committee agreed with this in the proposed dental rules and the language is carried over. Zink stated MDH should revisit the dental proposed rules again. Hanson stated in medical procedures, there might be more people in the room. Purrington questioned why we would be more strict in dental, but not fluoroscopic.

Purrington stated the rest of the rule parts not discussed at this meeting would be finalized via email with the Advisory Committee, and the November meeting will be canceled. She mentioned anyone who would like to comment in the public to provide comments to our dedicated rule inbox for consideration.

Public Comments

- Jeff Brunette: When we talked about qualified, do like the NRC does and keep a list of who is exempt. He also stated the radiation safety committee should consider a designated RSO, and that the committee should meet at least quarterly.
- Julie Jaroscak: Stated that fluoroscopy is being used in more places, and it is her observation/opinion that those operators know less and less. She stated there should not be exempt from any training, and they should need to take a test.
- Scott Haglund: Asked about supervisory guidelines with fluoroscopy and operator qualifications, and asked MDH to take into consideration the academic research performed on humans.
- Barb Hodge: Questioned subpart 19, items C(1 and 2), and meters that provide the half value layer. Geise stated this is covering the numbers in the table, not measurement. She ask if MDH was considering the need for a definition of what it means to operate equipment. Purrington stated only one state defines this, New Jersey. Purrington asked the Advisory Committee if they would like operation defined, no comments from the Advisory Committee. Hodge also asked about the apps training, and asked if those who receive the training can give new staff the training. Purrington stated MDH would look at that. Hodge also asked who is qualified for the ongoing training. Purrington stated MDH would take those into consideration.
- Linda Laman: Asked if air derma definition could be added back to the definitions. Duppler stated the committee took out air kerma because it is not being used in the rules. He added that the advisory committee was discussing “reference air kerma”, which is different.
- Ken Fetterly: Stated the discussion on the training course was not clear. He asked if the committee would reconcile the questions that were unresolved and will the public receive

another draft? Cavanagh stated there will be many versions of the rule draft and all of them are posted on our website. We will notify those on our email list when new documents are on the website. When the rules are formerly proposed, there is a 30-day comment period. Fetterly stated this is a substantial change for many and this should be clear in the rule. He also asked that the lead apron requirement not discussed today be lowered from 0.35mm lead requirement.

- Andy Johnson: Stated he works at a rural facility that has a speech therapist who performs swallow studies. He asked who would supervise a swallow study. Purrington stated they would not be able to operate equipment, but the supervision question would be a question for the x-ray program to review. Hanson added that every speech therapist is supervised by a radiologist at the VA.
- Jeff Brunette**:** Asked how the public can get their comments in for the last subparts not discussed today. Purrington stated that comments could be provided at our dedicated rule email box.

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