X-ray Advisory Committee Meeting

MEETING MINUTES 11/13/19

Date: November 13, 2019

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

Attendees: Brian Hall (Service Provider), Dan Lind (Service Provider), Frank Zink (Medical Physicist), Jon Wohlhuter (MN Association of Nurse Anesthetists), Richard Geise (Medical Physicist/PhD), Ronnell Hanson (MN Radiological Society), Scott Haglund (St. Catherine University), Tony Murphy (Medical Physicist).

Conference Call: Beth Schueler (Medical Physicist), Julie Sabo (MN Nursing Board).

Absent: Bridgett Anderson (MN Dental Board), David Eastman (Medical Physicist), Karyn Warnert (Minnesota Veterinary Associates), Louis Saeger (MN Medical Association), Michael Lewandowski (Health Physicist/CHP), Vinton Albers (MN Chiropractic Association).

MDH: Bevin Beaver, Craig Verke, Jacquie Cavanagh, Kelly Medellin.

Absent: 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

Jacquie Cavanagh, Section Policy and Rules Analyst

Cavanagh welcomed everyone to the meeting. She stated that Teresa Purrington could not attend this meeting. She introduced MDH staff filling in for Teresa and Revisor's office attendees, Corrine Staeheli and Sandy Glass-Sirany. Stated there are seven rule parts left, and four committee meetings scheduled into 2020.

Review of Radiographic X-ray Systems

Bevin Beaver, X-ray Inspector
Craig Verke, X-ray Inspector
Jacquie Cavanagh, Section Policy and Rules Analyst

Subp. 1. Applicability.

Frank Zink (Advisory Committee Member - ACM) asked why item D, podiatry x-ray systems, is specifically listed. Zink added this allows for more questions than answers when it is enumerated. Richard Geise (ACM) stated mammography must meet the requirements of this subpart, but mammography is not enumerated.

Subp. 9. Technique factors.

Beth Schueler (ACM) suggested the wording "*readily available to the operator*" instead of "*available at the control panel*" in item C. She stated this is similar to SSRCR.

Subp. 10. Equipment performance evaluation; testing requirements; frequency.

Zink questioned item A(2) and the "*730 calendar days*" wording. Cavanagh stated this is still not entirely resolved. Geise asked if this is 730 days from the initial start or from each calibration. Cavanagh stated other programs need to be considered before MDH makes a final decision. Jon Wohlhuter (ACM) stated that he supports the language here. Zink stated he agrees.

Zink stated item D(1) wording "*not use the radiographic x-ray system*" could be problematic. He suggested using the current requirement of "*having the x-ray system repaired within 14 days*" instead of not being able to use the x-ray system until it is calibrated by a service provider. Geise stated MQSA requires 30 days. Cavanagh stated MDH would take that under advisement.

Subp. 11. Equipment performance evaluation; filtration (half-value layer) test.

Zink questioned item C and stated this language needs more flexibility. Schueler stated this wording should state, "*kVp not listed under item B*", not "*kVp listed under item B*". Cavanagh stated MDH would review this.

Subp. 12. Equipment performance evaluation; timer test.

Schueler asked if the registrant needs this available at all times. Cavanagh stated she believes that if the registrant is relying on manufacturer specifications, it should be available. Dan Lind

(ACM) asked if this is only at half a second. Geise asked if MDH considered if there are timers on the mAs. Verke confirmed.

Subp. 16. Equipment performance evaluation; collimator dial accuracy test.

Zink asked advisory committee members what the effect would be to an x-ray system if a collimator were off. Verke stated this is a federal requirement. Geise stated there are some units that have no numbers on the collimator dial. Zink stated that although an MDH inspector can test this, maybe it is not necessary to do so. Cavanagh asked Zink if this is the subpart that he thinks should be removed. Zink stated that it is.

**Note: This discussion of the collimator dial took place while during the committee's discussion of subpart 12.*

Subp. 18. Equipment performance evaluation; linearity test.

Zink questioned item B and the format of the example. Bevin Beaver (MDH) stated the example is the same as the source document. Giese questioned using mGy in the example. Verke stated MDH would review this.

Subp. 22. Equipment performance evaluation; positive beam limitation (PBL).

Zink asked if the PBL needs to be tested on each of these statements. Verke stated that not every item needs to be tested. Zink stated that the language does not specify what should be tested every two years. Cavanagh stated MDH was careful not to alter or modify the language from 21 CFR and asked for suggestions on how best to refer to this federal regulation. Zink stated the rule should clearly indicate the MDH requirements. Lind stated that he has one check-box document that specifies all these items. Verke stated MDH would review this language. Cavanagh asked the committee to suggest and provide language. Geise stated that all these items should be tested. Zink questioned if there should be a test scenario for each of these requirements. Currently, it is not written in such a way.

Subp. 23. Analog imaging; screen-film evaluations.

Scott Haglund (ACM) asked if there is a shelf life for analog requirements. Verke stated there are registrants that operate using film. Zink asked if CR is considered digital. Verke confirmed that CR is considered digital.

Subp. 25. Shielding requirements.

Haglund asked if this subpart includes the movement (or trend) of cessation of patient shielding. Verke stated that this is addressed later in the rule part.

Subp. 26. Radiographic qualified operator qualifications.

Zink asked if the coroner's office (ie – medical examiner) would be exempt from this subpart. Verke stated this is correct.

Subp. 27. Prohibited uses.

Haglund questioned item B and asked if adequate positioning should be in this item. Verke stated MDH would look at fluoroscopy to see if this is included. Cavanagh stated this could be under training, but MDH will review.

Subp. 28. Ordering of diagnostic radiographic examinations.

Zink asked if this is an expansion of our current order requirements. Verke stated that is correct. Zink asked if all orders would come up with clinical indication, or would this be after the fact? Verke stated the intent of this requirement is not to be after-the-fact. Geise stated items B, C, and D do not flow correctly. Verke stated MDH would review this language.

Subp. 29. Utilization record.

Schueler stated this subpart seems onerous, and does not have any benefits for public health or safety. She also questioned item D and identifying the "*room in which it is used*". Verke stated MDH would like suggestions from the committee. Schueler responded that most databases do not contain fields to include all these items. These items would need to be collected using a manual process. Verke reiterated that the documentation needs to be maintained and the rule does not prescribe how.

Geise questioned recording the number of repeats/retakes in item G. He asked if this is specific to each patient, or if it includes all repeats/retakes. Verke stated that MDH currently requires all repeats/retakes. Schueler stated this is not easily translated into electronic health records. Verke stated MDH would review this. Schueler stated their organization had to customize their electronic health records system to include this information.

Schueler asked if item F pertains to only holders of a patient, or anyone in the room. Beaver stated that "*support*" includes anyone in the room. Schueler stated she does not see value in that, and this should only include the holder of a patient. Cavanagh stated MDH would take these comments under advisement.

Subp. 30. Repeat analysis.

Zink asked if item D is new or in the current rule. Beaver stated this is new and specifically for registrants when the doctor or provider is the only one imaging. Zink stated if they are acting as an operator, they should be subject to repeat/retake analysis. Cavanagh stated MDH would review this.

Subp. 32. Protection from radiation.

Murphy stated this should include mobile/portable systems, not just stationary systems. Zink asked if this is also for fluoroscopy. Verke confirmed.

Geise asked if the .25 mm lead equivalent is new. Verke stated this is a change and it is new. Currently the rule states .5 mm but MDH is proposing .25 mm to be consistent with SSRCR. Zink asked if there would be implications to the dose calculations with a lower lead equivalent when

MDH used to ask for a higher lead equivalent. Geise stated that calculations would need to be adjusted if the lead equivalency is adjusted. Jeff Brunette (public) stated NCRP 22 calculations are based on .35 mm. Zink stated this needs to be looked at with other states to make sure the effective dose equivalent calculations still work with the reduction. Lind stated distance should be taken into consideration because those closer to the beam should have more lead protection. Verke stated that would be difficult to regulate but that MDH should consider the range using NCRP 22 calculations.

Geise asked about item B. Does it take into consideration other individuals in the room, including patients in the next bed? Verke stated MDH is looking into this. Schueler stated the 6-foot rule could apply here.

Haglund asked about item E and facilities that have their own policies regarding shielding. Verke stated a registrant's policy and procedures will be reviewed at the time of inspection, but MDH will not tell registrants how to do this. Murphy stated this could be confusing if a registrant's policy and procedures are contrary to the rule requirements.

Subp. 33. Digital imaging.

Zink asked about the wording "*according to the manufacturer specifications*" in item A. He suggested including the written recommendations of a qualified medical physicist. Cavanagh stated this subpart does specify that. Zink stated there should be an "or" between item A and B. Cavanagh stated MDH would look at this language to allow some flexibility. Verke stated there is a AAPM document* that talks about digital quality control and asked committee members if anyone knows if the document is finalized. Zink asked if this document is inclusive of CR. Verke stated it is CR and DR.

Schueler questioned items E, F, and G and stated the exposure index values are highly unreliable. Zink agreed. Cavanagh asked for committee suggestions. Zink stated there is not a uniformly suggested way to go about this. Schueler stated it does not make sense to do this at this point. Verke stated MDH review this.

Murphy stated the language in item H about phantom image evaluation needs to be clarified. He suggested that it does not seem to make sense in this subpart. Zink stated this is another area where QMP discretion would make sense. Verke stated this language comes from SSRCR and MDH would review this. Schueler and others stated that most manufacturers do not provide phantoms.

** **Report of AAPM Imaging Physics Committee Task Group 151*** is published.

Subp. 34. Film processing; manual or automatic.

Zink asked if there are any changes from current rule. Cavanagh stated this is the same as the current rule. Zink suggested seeking feedback from providers or distributors who uses film. Lind stated that film can only be purchased online, and that there are no current dealers. Verke stated that approximately ten percent of registered facilities use film. Cavanagh stated that this subpart and the remainder pertaining to film processing will likely be repealed in further rule

revisions. Geise stated current x-ray operators are not taught anything about film processing. Haglund stated new x-ray operators are not qualified to test or use film. Cavanagh stated MDH would take these comments under advisement.

Review of Bone Densitometry X-ray Systems

Bevin Beaver, X-ray Inspector
Craig Verke, X-ray Inspector
Jacquie Cavanagh, Section Policy and Rules Analyst

Subp. 1. Applicability.

Schueler responded to the comment in rule draft asking for feedback on CT scanners performing DEXA scans and asked if MDH is referring to full body CT scanners. Verke confirmed.

Subp. 2. Radiation exposure control.

Zink asked if MDH is giving registrants the specifications. He suggested removing this subpart if registrants will be referring to manufacturer specifications. Verke stated that the manufacturer specifications might be different from MDH requirements.

Geise asked why bone densitometry requirements are required every year when the safety issues low. Zink responded that the radiation risk is low but the system could be inaccurate and needs to perform consistently and accurately. Verke stated that precision error is important.

Subp. 4. Equipment preventative maintenance.

Cavanagh asked if there were any comments on the rule draft comment in this subpart. Zink stated the wording should be "*repair and correct*" and not "*calibrate*".

Subp. 6. Shielding plan exemption.

Geise stated that this exemption is expressed in the subpart where the reader is redirected. Cavanagh stated MDH understands this looks redundant but is needed to be consistent with the rule format and organization.

Subp. 7. Bone densitometry qualified operator qualifications.

Schueler asked if there is a bone densitometry registry. Verke stated that the ARRT does have a bone densitometry exam but it is not addressed in statute. Haglund stated it should be kept the way it is. Schueler stated that the International Society for Clinical Densitometry (ISCD) offers this registry and asked if it is recognized in Minnesota. Verke stated it is not.

Subp. 8. Prohibited uses.

Zink stated that item B(1) (precision assessment) should be not prohibited if there is a written order from a qualified practitioner. Verke stated MDH would review this.

Subp. 10. Utilization record.

Zink stated that his earlier comments about utilization record in Radiography apply here. Schuler agreed.

Subp. 11. Repeat analysis.

Schueler stated that repeat is not needed for bone densitometry, as repeat rates are so low. Cavanagh stated MDH would take this comment under advisement.

Subp. 12. Protection from radiation.

Murphy asked what the wording "safe distance" means and stated that items A, B and C do not flow. Verke responded that some rooms do not have a 6-foot distance. Zink stated he agrees, but item C is not needed with item B. Geise suggested changing the order of items A and B. Verke stated this language was taken from SSRCR. Cavanagh stated MDH would take these comments under advisement.

Review of Breast Biopsy X-ray Systems

Bevin Beaver, X-ray Inspector
Craig Verke, X-ray Inspector
Jacquie Cavanagh, Section Policy and Rules Analyst

Subp. 1. Applicability.

Geise suggested revising or clarifying the wording in item D.

Subp. 3. Radiation exposure control.

Verke stated MDH is unsure if there are battery-powered generator systems for breast biopsy systems. Geise stated he does not believe that there are any. This was the consensus of the advisory committee.

Subp. 4. Technique factors.

Geise questioned E(7) and stated that some units are mAs controlled. He also questioned item E(10) and the number of grids. Verke stated MDH review these items.

Geise asked what the rule draft comment is referencing. Cavanagh stated the numbering is off, and MDH would fix that. Geise stated that the items highlighted in blue are not necessary.

Subp. 5. Equipment performance evaluation; testing requirements; frequency.

Geise stated item D(1) is excessive. He stated these systems are MQSA regulated and all fall under these items, except for dose and phantom requirements.

Zink asked if it is possible for a breast biopsy system not to be accredited. Geise responded that most issues are adequately covered by MQSA. Geise asked if it would be worth considering

exempting facilities that have ACR accreditations. Cavanagh stated MDH will take this under advisement.

Subp. 6. Equipment performance evaluation; filtration (half-value layer) test.

Murphy stated this is at 28 kvP, and provided a formula to MDH. Verke asked if ACR guidelines cover all these areas. Geise stated that is correct. Verke stated MDH would review this.

Verke asked if there are any stand-alone breast biopsy facilities. Geise stated that there are not. Verke asked Geise if a QMP does the mammography ACR accreditation for a breast biopsy facility. Geise stated that they do. Murphy stated that most of his systems are not ACR accredited, but he tests all those systems.

Subp. 7. Equipment performance evaluation; collimator assessment test.

Geise stated the "*more than 5 mm*" wording in this subpart should be "*two percent*". Murphy stated he agrees and that it cannot fall within the detector by any margin at all.

Subp. 8. Equipment performance evaluation; focal spot performance and system limited special resolution test.

Geise stated that the headnote and first sentence should read: "focal spot performance OR system limiting spatial resolution test." Change "and" to "or".

Zink stated that the wording "not degrade" is incorrect. Geise stated it should meet the requirements similar to the equipment manufacturer. Schueler stated it should say "significant degradation".

Subp. 9. Equipment performance evaluation; kVp accuracy.

Geise stated this EPE could be postponed for 30 days. He has them listed out and will provide to MDH.

Subp. 11. Equipment performance evaluation; automatic exposure control system or manual exposure performance assessment test.

Geise questioned the wording "*over a range of 4 to 8 cm*" when most systems ask for 2, 4, 6, or 8. Murphy stated he agrees and suggested looking at this subpart again. Cavanagh stated MDH would review this.

Subp. 13. Equipment performance evaluation; breast entrance exposure and average glandular dose test.

Geise stated this is based on asymptomatic screening and this is not the case for breast biopsy x-ray systems. Verke stated that MDH would review this and look at ACR accreditation requirements. Geise followed up and reported that ACR Accreditation for Stereotactic Breast Biopsy Physicist's test survey includes a breast entrance exposure and average glandular dose evaluation.

Subp. 15. Equipment performance evaluation; image quality evaluation test.

Zink stated this is from ACR and it is outdated as there are three different phantoms now. Verke stated MDH would review this.

Subp. 17. Equipment performance evaluation; localization accuracy test.

Geise and Zink stated this test is performed with a phantom you can purchase and the phantom is not well designed. Suggested that subpart 18, item A(1), is adequate, as the phantom does not work correctly.

Subp. 18. Routine quality control; development and requirements.

Geise stated these items should be included with the same concept as 30 days, we should not use it.

Referring to item A(3), Verke asked if anyone does hard copy for interpretation. Zink stated that this is only if hard copies are produced. Verke asked if we need to have this piece in there. Geise and Murphy both stated that is not the case.

Geise suggested adding manufacturer recommendations to item A(4). Verke stated MDH would look at that.

Zink suggested adding 'QMP' to Subpart 18, item A, instead of referencing only a radiation safety officer. Zink stated that an RSO or a QMP could perform this requirement.

Subp. 19. Shielding requirements.

Geise stated that if mammography systems are exempt from the rule chapter, why do biopsy systems have to meet these requirements? He also added that Tomosynthesis units should be exempt as well. Murphy stated he agrees that biopsy systems should be exempt, but he is unsure about Tomosynthesis units.

Subp. 23. Utilization record.

Zink stated that his earlier comments about utilization record in Radiography and Bone Densitometry apply here. Schuler agreed.

Subp. 24. Protection from radiation.

Murphy stated that the control booth is in the same room but shielded. Geise stated that the operator could be seated and shielded without a full body shield.

Subp. 25. Digital imaging.

Geise stated this subpart (Item D) should state 30 days as well.

Zink questioned why we would need this section, as these are mostly digital. He also stated that the exposure indices would be onerous. Verke stated that he talked to FDA and there are no film systems in Minnesota that are accredited or certified right now.

Zink asked who could be the operator with specimen imaging. Cavanagh stated this could be under research or forensic. Zink stated this is clinical, so it would not fall under those sections. Verke stated if it is a non-living human, then MDH does not have qualification training requirements.

Public Comments

- Barb Hodge, University of Minnesota. Hodge asked if the department's assumption regarding verbal orders is the communication between a doctor (ie – qualified practitioner) and a technologist (ie – qualified operator) of the medical need/order for diagnostic procedure. Cavanagh stated that the rule assumes this unless a facility/registrant has a different procedure for verbal orders. Commenter expressed concern with the accuracy of read-backs.

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