X-ray Advisory Committee Meeting

MEETING MINUTES

Date: October 18, 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), Jon Wohlhuter (MN Association of Nurse Anesthetists), Julie Sabo (MN Nursing Board), Michael Lewandowski (Health Physicist/CHP), Ronnell Hanson (MN Radiological Society), Tony Murphy (Medical Physicist), Vinton Albers (Chiropractic Association).

Via Conference Call: William Duppler (Medical Physicist).

Absent: Bridgett Anderson (MN Dental Board), Louis Saeger (MN Medical Association), Richard Giese (Medical Physicist/PhD).

MDH: Jacquie Cavanagh, John Olson, Kelly Medellin, Mary Navara, Michelle Ambrose, 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

Welcome and Introductions

Mary Navara, Indoor Environments and Radiation Manager

Navara welcomed everyone. She shared the sad news that Kathryn White, Advisory Committee member, passed away this week.

Teresa Purrington, X-ray Program Supervisor

Purrington introduced Michelle Ambrose (MDH) as the X-ray unit staff member who is part the H-44 CRCPD Taskforce on Cone beam Computed Tomography (CBCT), https://c.ymcdn.com/sites/crcpd.site-ym.com/resource/resmgr/Docs/Working_Groups/HAC/H-44.pdf?hhSearchTerms=%22h-44+and+task+and+force+and+group%22.

Rulemaking Process Update

Jacquie Cavanagh, Section Policy and Rules Analyst

Asked the committee to send her their availability for the 2018 Advisory Committee meeting schedule in the next 7-10 days. Dental rule drafts will be sent to the Revisor soon. MDH will continue to accept comments and changes to the rule drafts.

Teresa Purrington, X-ray Unit Supervisor

Announced that the next Advisory Committee meeting is canceled. Instead, the industrial focus group will meet during the December 5, 2017 time slot. The Advisory Committee will meet on January 17, 2018 and will review industrial rule drafts at that time. The Service Provider focus group will start in early 2018.

Review of Dental Extraoral Rule Draft

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

Ronnell Hanson (ACM) asked for the definition of qualified operator for context. Purrington stated that this will be addressed later. Frank Zink (ACM) questioned the “Applicability” subpart language referencing registrant. Cavanagh stated that the word "registrant" is used for enforcement purposes because it is the registrant who is cited for violations of the rules. Hanson asked about the enforcement process. Purrington responded that MDH has the authority to administer enforcement penalties according to Minnesota Statutes §§ 144.989 to 144.993, also known as the Health Enforcement Consolidation Act. She briefly explained the enforcement process.

Subp. 4. Radiation exposure control.

Lewandowski stated that having the registrant responsible for this section is unusual because it has to do with equipment requirements. Purrington responded that MDH will review.

Subp. 7(B). Equipment performance evaluation; testing requirements; frequency.

Lewandowski questioned why MDH is using "qualified service provider" instead of “qualified expert”. Purrington replied that MDH continues to research this topic and it is a placeholder for now. This topic will be a central discussion point with the service provider focus group. Lewandowski also pointed out some readability issues.

Subp. 8. Equipment performance evaluation.

Frank Zink (ACM) asked what documentation is needed to report on calibrations, and when do service providers need to provide that. Purrington replied that in the proposed rule revision, it is the intent that service providers will be required to provide this information. Zink stated that if MDH is requiring registrants to have this prior to first use, we need to make sure the rule addresses this expectation for service providers.

Subp. 12. Equipment; quality control.

Tony Murphy (ACM) questioned recommendations for quality control. He suggested that MDH include the language to “follow a quality control program written by a qualified expert”. Zink stated that some manufacturers provide no recommendations or poor recommendations, and MDH should take this into consideration. Purrington responded that MDH will review.

Subp. 14. Qualified operators; dental extraoral x-ray systems.

Lewandowski noted that there is no mention of training for these qualified operators. He suggested that MDH include training on radiation safety, shielding, and proper operation. Purrington said that MDH intends to address training comprehensively in its own rule part.

Beth Schueler (ACM) asked why Radiologic Technologists weren't included among qualified operators. Purrington responded that this reflects what is provided in the Board of Dentistry rules, and that the Dental Board is the best source to answer this.

Zink asked what makes a system "extraoral", as there are some medical extraoral systems. Purrington replied that medical extraoral x-ray systems will be considered later. Scheuler asked how MDH will address this distinction in the rule. Purrington responded that this will be reviewed under the medical rule parts.

Lewandowski added that it's about the facility of use, not about the equipment. As a refresher, Cavanagh displayed the website for Michigan’s rules. The structure and format are the basis for MDH’s rule revision. Hanson questioned if this organizational structure prohibits experts, or “qualified operators” from operating the same equipment in different types of facilities. Purrington asked Majda Hodzic, Regulatory Affairs Manager for the Minnesota Dental Association, to comment. She stated that unless an operator is licensed by the Dental Board, he or she cannot operate dental x-ray equipment.

Subp. 17. Qualified operator protection.

William Duppler (ACM) asked if the operator should be 6 feet away and wearing lead PPE. Purrington replied that under the existing rules, it’s one or the other. Duppler asked if this is enforceable. Purrington responded that inspectors do ask and review during an inspection.

Murphy stated it is unclear because it appears you must comply with Item C. Purrington stated MDH will review the wording.

Subp. 20. Digital imaging.

Zink asked if it's arbitrary to require a daily procedure. Purrington responded that quality control recommendations must be followed according to manufacturer's specification. Lewandowski questioned quality control and digital. Zink responded that we shouldn't require something that the manufacturers don't require. Purrington responded that MDH will review the wording.

Murphy asked how MDH will document the version changes. Cavanagh said that she will include a preface and summary of the changes at the beginning of every rule draft document after version 1.0.

Review of Dental ConeBeam CT (CBCT) Rule Draft

Jacquie Cavanagh, Section Policy and Rules Analyst

Teresa Purrington, X-ray Unit Supervisor

Purrington asked the committee their views on requiring a repeat and reject analysis program. MDH's research of other states found that only five states require this. MDH discussed with the states on a CRCPD conference call and it was determined it is only required by most states for Mammography. A few states felt strongly repeat and reject analysis adds value to regulate dose creep. Purrington asked the committee if repeat and reject analysis should be required for all registrants. Zink offered that if we require a utilization log, then we should also require repeat and reject analysis. Murphy stated he's in favor of keeping the repeat and reject requirement, and agrees with Zink's rationale. Zink stated that it might be useful for an evolving modality, like CBCT, where the equipment could be used for a different reason in the future. Purrington asked the committee to provide further comments.

Purrington stated there are only three states that have rules for CBCT: New Jersey, Pennsylvania, and Washington. She asked the committee that if CBCT reaches a threshold for dose, should it be a qualified medical physicist to perform the equipment performance evaluation? SSRCR requires a qualified medical physicist as the operator, but there are very few guidelines to reference.

Schueler questioned what the definition of a CBCT will be and how it will be distinguished from extraoral. Purrington responded that this is where the equipment output thresholds will be a determining factor. Ambrose stated that the CRCPD H-44 Taskforce group reviewed equipment outputs for dental CBCT. Hanson suggested categorizing by output threshold and potential delivery levels. Ambrose stated that H-44 found three units above 110 ma.

Subp. 7. Equipment performance evaluation; testing requirements; frequency.

Lewandowski asked about the distinction between qualified medical physicist and a qualified service provider. If the assumption is that they have different qualifications, would there be situations where a qualified service provider would not be allowed to perform the same

activities as a QMP. He suggested that the definition of "qualified expert" outline the activities each professional can perform. Purrington responded that our research to date suggests that only a QMP can perform testing and evaluation on dental CBCT.

Schueler asked if MDH knows how many CBCT units registered in the state with the higher output. Purrington said that she believes there are ten different types of CBCT equipment with higher output. Purrington offered to provide this information to advisory committee members in an email.[1]

Zink stated that there are competing issues with limited resources of medical physicists in the state and evolving/emerging technology. He suggested that equipment performance evaluations are signed off by a medical physicist, which would be efficient and convenient. Purrington responded that the CRCPD stated that if these requirements are in rule, medical physicists will come to the state.

Zink agrees that someone other than a QMP could check the baseline, but under QMP supervision. Duppler stated that if other states are requiring medical physicists, he sees no reason why Minnesota would differ from that. Murphy and Hanson stated he doesn't think we should lower the state's standards based on limited resources of QMPs. Hanson asked if other states require barriers for this equipment. Purrington added that higher dose equipment may replace panoramic unit in alcoves, and MDH needs to protect public and occupational health.

Subp. 8. Equipment performance evaluation; dental CBCT x-ray system.

Purrington stated that MDH took this directly from IAC. Murphy stated that these values would be difficult to perform, and that a qualified medical physicist is imperative for image quality. Schueler stated manufacturers might not provide everything a registrant needs to comply with the rule, and often there is no way to get it. Zink suggested in the absence of a manufacturer, they could seek guidance with a medical physicist. Schueler mentioned that there is an AAPM task force working on this, but does not know the status of their work. Additionally, there is an NCRP report due January 1, 2018.

Subp. 9. Quality control.

Purrington stated the terms "registrant" and "radiation safety officer" are used in the part and was requesting feedback from advisory committee. She also stated that CRCPD recommends using qualified medical physicists. Lewandowski stated that the current qualifications for a radiation safety officer do not include all the new recommendations. He also suggested this might be a case for the qualified expert definition, as this would require greater knowledge and skills not necessarily acquired by an RSO or registrant. Zink agreed.

Purrington asked the committee about the definition of quality control tests. The term "periodic" is vague because it's not a frequency. Zink noted that item B, should be a CBCT

[1] There are 203 CBCT dental tubes registered in Minnesota, and 23 CBCT tubes that are registered in Minnesota that are at the threshold requirements listed for a QMP. (MDH email, 11/1/17)

phantom, not CT phantom. He also stated that he believes item B(1) should not be low contrast spatial resolution. Lewandowski suggested that item B might not be needed in rule, but in regulatory guidance. Purrington responded that daily quality control is imperative for image quality. Lewandowski responded that because this is emerging technology, MDH should take that into consideration when writing the rule.

Murphy stated that we're talking about accreditation and standards, and minimum requirements. Cavanagh responded to the question about rules becoming obsolete, and said that MDH can refer to an external, published reference in the rules. Zink stated that we should be as flexible as possible with emerging technology. Purrington responded that MDH will be revising the rule on a cyclical basis, especially where emerging technology is concerned.

Subp. 10. Shielding requirements.

Purrington pointed out that item B refers to a "permanently mounted" structure and the language is based on MDH research. She asked the committee if they think this would be feasible for registrants. Hanson commented that it is part of doing business, but also questioned if it would be a heavy burden to create a permanently mounted barrier instead of standing six feet away.

Lewandowski responded that MDH wants to make sure registrants meet the dose limitations. There may be other options than remodeling that would be more flexible.

Schueler asked if you have a pan/ceph (less than 100 kv system) and can remain six feet away, would MDH still require a control booth? Purrington responded that MDH is aligning themselves with SSRCR. Schueler commented that, for some systems, only a software upgrade is needed to convert from 2D to 3D and so would this requirement make sense? Purrington asked if any measurements were obtained. Schueler responded that it is the same image with reconstructions.

Zink stated there may be FDA approved systems that are not designed to operate in these described situations.

Subp. 11. Shielding plan.

Schueler asked if no lead is necessary in the room, do you still need to submit a shielding plan? Purrington responded that intraoral equipment is the only type of equipment that is excluded from a shielding plan. At this time, it is MDH’s intent to maintain the shielding plan exemption for dental intraoral x-ray systems.

Subp. 14. Ordering of diagnostic radiographic examinations.

Purrington asked Majda Hodzic, Regulatory Affairs Manager for the Minnesota Dental Association, to comment on this discussion. She stated that Minnesota Dental Hygienists have a collaborative agreement with a dentist that is authorized by the Minnesota Dental Board.

Subp. 16. Utilization data.

Purrington stated that requiring utilization data is important for protecting public and occupational health.

Public Comments

Purrington stated that the meeting has gone over time, but that she will remain after the meeting to listen to or answer questions from the public.

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