X-ray Advisory Committee Meeting

MEETING MINUTES

Date: July 25, 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), Michael Lewandowski (Health Physicist/CHP), Richard Giese (Medical Physicist/PhD), Ronnell Hanson (MN Radiological Society), Vinton Albers (Chiropractic Association), William Duppler (Medical Physicist).

Via Conference Call: Julie Sabo (MN Nursing Board).

Absent: Bridgett Anderson (MN Dental Board), Louis Saeger (MN Medical Association), Tony Murphy (Medical Physicist).

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

Welcome and Introductions

Teresa Purrington, X-ray Program Supervisor

Purrington welcomed the Advisory Committee. She reminded the advisory committee and the public that comments can be made through the Request for Comments on the website. She stated all rule documents are available on our website. She stated that service provider training and responsibilities will be discussed at the next Advisory Committee meeting.

Service Provider Update

Teresa Purrington, X-ray Program Supervisor

Purrington gave a brief presentation on the Department's vision and direction for service providers in the proposed rules. She stated that service companies would be required to register the service providers who work for them. Frank Zink (Advisory Committee Group – ACG) asked how MDH would enforce rules with service providers, and if MDH will hold the registrant responsible for enforcement. Michael Lewandowski (ACG) asked if the purchaser needs to make sure the vendor is registered. Purrington stated she could not answer that at this point, but would when MDH reviews registration rules. He also asked the difference between the service company and the vendor. Purrington stated we will discuss this when we go through the definitions.

Review of Service Provider Definitions

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

Subp. ##. Assemble or assembled.

Lewandowski asked if putting a battery in equipment is assembly. Purrington stated she would have to refer to the FDA definition.

Subp. ##. Direct supervision.

Richard Geise (ACG) asked if being virtually present, such as with Skype, would suffice for "direct supervision". Zink suggested using "supervisor" and "supervisee" rather than specifying the service provider roles. Julie Sabo (ACG) agreed with his definition of direct vs. general supervision and asked if these definitions are specifically for service providers. Purrington confirmed. Beth Schueler (ACG) stated that CMS has already defined these terms and MDH should consider these definitions. Stephanie Welvaert (MDH) reminded the committee of CRCPD's definition. Lewandowski questioned the wording "physically present". Purrington stated that this would be in the room, not in the facility.

Subp. ##. General supervision.

Zink stated the terms "supervisor" and "supervisee" should be used in this definition as well.

Subp. ##. Install or installed.

Schueler questioned equipment that is calibrated at the factory and then shipped to a registrant, and requires no calibration once it is received by the registrant. Purrington stated MDH would discuss this at the fluoroscopy rule meetings. Lewandowski stated that most industrial equipment is calibrated at the factory. Purrington asked if the original subpart 42 definition was better. Lewandowski stated both definitions do not apply to industrial equipment. Geise stated he prefers the original subpart 42 definition and suggested including what is required when equipment is installed in the definition. Lewandowski stated that following FDA recommendations would not pertain to industrial equipment.

Subp. 58. Qualified medical physicist or QMP.

Purrington asked the committee for feedback on the naming and definition of this part. Zink suggested not including the wording "is trained…" and use in the rule requirements. Purrington stated that this is included because MDH is going to suggest that in the training section. Geise stated MDH should not limit the definition to only specific areas, and suggested removing CT and interventional.

Subp. ##. Service company.

Lewandowski questioned the definition of a vendor and a service company, and asked why there is an A and B for service company, but not for vendor. Craig Verke (MDH) stated that a vendor is a service company, but a service company might not be a vendor. Schueler questioned “preventive maintenance visit”. She also questioned the word “demonstrate”. Verke responded this would only be for demo equipment for selling purposes. Zink suggested being consistent with wording throughout the rule with the wording “person” and “individual”. Jon Wohlhuter (ACG) suggested using the word “individual” instead of “person” to clarify this.

Subp. ##. Service technician.

William Duppler (ACG) asked for clarity for the relationship between service technician and if there is a limit to the number of service technicians a QE/QMP can attest to and oversee. Geise stated that c-arm’s should be included as a QMP testing.

Purrington stated that currently there is a gap in our rule with shielding and radiation protection surveys. Zink stated item B suggests training, and this should not be in the definition. Geise stated reference the rule part in the definition. Hall suggested field service engineer vs. service technician as it is a more common term used by manufacturers.

Subp. 89. X-ray imaging system.

Lewandowski asked if this would pertain to industrial. Purrington stated it would for some equipment.

The committee discussed fluoroscopy systems in Minnesota. Purrington asked Bevin Beaver (MDH) if other states require QMP testing for fluoroscopy. Beaver stated that she would review other state fluoroscopy rule parts for clarification. Ronnell Hanson (MDH) stated that most

health care systems need to follow the Joint Commission recommendations for accreditation purposes. Geise referred to percentages of overall dose for different types of equipment is higher according to NCRP 160.

Review of QMP/QE Qualifications

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

Subp. 1. Qualified expert.

Geise believes this should be “American Board of Science in Nuclear Medicine”.

Subp. 2. Qualified medical physicist.

Zink stated this should be an "and" not "or". Schueler stated she does not agree, as you could be qualified with an older degree. Purrington stated that it is meant to be an "and". Geise stated we should not limit people already in these positions from doing a job they have been doing for years. Geise suggested removing B and having those individuals apply for a variance. He stated that he sent those suggested qualifications to MDH. Zink stated if the wording includes "or", item B needs more information. Purrington asked the physicists on the committee to provide comments to the rule for this part. Lewandowski stated MDH could leave in item B to meet the demand for these services. Duppler stated the service technician could be an alternate pathway.

Review of Service Provider Registration

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

Subp. 1. Applicability.

Lewandowski asked if the company and the service provider would be registered. Verke stated that both would be registered. Lewandowski suggested adding this to the definitions.

Subp. 2. Registration.

The committee asked for clarity with the current registration process. Geise questioned who is considered a service provider. Verke stated if someone were working on the system, they would need to be registered. Hall questioned the validity of services under service providers that are not registered. Purrington stated that would need to be discussed further. Lewandowski questioned having to register sales representatives as vendors. Dan Lind (ACG) stated that many people can install a piece of equipment at the same time, and questioned who verifies they are all registered. Zink questioned waiting for a service provider card. Purrington stated that MDH anticipates a system in place that emails that card to them. Zink suggested the rule wording could state that you have to be registered, not received a card, to perform services.

Subp. 3. Application.

Schueler questioned a health care facility that employs in house service providers, and how they would register. Verke stated that service providers would only provide services under the one facility. Lewandowski stated he does not agree with this part. Purrington stated MDH would gather more information from the other state that has this in their rules. Zink questioned any in house exception, regardless if the facility has one site or many. Geise agreed, and stated if registration is important than it should be the same for all service providers. Purrington stated this is in the current rule, and MDH is trying to work with these individuals in the new rule. Schueler questioned item B(12), and asked if this should state “a qualified expert”. Purrington stated MDH would look at this. Zink stated that best practice now is to have additional training, and ongoing training. Purrington stated this will be discussed when we get to training.

Subp. 4. Service categories.

Purrington asked Lewandowski about item E. Lewandowski stated there should be requirements for shielding for cabinet systems only.

Subp. 8. Changes to registration.

Lewandowski questioned the wording "within", and suggested it be "at least 30 days" to be consistent. Zink questioned the wording "invalidates". Purrington stated this would be anything in the application. Cavanagh stated MDH is trying to be consistent with all rules, and within is a word MDH tries not to use in rule writing. Zink suggested including someone who is terminated in the rule. Lewandowski stated the service provider would be responsible for letting MDH know when someone is terminated.

Public Comments

- Jeff Brunette: Provided some context as to the intent of the current rule and in house service providers. Purrington stated that the rule states each registrant, and registrant is each facility. This is what MDH is proposing right now. He also questioned who in the service company needs to be registered, especially those that have sub-entities. He asked if they can be separated.
- Kelly Daigle: Asked if MDH will develop the attestation form. FDA for mammography currently has a developed attestation. Purrington stated that MDH would take that under review.

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