Service Provider Focus Group Meeting

MEETING MINUTES

Date: May 1, 2018

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

Attendees: Brett Muehlhauser (Service Provider), Duane Juran (Service Provider), Jeff Brunette (Health Physicist), Richard Giese (Medical Physicist/PhD), Rick Lund (Service Provider).

Absent: Don O'Handley (Service Provider), Geoff West (Medical Physicist/PhD).

MDH: Craig Verke, Jacquie Cavanagh, Kelly Medellin, Mary Navara, Stephanie Welvaert, Teresa Purrington.

Acronyms and Terms

CRCPD – Council of Radiation Control Program Directors

CT – Computed tomography

FDA – Federal Drug Administration

MDH – Minnesota Department of Health

NCRP – National Council on Radiation Protection and Measurements

SPFG – Service Provider Focus Group Member

QMP – Qualified medical physicist

Welcome and Introductions

Teresa Purrington, X-ray Program Supervisor

Purrington welcomed the Service Provider Focus Group. She announced that the June 1, 2018 meeting is cancelled, as we will need only two meetings to go through the rule drafts. She introduced Craig Verke and Stephanie Welvaert as the MDH staff who are working on these rule drafts. The focus group introduced themselves. Purrington reminded the group that comments can be made through the Request for Comments on the website. Minutes and agendas will be available on the website.

Rulemaking and Service Provider Updates

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

Jacquie Cavanagh introduced herself and described the rulemaking process. Purrington went through some of the important issues that need to be addressed with service providers.

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. One of the key tenets of the proposed changes are that data will be reportable and accurate, and accessible for registrants on MDH's website. Brett Muehlhauser (Service Provider Focus Group Member - SPFG) stated that the data should specify the type of equipment and services of all registered service providers.

Purrington clarified that a "service provider" encompasses: 1) a qualified expert, 2) a qualified medical physicist, 3) a service technician, and 4) a vendor and described each type of service provider. Duane Juran (SPFG) asked for clarification of the duties for a qualified medical physicist. Purrington responded that the proposed rule requirements are consistent with the Joint Commission. Rich Geise (SPFG) noted that the Joint Commission recommendations are not required at this point, but proposed. Muehlhauser added that the Joint Commission recommendations are only for medical use. Rich Lund (SPFG) asked if shielding plans need to be approved by a qualified medical physicist. Purrington responded that MDH currently requires a notification that a shielding plan is completed but does not approve shielding plans. Juran asked if a service technician could perform general evaluations for fluoroscopy. Purrington answered the rule draft is proposed that a service technician can perform general evaluations for fluoroscopy, however not on higher dose equipment. Muehlhauser asked if these service provider categories are for all equipment types. Purrington answered yes. Muehlhauser stated that some of these categories are not used to describe industrial service providers.

Review of Service Provider Definitions

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

Subp. ##. General supervision.

Geise stated that a qualified expert should be qualified medical physicist. Purrington stated that a qualified expert is also qualified medical physicist.

Subp. ##. Qualified expert.

Purrington stated that additional language for QMP was added. Purrington asked the committee for their suggestions on higher output or fluoroscopy x-ray equipment. Geise responded that CRCPD has a term they use for this type of equipment and procedures called FGI -fluoroscopically guided intervention. He added that if a service provider is performing this procedure under the direction/supervision of a qualified expert, then MDH should only be concerned with high dose equipment. Juran stated that the length of the exam is important because that affects how much dose is received. Geise asked if it can be defined, it should be.

Jeff Brunette (SPFG) stated the Joint Commission has discussed this matter and continue to grapple with a definitive answer. Whatever MDH decides, the definition should be clear. Purrington asked the committee what they thought about the Joint Commission suggestions. Brunette stated that they are adding fluoroscopy, but already have CT in place. Geise stated he has seen images of patients who have been burned with c-arms. Suggested including wording about fluoroscopic systems that have a high-level switch on them, but that might exclude the mini c-arms. Juran suggested anything over 10 mR per minute.

Subp. ##. Service company.

Brunette noted that the rule draft states “service provider” but it should read “service company”.

Subp. 72. Service Provider.

Purrington stated that “service company” was added as along with the categories of service providers.

Subp. ##. Service technician.

Brunette stated that after item B, there should be an "or" added because there may be two different qualified experts that sign off on different things; the same person doesn't necessarily do all the same work. Purrington agreed with adding an "or". Muehlhauser stated this relates to medical, but not industrial.

Subp. ##. Vendor.

Juran stated that there are vendors who install equipment but do not register as a service provider. Purrington stated that is what MDH is seeking to change with the proposed rules. Brunette stated that the categories could overlap. Lund asked if MDH uses 2579 forms[1]. Purrington stated MDH receives some, but not from every service provider. She stated that 2579 forms may be obsolete soon, and MDH does not receive them for non-human use equipment. Geise questioned demonstrating of x-ray systems and stated the word vendor could be confusing, as a demonstrator might not be a vendor. Stephanie Welvaert (MDH) stated she has seen “demonstrators” on other states’ application form. Brunette suggested adding “temporary training and demonstrations”. Craig Verke (MDH) stated that vendor for demonstration is not an application specialist and is intended for temporary use situations only. Purrington stated MDH would clarify this wording. Juran stated that as a service provider, a vendor can be understood to mean someone who manufacturers equipment or who is a service provider. Purrington agreed that they could overlap. Muehlhauser responded that a manufacturer would not need to be registered. Juran stated responsibilities need to be

[1] Manufacturers of diagnostic x-ray systems intended for human use are required to file reports of assembly upon installation of a certifiable system or component(s). The report of assembly (Form FDA 2579) represents the assemblers certification that the system or component(s) are of the type called for by the Standard (i.e., certified), have been assembled according to the instructions provided by the manufacturer, and meets the requirements of the applicable Federal standards contained in 21 CFR 1020.30 through 1020.33.
https://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107879.htm

considered when they overlap. Brunette stated that the word “sells” should be clarified, because registrants can also sell equipment. Geise stated the wording should include “selling to a registrant”. Brunette stated that “x-ray imaging systems” does not include industrial equipment since it refers to the body. Verke stated the reference to the body should be removed.

Review of QMP/QE Qualifications

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

Subp. 1. Qualified expert.

Purrington asked the focus group if they agree with the Colorado rule reference note off to the side for a qualified expert in this subpart. Brunette stated that this is in reference to qualified medical physicist. Geise asked if they could have a preceptor provision. Purrington stated that a preceptor provision would be included in the application, as well as a preceptor. Geise stated that item 1 of the Colorado rules is from the board exam, and item 2 is a grandfather clause. Could be restraining trade if item 2 is included. Purrington stated that Welvaert would contact Colorado to clarify. Geise suggested adding a provision that allows for a completed residency.

Subp. 2. Qualified medical physicist.

Purrington stated that she prefers the definition provided in the rule draft comments (in the margin), rather than the one in rule draft. Geise questioned the degree of a medical physicist, since QMPs do not always take the board exam. He stated item B should be an "and" not "or". Muehlhauser stated that where these are referenced is important to consider for industrial use.

Review of Service Provider Registration

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

Subp. 3. Application.

Brunette questioned the “if applicable” wording in this section. Muehlhauser asked about the intent of this section. Brunette stated that a service company might not have an RSO, only a responsible individual. Muehlhauser stated responsible individual should be defined further to include someone who is the contact for MDH. Juran asked if individual service providers will still have an MDH ID number. Purrington stated that both the service provider and the company would have an MDH ID number. Focus Group agreed that responsible individual would be preferable to RSO.

Purrington stated that other states register those individuals that service the processor and asked the focus group if Minnesota should do the same. Juran stated that the processor affects the image quality, so they should. Muehlhauser stated that a processor does not affect image quality for industrial purposes, and should be differentiated. Geise does not agree with MDH

regulating the individual installing the processor when the registrant is responsible for it working properly.

Muehlhauser asked if item 12 is only for medical. Purrington confirmed that item 12 is medical and in reference to the CT preceptor.

Brunette asked what a vendor needs for experience (item 8). Purrington replied MDH would be talking about responsibilities and training at the next meeting. Juran asked about the difference between calibration and performance evaluation. He stated that sometimes a calibration is only pushing a button and wondered if this could be considered a performance evaluation. Purrington stated that MDH is distinguishing the two activities by defining "calibration" and "equipment performance evaluation". Purrington reviewed the draft Definitions rule document on the X-ray rulemaking website.

Brunette question item 11 and suggested adding "if applicable". Juran asked how demonstrating would be checked. Purrington stated the service company would be responsible for attesting to this understanding. Muehlhauser stated the word "demonstrates" refers to a practical exam, not a written exam, and suggested clarifying what MDH means by "demonstrate". Jacquie Cavanagh (MDH) stated that the attestation would be signed by the company's responsible individual. MDH does not intend to prescribe how service companies determine their employees' competence and understanding of the rules and federal regulations but service companies must attest to it before their service provider's work on x-ray systems.

Subp. 4. Service categories.

Purrington asked the focus group who should be trained to perform shielding designs for registrants. Lund stated that if MDH is only requiring a notification, then it is assumed that the service provider is responsible for the design. In this case, it should be a qualified medical physicist. Lund asked about the qualifications for those who approve the shielding plan. Brunette stated a health physicist or medical physicist would verify shielding plan requirements by conducting/performing a survey during the construction process. Geise stated that this is true for a large institution, but maybe not for smaller ones that are usually done by outside consultants. Purrington asked the focus group about the radiation protection survey. Geise responded that the individual should be qualified to perform the survey or under the direction of someone who is qualified. Geise questioned item H. Purrington stated X-ray is working with Radioactive Materials to determine where this will be cited.

Subp. 6. Notice of registration; issuance.

Juran asked about service providers who change companies during the year. Purrington stated the service company is responsible for keeping registration current. Burnette questioned if the entire application would have to be filled out. Purrington stated that the intent is for the service company to update service provider status online at any time.

Subp. 8. Changes to registration.

Lund questioned if companies would still receive a notice of registration renewal. Purrington stated that this is unknown at this time.

Subp. 10. Exemption for in-house service providers.

Geise questioned item B and the wording of only one registrant. The exemption does not seem necessary if it is only applicable for one registrant. Purrington stated in review of other states, they do not allow for in-house service providers.

Juran asked about the rulemaking process and the potential end date. Cavanagh stated the earliest we anticipate adopting the rules is in the summer of 2019. Asked if fees will be assessed with service providers. Cavanagh stated that state agencies are prohibited from modifying or otherwise adopting fees in rule. All fees are determined by the legislature and codified in Minnesota Statutes.

Purrington stated this would be the last focus group of the X-ray rulemaking. She anticipates that the rule development process will move along more rapidly and MDH hopes to meet with the Advisory Committee every month until the draft rules are fully vetted.

Purrington asked for Public Comments

- Liliosa Fajardo: Stated shielding information can be found in NCRP 147.
- Kelly Daigle: Asked about adopting a grace period for facilities that need to locate a physicist. There is only one school that provides that training in Minnesota.
- Kelly Daigle: Asked about students having hands-on experience learning to be a service provider. Purrington replied that students must be overseen by a qualified expert.
- Kelly Daigle: Asked why social security numbers are being collected. Cavanagh stated it is a statutory requirement. If the Department of Revenue must collect on an unpaid fine, then this information is required. SSN and tax ID are private data under Minn. Stat. chapter 13

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