

Service Provider Focus Group Meeting

MEETING MINUTES

Date: June 28, 2018

Location: Orville Freeman Building

645 Robert St. N. Saint Paul, MN 55155

Attendees: Duane Juran (Service Provider), Jeff Brunette (Health Physicist), Richard Geise

(Medical Physicist/PhD), Rick Lund (Service Provider).

Absent: Brett Muehlhauser (Service Provider), Don O'Handley (Service

Provider), Geoff West (Medical Physicist/PhD).

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

Welvaert, Teresa Purrington. Absent: Jacquie Cavanagh.

Acronyms and Terms

AAPM – The American Association of Physicists in Medicine

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 Bevin Beaver (MDH) would be sitting in for Jacquie Cavanagh at this meeting. She reminded the focus group how important service provider training and responsibilities are to protecting, maintaining and improving the health of all Minnesotans. She stated the highest violations for registrants are not having a shielding plan, not registered, and not having x-ray equipment calibrations performed.

Review of Service Provider Responsibilities

Teresa Purrington, X-ray Unit Supervisor Bevin Beaver, X-ray Unit Inspector

Subp. 1.

Purrington stated that other states require service providers to verify that a facility is registered and to show proof of a shielding plan. Jeff Brunette (Service Provider Focus Group Member - SPFG) stated that item B should state "subpart" not "part". Duane Juran (SPFG) asked what happens if a facility is not registered when installing the equipment. Purrington stated that service providers should tell them they could not use their equipment until it is registered. Rick Lund (SPFG) questioned the checklist and if service providers should make a copy of the checklist as proof it was provided to the facility. Purrington stated MDH would consider adding this to this rule part. Juran asked what proof of registration service providers need to verify. Purrington replied that this subpart lists the proof that is needed.

Subp. 2

Purrington stated the checklist would be a form that MDH creates and provides online. Brunette asked about item A and how does the service provider verify that they have a shielding plan. Purrington stated that a service provider would need to visually see it, and MDH would make that clear in the checklist. She also stated that shielding plans would be maintained onsite by the registrant, and not reviewed by MDH. Brunette asked for clarification on the definition of a shielding plan.

Brunette asked about item B and if the certificate will have a registration number. Purrington replied that is unknown at this time.

Juran asked about manufacturer guidance. Purrington stated that registrants do not always have manufacturer guidance documents onsite and a phantom might not be provided by the manufacturer. Juran stated that registrants do not realize that operator manuals are included in their manufacturer guidance.

Rich Geise (SPFG) questioned item C and whether it should be in the service provider rules. If yes, then it should include maintaining the shielding plan.

Brunette asked if the wording "as applicable" in item E should be added to anticipate future equipment. Craig Verke (MDH) suggested adding the wording "successor requirements" as in the dental rules. Geise asked if this also includes the reference in E(3) to 21 CFR. Purrington replied that "successor requirements" pertains to this as well.

Subp. 3.

Purrington stated this subpart is consistent with the current rule. Geise stated that item A is unnecessary if item B is true. Purrington stated she would discuss this with Jacquie Cavanagh (MDH).

Brunette asked if the last paragraph is part of this section. Purrington stated yes, this is a definition of a service report. Geise stated that the last sentence should be "or", not "and".

Subp. 4.

Geise suggested removing the word "testing" in item B as the service could be a shielding plan.

Purrington stated that item J is up for discussion and asked the focus group if this provision is too restrictive. Geise stated by the service provider should be removed and just refer to the instruments used.

Juran questioned item H and stated that images are not always saved after data are retrieved. Purrington stated that other states have this provision. Verke stated that an image should be saved to verify the data. Juran stated this would be labor intensive for the service provider. Geise agreed. Purrington stated MDH would review the comments.

Brunette questioned the definition of electronic authorization. Purrington stated this is an electronic signature, and Cavanagh used this wording because it is consistent with other rule documents.

Brunette questioned the wording in M(1) as it is confusing. Purrington stated MDH would review the wording in M(1).

Subp. 5

Purrington stated that MDH looked at radiation therapy rules to verify consistent language. Geise questioned item C and where this is supposed to be included. Purrington stated this in subpart 4(J). Geise asked which calibration date should be included.

Subp. 6.

Purrington stated that in the current rule, prohibited use is in one part. MDH has received concerns of service providers using staff for training.

Subp. 7.

Purrington stated this subpart is a vendor responsibility only. Brunette questioned if this happens now, and Purrington stated it does. Juran questioned demo equipment. Purrington asked Stephanie Welvaert (MDH) if this is temporary use. Welvaert responded this only applies to the sale. Lund asked how this would work. Purrington stated this would be for vendor only.

Brunette questioned the shielding plan and portables or preinstalled equipment. Purrington stated these rules have not been developed yet.

Review of Service Provider Training

Teresa Purrington, X-ray Unit Supervisor Bevin Beaver, X-ray Unit Inspector

Purrington stated the Joint Commission standards on fluoroscopy have been included in the meeting packet. She asked the focus group to look at number 34, and the exclusion of health physicist and reference to all fluoroscopy equipment. She also stated that the standard references a qualified medical physicist, similar to what MDH is proposing in rule revision. This is required by January 1, 2019.

Subp. 2

Purrington stated that several other states refer to an eight-hour training for vendors. Brunette asked what is involved in the training. Purrington stated it covers x-ray system safety. Geise asked where eight hours derives from. Purrington stated this comes from other states' rules. Juran asked for the definition of a vendor. Welvaert gave the definition of a vendor. Juran asked if this should be only those who manufacture, not someone who sells the equipment. He also asked who in the company would need the training. Purrington stated it would be the vendors registering with MDH. Lund asked if the manufacturer training would suffice. Purrington stated that manufacturer training would suffice.

Geise questioned the word "or" in subpart 2, should require training on system and equipment safety.

Brunette asked if a facility selling equipment to another facility is considered a vendor. Purrington stated that MDH would review this. Brunette also questioned equipment transferred from one registrant to another one of their sites. Purrington stated MDH would review this as well.

Subp. 3

Juran questioned if a service provider can show past training as proof of the six months of training requirement. Purrington stated MDH is still reviewing how this will look. Juran stated this reads as if a service technician has to go to school for six months. Welvaert responded that the wording includes the word "or".

Juran questioned manufacturers that no longer provide training on some equipment and stated that the wording is confusing. Purrington stated MDH would review this.

Geise questioned item A(1). Purrington stated this is on-the-job training. Lund asked about service technicians who have been in the business for a long time, but have no documentation of training and own the company. Purrington stated MDH is reviewing this part. Brunette asked about the "and" and "or" in this subpart. Purrington stated it should be item A(1) and A(2), or just A(3). Geise suggested removing number 2 and combining items 1 and 2. Brunette stated that item A(3) should be removed from the six month training. Purrington stated MDH would review this wording, and suggested the focus group provide wording to MDH.

Purrington asked the focus group about the six-month training requirement. Lund stated that Nebraska provides its own two-day test. Purrington stated that MDH could not provide that training. Geise stated that this training is not excessive. He asked if the training could be provided by a school. Purrington stated this could be included as a possible avenue for training.

Juran asked if individuals in training are not service technicians until they complete training. Purrington stated that is the case.

Geise questioned if A(3) should include manufacturer instruction onsite. Purrington stated MDH would look at that.

Juran asked if the training is initial only or continuing. Purrington stated that is initial only, but asked the focus group if there should be continuing education annually. Juran responded each individual is different, as those who have been in the field for a while would have a lot of training. Geise stated he does not agree with continuing education, as it is not effective if there's no test involved. Brunette stated a test would be more effective. Geise agreed.

Subp. 4

Brunette asked if the service technician is expected to be under the supervision of a QE. Purrington confirmed. Brunette suggested including the wording "if applicable", or saying if they provide shielding evaluations then you must do this. Purrington stated this would be included with other service provider rules, so it will be easier to reference.

Brunette questioned A(3) and six months of personal supervision. He stated this would be difficult to achieve and document. Geise stated he agrees, as no one continuously does shielding plans. He suggested experience could be a certain number and/or certain types. Purrington stated MDH would bring this information to the Advisory Committee. Brunette also stated that some years he has no shielding, and other years he has several. It is not consistent and the six-month training is not feasible. Verke stated that shielding includes other types of facilities, like veterinary and chiropractic. Purrington agreed, and stated that is why we are having these discussions.

Juran stated that the wording "service technicians" should not be included in this subpart because these individuals would not necessarily do shielding. Brunette stated this is the same question that the service providers have in the field. Juran responded that a service technician should have electronic knowledge of the systems, and those who do shielding plans are not doing testing and diagnostics.

Subp. 5

Purrington stated this subpart is for CT and interventional fluoroscopy. Geise stated that not everyone needs six months of training, as everyone learns differently. He also stated he does not know how this would be defined. Purrington stated this suggestion is from the Advisory Committee and other states rules. Geise stated he is concerned someone would abuse this sixmonth rule. He suggested including a number rather than a period so it is more specific. Purrington stated a number is difficult too, as who determines what number is good enough. Geise suggested bringing this to the Advisory Committee and AAPM, and asking the Medical Physicists what they think. Purrington stated that the MDH rule would go to AAPM for review.

Subp. 6

Purrington asked the focus group about Joint Commission proposing Health Physicist performing fluoroscopy testing. Brunette responded there are health physicists that would be upset over this. Purrington stated that the Joint Commission has already set the standard. Geise stated that health physicists do not get fluoroscopy training, and this is why they were removed.

Purrington asked the focus group about smaller sites and hospitals. Geise stated not everyone is Joint Commission accredited, but maybe the state rules should follow that standard. Purrington stated MDH would bring the Joint Commission data and the focus group suggestions to the Advisory Committee. Brunette stated that maybe this subpart should just focus on medical use. Geise stated that this also includes occupational safety, not just patient safety. Purrington stated that CT has become more prevalent in the veterinary industry as well. Geise asked if subpart 6 includes companies that are the service company and technician. Purrington stated MDH is currently reviewing this. Geise asked if the QMP needs training as well. Purrington responded that they do. Geise stated if a QMP is board certified, they have already had eight hours of training.

Purrington thanked the focus group for their time and valuable discussions.

Purrington asked for Public Comments

- Jim Jaglo: Asked if online training would suffice. Purrington stated that is a good suggestion, and asked him to provide some documentation. He also stated Idaho has online training, and agreed with adding a number of trainings, rather than a period of time.
- Dan Lind: Asked if MDH reviews shielding plans. Purrington stated that MDH does not review them. He suggested using the 2579 form as proof of training. Purrington stated that MDH does not keep 2579s for more than a year for record retention purposes.
- Steve Danielson: Asked if ASI standards continuing education training is sufficient for training documentation. He also asked if those who retire would have to keep calibration reports. Purrington stated that our current rule states to keep calibration records for four years.
- Linda Laman: Stated that a QE can deny a service technician who is not adequately trained, and tell them they need additional training. She also stated that many people in the field do not know that MDH is revising their rules, and asked everyone to add the MDH Rule Flyer to their work areas.
- Henry Perez: Asked how much of the service provider rules will pertain to the dental
 industry. The rules do not seem to take into consideration dental service providers.
 Purrington stated the Advisory Committee encompasses many different modalities,
 qualifications, and experts. She also stated that anyone could provide comments. Perez
 referenced the Joint Commission documentation. Purrington stated that dental is excluded
 with Joint Commission.
- Sue McClanahan: Stated that the flyer would help people in the communities talk about how this rule affects them.

- Amos Tarfa: Stated that leaving images onsite could be a problem for their customers, who
 do not want to keep them. Suggested maybe providing them with a CD.
- Kelly Daigle: Asked if there will be online registration for service providers. Purrington stated that MDH is hoping this will be an option in the future. Daigle clarified her question by asking if service providers will be able to verify that a facility is registered online. Purrington stated this should be the case.

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