DEPARTMENT OF HEALTH

Minnesota Rules, Chapter 4732 X-Ray Revision

DRAFT SERVICE PROVIDER RESPONSIBILITIES RULES, 2.0

Summary of Changes

MDH made a number of changes to the Service Provider Responsibilities rule draft v1.0 based on the service provider focus group's review and feedback at the June 28, 2018 meeting. The changes are listed below.

Subp. 1. Service company or service provider responsibilities for a registrant.

- Revised subpart 1 introduction.
- **Item A. [formerly item B]** is revised
- **Item C. [new]**

Subp. 2. Checklist contents and requirements.

- **Items B and C.** Syntax edits
- **Item D.** Revised item D and moved to item F.

Subp. 3. Notice of assembly or Installation.

- Added "calibration, equipment performance evaluation, preventive maintenance"
- **Item A.** Deleted "six months" and replaced with "480 hours"
- **Item A(1).** Deleted "didactic or"

Subp. 4. Service report; frequency.

- Updated subpart numbering.
- Deleted "at the time of testing"

Subp. 5. Service report; contents.

- **Item B.** Deleted "testing" and replaced with "service"
- **Item D.** Deleted "equipment" and replaced with "x-ray system"
- **Item G.** Deleted "in applicable x-ray system parts"
- Deleted "any images obtained at the time of testing must be provided to the registrant" [formerly item H]
- **Item I [renumbered].** Deleted "by the service provider"

Subp. 7. Vendor notification.

- Revised headnote from "Notice of sale of x-ray systems "

4732.#### SERVICE PROVIDER RESPONSIBILITIES.

RESPONSIBILITIES

Subpart 1. **Service company or service provider responsibilities for a registrant.** Before a registrant's first use on individuals or before first use in an industrial, research, or veterinary setting, a service company or service provider that installs, assembles, transfers, or replaces x-ray systems must provide a registrant with a checklist under subpart 2.

A. This subpart applies to a service company's or service provider's initial installation of an x-ray system:

(1) in a new facility;

(2) in a new room; or

(3) in an existing room that was not previously designed or shielded for use of x-ray equipment.

B. The checklist must be on a form provided by the commissioner.

C. A service company or a service provider must maintain a copy of the checklist for each registrant for four years.

Subp. 2. **Checklist contents and requirements.** A service company or service provider must complete and verify that a checklist meets the requirements of this subpart.

A. A service company or service provider must verify that the registrant has completed the shielding plan under part 4732.####;

B. Before a registrant's initial x-ray system installation, a service company or a service provider must verify proof of:

(1) initial registration with the commissioner; or

Commented [JC(1]: CO 2.7 Service company registrant responsibilities
TX (O)(2)

(2) facility registration number.

C. For an existing registrant, a service company or a service provider must verify proof of:

(1) a valid certificate of registration; and

(2) facility registration number.

D. Before first use on individuals or before first use in an industrial, research, or veterinary setting, an x-ray system must meet initial x-ray system installation equipment performance evaluations according to:

(1) the manufacturer specifications;

(2) the equipment performance requirements under this chapter; and

(3) applicable requirements under 21 CFR 1020.30 to 1020.33, and 1020.40, or successor requirements.

E. For each installed x-ray system, a service company or a service provider must provide a registrant with manufacturer guidance documents, instruction manuals, and manufacturer specifications; and

F. A service company or a service provider must submit an assembly or installation notification under subpart. 3.

Subp. 3. **Assembly or installation notification**. A service company or service provider must notify the commissioner an assembly or installation notification of an x-ray system or x-ray system component on a form provided by the commissioner, no later than 15 days after assembly or installation. FDA Form 2579 must not be used to meet the requirements of this subpart or subpart 1.

Commented [JC(2]: TX 289.226(o)(1) p. 22 of 28

Commented [SW(3]: CO 2.7.1.3 Service company registrant responsibilities for E (1)(2)

Commented [JC(4]: Assembler and or Transfer Obligation:
States
AZ, AR, DE, IN, IA, LA, ME, MA, MI, OR, RI, VA
Rule part in some states:
"In the case of diagnostic x-ray systems which contain certified components, a copy of the assembler's report prepared in compliance with requirements of the Federal Diagnostic X-Ray Standard (21 CFR 1020.30(d)) shall be submitted to the board within 15 days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler".
AZ, AR, DE, FL, IN, IA, LA, ME, MA, MI, OR, RI,

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=1020.30

Commented [SW(5]: SSRCR B15-Assembler and/or Transfer Obligation
States with 15 days: SSRCR, AZ, AR, DE, FL, HI, IN,IL, IA, LA, ME, MA, MS, NE, NM, ND, OK, OR, RI, VA, PA
States with 30 days: AL, SC

Subp. 4. **Service report.**

A. A service report must be completed by a service provider and provided to a registrant no later than thirty days after the date of the service.

B. A service company or a service provider must maintain a copy of the service report for four years.

For purposes of this part, a service report includes calibration, equipment performance evaluation, preventive maintenance, shielding plan, shielding evaluation, or radiation protection survey.

Subp. 5. **Service report; contents.** A service report must include:

A. registrant name, address, and contact person;

B. the date that the service was performed;

C. the manufacturer, serial number, model number of the registrant's x-ray system;

D. the location of the x-ray system;

E. the service company and the service provider registration number;

F. the service report must include the testing requirements under part 4732.####;

G. all x-ray systems parameters tested must include numerical results of the tests and a designation of "pass/fail" or "compliant/non-compliant". If the result of the test is not a numerical result, then a designation of "pass/fail", "compliant/non-compliant" is acceptable;

Commented [JC(6]: CO 6.3.4.1 General Requirements
The registrant shall maintain for inspection by the Department records for the previous three (3) years of survey measurements, calibrations, maintenance, modifications, certification evaluations pursuant to 2.5, Department Forms 59-1 and 59-2, and corrective actions for each x-ray imaging system with the names of persons who performed such services
Note: We only require that the SP keeps calibration and EPE. What about surveys and shielding plans?

Commented [JC(7]: SC Rule 2.7.3.6

Commented [JC(8]: SC rule 2.7.3.6.3

H. a summary of findings and recommendations for necessary improvements or corrective actions. The summary of findings and recommendations must be documented electronically or in written format;

I. manufacturer, model number, serial number, and the calibration date of the radiation measurement instruments used;

J. the electronic authorization or written signature of the individual performing the service;

K. the electronic authorization or written signature of a qualified expert when a service technician who is under the general supervision of the qualified expert is preparing:

(1) a shielding plan;

(2) a shielding evaluation, or

(3) a radiation protection survey report; and

L. the electronic authorization or written signature of a qualified medical physicist when a service technician who is under the general supervision of the qualified medical physicist is preparing:

(1) a service report for a CT x-ray system; or

(2) a service report for a fluoroscopic x-ray system.

Subp. 6. **Radiation measurement instruments.** Service testing of x-ray systems must be performed by a service provider with radiation measurement instruments according to this subpart.

Commented [JC(9]: SC 2.7.3.6.4

Commented [JC(10]: TX 289.227 (i)(14) pg 21 of 51 Subpart 4, A-C, all from TX

A. A radiation measurement instrument must be calibrated to its standard according to the National Institute of Standards and Technology (NIST).

B. A radiation measurement instrument must be calibrated within 24 months from the date of the previous calibration.

C. Record of a radiation measurement instrument calibration must include:

(1) the manufacturer's name, model and serial number; and

(2) the date of the calibration.

Subp. 7. **Vendor notification.**

A. A vendor must notify the commissioner no later than 30 days after selling, leasing, lending, transferring, or demonstrating an x-ray system on a form provided by the commissioner.

B. A vendor notification form includes:

(1) the name, address, and registration number of the registrant that acquired the x-ray system;

(2) the type of x-ray system, the manufacturer name, model number, control panel serial number of each x-ray system acquired;

(3) the date of acquisition of each x-ray system;

(4) services under part 4732.####, subpart 4, item A; and

(5) any additional information the commissioner deems necessary for review of the vendor notification.

Commented [JC(11]: SSRCR B15 (when it includes sells, leases, lends, etc.
SC-Vendor Obligation 2.7.1
TX-Respons. Of assemblers o(2) pg 22 or 28
States with 15 days: SSRCR, AZ, AR, DE, FL, HI, IN,IL, IA, LA, ME, MA, MS, NE, NM, ND, OK, OR, RI, VA, PA
States with 30 days: AL, SC

Commented [JC(12R11]: This comes from SC-Vendor Obligation 2.7.1

Commented [JC(13]: TX- o(2)(B)

Commented [JC(14]: Reference to Service Provider Registration,
Subp.4. **Service Categories**. Item A - sale, lease, lend, transfer, or demonstration of x-ray systems and x-ray system components.

C. A vendor must submit a vendor notification form every 30 days regardless of whether an x-ray system was sold, leased, lent, transferred or demonstrated in the previous 30 days.

Commented [SW(15]: SC 2.7.1.4

Subp.8. **Prohibited use.** It is unlawful for a service provider to apply radiation on an individual for training, demonstration, or other non-healing arts purposes. A phantom must be used for these purposes.

Commented [SW(16]: SC- Part 1 General Provisions 1.2 Prohibited Use. (1.2.2)
Mix of SC and MN

Environmental Health Division, Indoor Environments and Radiation Section
Minnesota Department of Health
PO Box 64975
St. Paul, MN 55134-0975
x-rayrules@state.mn.us
www.health.state.mn.us

08/10/2018

To obtain this information in a different format, call: 651-201-4538. Printed on recycled paper.