DEPARTMENT OF HEALTH

Minnesota Rules, Chapter 4732 X-Ray Revision

DRAFT SERVICE PROVIDER RESPONSIBILITIES RULES, 1.0

4732.#### SERVICE PROVIDER RESPONSIBILITIES.

RESPONSIBILITIES

Subpart 1. **Service company or service provider responsibilities for a registrant.**

A. Before a registrant may use an x-ray system for its intended use, a service company or service provider must provide a registrant with a checklist of the service company's or service provider's completed responsibilities under subpart 2.

B. This part applies only to a service company or service provider that installs, assembles, transfers, or replaces x-ray systems.

C. The checklist under item A must be on a form provided by the commissioner.

Subp. 2. **Checklist contents and requirements.** A service company or service provider must verify that the checklist required under subpart 1 meets the requirements under this subpart.

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

B. For an existing facility, a registrant must provide a service company or a service provider with proof of:

(1) a valid certificate of registration; and

(2) its facility registration number.

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

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

C. For an initial installation, a registrant must provide a service company or a service provider with proof of:

(1) initial registration with the commissioner; or

(2) its facility registration number.

D. The service company or service provider submits a Report of Assembly of X-ray Systems, on a form provided by the commissioner, no later than 15 days after assembly. FDA Form 2579 may not be used to meet the requirements of this subpart or subpart 1.

E. Before first use on individuals or before first use in an industrial application, an x-ray system that is installed, assembled, transferred, or replaced by a service company or service provider must meet:

(1) the manufacturer specifications;

(2) the requirements of this chapter; and

(3) applicable requirements under 21 CFR 1020.30-1020.33, and 1020.40;

F. A service company or a service provider has provided the registrant with manufacturer guidance documents, instruction manuals, and manufacturer specifications for each assembled x-ray system.

Subp. 3. **Service report; frequency.** A service report must be completed by a service provider and provided to a registrant:

A. at the time of testing; or

B. no later than thirty days of the date of the x-ray system testing.

Commented [JC(3]: 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(4]: 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

Commented [SW(5]: CO 2.7.1.3 Service company registrant responsibilities for E (1)(2)

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

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

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

Subp. 3. **Service report; contents.** A service report must include:

A. facility name, address, and contact person;

B. the date that the testing was performed;

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

D. the location of the equipment;

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 in applicable x-ray system parts 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;

H. any images obtained at the time of testing must be provided to the registrant.

I. a summary of findings and written (or electronic) recommendations for necessary improvements or corrective actions;

J. manufacturer, model number, serial number, and the calibration date of the radiation measurement instruments used by the service provider;

Commented [JC(8]: SC rule 2.7.3.6.3

Commented [JC(9]: SC 2.7.3.6.4

Commented [JC(10]: Focus Group: Is "by the service provider" too restrictive?

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

L. the written signature or electronic authorization 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

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

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

(2) a fluoroscopic x-ray system report.

Subp. 4. **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(11]: 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. 5. **Prohibited use.** It is unlawful for a service provider to apply radiation to an individual for training, demonstration, or other non-healing arts purposes. A phantom must be used for these purposes.

Subp. 6. **Notice of sale of x-ray systems.**

A. A service company or a service provider that sells, leases, or lends of an x-ray system must notify the commissioner within 30 days of:

(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; and

(4) any additional information the commissioner deems necessary for review of the application for notification.

B. Notification to the commissioner under this subpart must be made on a form provided by the commissioner and must be submitted monthly regardless of whether x-ray equipment was sold that month.

Commented [SW(12]: SC- Part 1 General Provisions 1.2 Prohibited Use. (1.2.2)
Mix of SC and MN

Commented [JC(13]: 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 [SW(14R13]: This comes from SC-Vendor Obligation 2.7.1

Commented [JC(15]: TX- o(2)(B)

Commented [SW(16]: SC 2.7.1.4

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