

## Minnesota Rules, Chapter 4732 X-Ray Revision

DRAFT SERVICE PROVIDER DEFINITIONS, 2.0

### 4732.#### SERVICE PROVIDER DEFINITIONS.

*Note: This document is intended as a reference for the Service Provider focus group. Some of the definitions are already contained in the Definitions part of Chapter 4732. MDH intends to incorporate newly proposed definitions in this document into the Definitions part of Chapter 4732.*

Subp. ##. **Assemble or assembled.** "Assemble" or "assembled" means to fit together the parts or pieces of an x-ray system or x-ray system components.

Subp. ##. **Direct supervision.** "Direct supervision" means guidance and instruction by a qualified expert or a qualified medical physicist who is physically present, is in direct contact with a service technician, and is able to give immediate assistance.

Subp. ##. **General supervision.** "General supervision" means services performed under the overall direction and control of the qualified expert or qualified medical physicist and who is not required to be physically present during the performance.

Subp. 37. **Individual.** "Individual" means a living human being.

Subp. ##. **Install or installed.** "Install" or "installed" means to set up an x-ray system for use by a registrant where the assembly, adjustments, testing, and tolerances are performed according to this chapter.

Subp. 52. **Person.** "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this

**Commented [JC(1):** Added after Service Provider Focus Group meeting.

FDA guidance explanation of terms-  
<https://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/IndustryGuidance/ucm136729.htm>

**Commented [JC(2):** Definition added after Service Provider Focus Group meeting.

**Commented [JC(3):** Added "or qualified medical physicist" after Service Provider Focus Group meeting.

**Commented [JC(4):** Intent is to replace MDH's proposed definition of "install or installed" in the main Definitions part with this revised definition. See below.

**Subp. 42. *Install or installed.*** *Install" or "installed" means deliver, assemble, or place X-ray equipment or X-ray machines so that the machines and equipment are: (1) in a registrant's possession; and (2) ready for use by a registrant.*

FDA guidance explanation of terms-  
<https://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/IndustryGuidance/ucm136729.htm>

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state, and any legal successor, representative, agent or agency of the foregoing, excluding federal government agencies.

Subp. ##. **Qualified expert.** “Qualified expert” means an individual who meets the qualifications under part 4732.####.

Subp. 58. **Qualified medical physicist or QMP.** “Qualified medical physicist or QMP” means an individual who meets the qualifications under part 4732.#### and is trained in evaluating the performance of CT or interventional fluoroscopic x-ray systems.

Subp. ##. **Responsible individual.** “Responsible individual” means an individual who has the authority to represent a service company in all matters relating to a service company registration under part 4732.####.

Subp. ##. **Service Company.** “Service company” means a person that is in the business of:

- A. selling, leasing, lending, transferring, demonstrating, installing, assembling, repairing, replacing, storing, disabling, disposing and preventive maintenance of x-ray systems and x-ray imaging systems; or
- B. performing calibrations, equipment performance evaluations, radiation protection surveys, shielding plans of x-ray systems and x-ray imaging systems.

Subp. 72. **Service provider.** “Service provider” means a service company or individual that is registered with the commissioner to provide services under part 4732.####, subpart 4, for a registrant. A service provider includes a qualified medical physicist, a qualified expert, a service technician, or a vendor.

**Commented [JC(5):** States with same definitions as CRCPD (def. Part A): IA, MA, ND, NH, NM, PA, WV  
**States with QE definition:** AL, AK, AZ, AR, CO, DE, FL, ID, IA, KY, ME, MA, MT, ND, NH, NM, NY, OK, OR, PA, SC, TN, UT, WV  
QE is used in 24 states as a definition (in some form)

**Commented [JC(6):** See Qualifications part. **Commented [JC(7):** See

**Commented [JC(8): Advisory Committee:** More discussion needed. Service Provider focus group feedback included:

- FGI
- Fluoroscopy equipment that produces 10R per minute
- Fluoroscopy equipment that produces 5R per minute
- Interventional – length of exam
- Fluoroscopy exams using vascular contrast agents

**Commented [JC(9):** Definition added after Service Provider Focus group meeting.

**Commented [JC(10):** Reference to Service Provider Registration.

**Commented [JC(11):** CO 6CCR1007-1 Part 2 2.2 Definitions  
**Item A:**  
Added “lending”, “replacing” and “preventive maintenance”.  
Deleted “maintaining” and “trading out”

**Commented [JC(12):** Based on Illinois and current proposed definition in Definitions.

**Commented [JC(13):** Reference: Service categories in Registration part

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**Subp. ##. Service technician.** "Service technician" means a person who is employed by a service company to:

- A. install, assemble, calibrate, perform equipment performance evaluations and preventive maintenance, replace, repair, or disable x-ray systems, x-ray imaging systems, and x-ray system or x-ray imaging system components;
- B. perform services under the general supervision of a qualified expert or a qualified medical physicist who assumes the responsibility for and signs or authorizes the final CT or interventional fluoroscopy equipment performance evaluation, shielding plan, or radiation protection survey report.

**Subp. ##. Vendor.** "Vendor" means a person who sells, leases, lends, transfers, disposes, or demonstrates x-ray systems or x-ray imaging systems and x-ray system components.

**Subp. 89. X-ray imaging system.** "X-ray imaging system" means an assemblage of components for the reception of x-rays and the transformation, storage, and visual display of the resultant x-ray image that are designed and used for irradiation for the purpose of diagnosis or visualization. X-ray imaging systems do not include therapeutic imaging systems under chapter 4733.

**Commented [JC(14):** CO rule 2.2.2 Definitions

**Item A:**

Added "perform equipment performance evaluations and preventive maintenance"  
Deleted "maintain"

**Item B:**

Added "or a qualified medical physicist", "or authorizes", and "CT or interventional fluoroscopy"

Deleted original item A: "lend, transfer, or dispose of x-ray systems"

**Commented [JC(15):** Added "lends" and "disposes"

**Commented [JC(16):** Deleted "of any part of the body" after "used for irradiation"

Deleted "generation and emissions"

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