

Minnesota Rules, Chapter 4732 X-Ray Revision

DRAFT SERVICE PROVIDER RULES, 1.0 (04/01/2018)

4732.#### SERVICE PROVIDER REGISTRATION.

Subpart 1. **Applicability.** A service provider or service company must comply with part 4732.####.

REGISTRATION

Subp. 2. **Registration.** A person or service company that provides services under subpart 4 must apply for registration of service categories with the commissioner within 30 days following the effective date of this part.

Commented [JC(1)]: CRCPD. Part B Sec B(9)a
Same as CRCPD: AR, DE, ID, IA, LA, ME, MS, NM, ND, NC, RI, UT,
Similar to CRCPD: AR,CO, KY, MA, OR, PA, SC,

Subp. 3. **Application.**

Commented [SW(2)]: CRCPD. Part B. Sec B(9)b
Same: AR, CO, DE, IA, LA, ME, MA, MS, NM, ND, NC, RI, SC
Similar: FL, ID, IL, OR,

A. An applicant for registration under this part must complete forms provided by the commissioner.

B. An applicant must provide all information required by the commissioner as indicated on the form including:

Commented [SW(3)]: CRCPD Sec B(9)c
NC 10A NCAC 15 .0205, b.
States w/ specific information: CO, ID, IL, KY, OR, SC,

(1) the name of the service provider or service company to be registered;

(2) service provider number and service company number, if applicable;

(3) the address, email address, telephone number, website address, if applicable, of the service provider or service company;

(4) the name of the responsible individual of the service company;

Commented [JC(4)]: Focus Group: Other states have RSOs. Should this be included here?
States with RSO on application: TX, NC, ID
Person responsible for rad. safety: AK, HI

(5) the Minnesota business identification number of the service company or social security number of the service provider;

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- (6) the service categories under subpart 4;
- (7) the type of x-ray system or x-ray imaging system;
- (8) the training and experience of each service provider who provides services under subpart 4;
- (9) the training and experience of the service provider for each type of x-ray system serviced and x-ray imaging system subitem (7);
- (10) the date of the application and the signature of responsible individual;
- (11) an attestation from the service company that each service provider is instructed in, and demonstrates an understanding of the requirements of this part and 21 CFR Chapter I, Subchapter J or successor requirements;
- (12) preceptor documentation for the service technician signed by the qualified expert who must be registered with the commissioner as a service provider;
and
- (13) any additional information the commissioner deems necessary for evaluation of the application for registration.

Commented [JC(5)]: CO references this in 6CCR 1007-1 Part 2 2.4.2.3, 2(b)(ii)

Subp. 4. Service categories. Service categories include:

- A. sale, lease, transfer or demonstration of x-ray systems and x-ray system components;
- B. installation, assembling, maintaining, replacing, or servicing of x-ray systems, x-ray imaging systems, or x-ray system and x-ray imaging system components;
- C. disabling or disposal of x-ray systems;
- D. calibration or equipment performance evaluations of x-ray systems;

Commented [SW(6): CRCPD. Sec B(9)d. States same as CRCPD: ID, MA, MS, NM, ND, States Similar to CRCPD: AR, CO, DE, IA, NC, OR, SC, UT,

Commented [JC(7): Focus Group: Should we consider installation and servicing of automatic X-ray film processors. (OR - OAR 333-101-0020; IA)

Commented [SW(8): Sub4, item A-H are from NC 10A NCAC 15 .0205 APPLICATION FOR REGISTRATION OF SERVICES

Commented [JC(9): TX, OR, PA, MD, ME (demonstration listed on their forms)

Commented [JC(10): 2.4.2.3-Reg. as a service company

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- E. radiographic or industrial facility and shielding design;
- F. fluoroscopic or CT facility and shielding design;
- G. radiation protection survey or shielding evaluation; and
- H. therapeutic facility and shielding design, area radiation survey or calibration.

Commented [JC(11): Service Provider Focus Group:
Thoughts on items E, F and G.

Commented [JC(12): Service Provider Focus Group: Is
"shielding evaluation" needed here?

Subp. 5. Denial of application.

- A. The commissioner shall deny an application for service provider registration if an applicant's registration does not meet the requirements of subpart 3.
- B. The commissioner shall follow the criteria for a denial of an application under Minnesota Statutes, section 144.99, subdivision 8, paragraph (a) or (b).
- C. The commissioner shall notify an applicant in writing of the denial of the registration and provide the reason for the denial.

Subp. 6. Notice of registration; issuance.

- A. The commissioner shall issue a notice of registration to an applicant that meets the requirements of subpart 3.
- B. A notice of registration is valid for two years from the date of issuance.

Commented [JC(13): Two years is consistent with
variance time period.

Subp. 7. Notice of registration; expiration and renewal. A service provider must renew by submitting an application for registration under subpart 3 at least 30 days before the expiration of the existing notice of registration on a form provided by the commissioner.

- A. If a notice of registration expires while a renewal application is pending approval, then a service provider or service company may continue to perform services

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under the expired notice of registration until the commissioner issues a new notice of registration or denies the renewal application.

- B. If a service provider does not submit an application for renewal according to subpart 3 on or before the expiration specified on the notice of registration, then the service provider must terminate services.

Commented [SW(14): TX rule 289.226(p)(2)

Subp. 8. Changes to registration. A service provider must notify the commissioner in writing within 30 days before making any change that would render the information contained in the application for registration or the notice of registration inaccurate.

Commented [SW(15): CRCPD B13
Same: NM, ND, OR,
Similar: DE, FL, RI, OH, SC

Commented [SW(16): SC – 30 days

Subp. 9. Prohibited services. A service provider is prohibited from performing services under subpart 4 that are not specifically stated on the notice of registration issued by the commissioner.

Commented [JC(17): CRCPD: Sec B(9)e
Same as CRCPD: DE, ID, IA, MS, NM, ND, OR

Subp. 10. Exemption for in-house service providers. An individual employed by a registrant to perform calibrations, equipment performance evaluations, or repairs in-house of x-ray systems and x-ray imaging systems is exempt from registering as a service provider if the individual:

Commented [JC(18): NH:
He-P 4040.06 Exemptions (g) An individual employed by a registrant to perform, on an in-house basis only, calibrations, equipment performance evaluations, or minor repairs of that registrant's diagnostic or industrial radiation machines, shall be exempt from the service provider registration requirements of this part, unless the individual also provides these services to other registrants

- A. meets the training and experience requirements under part 4732.####; and
- B. performs these services for only one registrant.
- C. A registrant must maintain documentation of training and experience for in-house service provider and must be available for review by the commissioner.

Commented [SW(19): SC Rule 2.6.1.1.1, 2.6.1.1.2, and 2.6.1.2

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