

Minnesota Rules, Chapter 4732 X-Ray Revision

DRAFT SERVICE PROVIDER REGISTRATION RULES, 2.0

Summary of Changes

MDH made a number of changes to the Service Provider Registration 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. 3. Registration.

- **Item B.** Added "applicable"
- **Item B (2).** Deleted ", if applicable"
- **Item B, subitem 6.** Added "for which the applicant is registering"
- **Item B, subitem 8.** Revised to: "each type of x-ray system or x-ray imaging system the applicant is servicing"
- **Item B (11).** Deleted "is instructed in, and demonstrates an understanding of" and replaced with "understands".
- **Item B, subitem 11(2).** Added "Minnesota Statutes, sections 144.121 and 144.1215;"
- **Item B, subitem 11(3).** Deleted "part" and replaced with "chapter"
- **Item B, subitem 11.** Added "When the service company is the sole service provider, the responsible individual must submit an attestation under this subpart."
- **Item B (12).** Revised "preceptor documentation" to "attestation from a qualified expert or qualified medical physicist".
- **Item B (12).** Added three service categories that a service technician may perform under the supervision of a QE or a QMP.

Subp. 4. Service categories.

- **Item A.** Added "lend"
- **Item B.** Deleted "maintaining" and replaced with "preventive maintenance"
- Deleted "radiographic or industrial facility and shielding design." [Formerly item E]
- **Item E.** Added "extraoral, radiographic, and CBCT, or CT" and deleted "design" and replaced with "plan"
- **Item F.** Deleted "fluoroscopic or CT facility and shielding design" and replaced with "shielding evaluation"
- **Item G.** [new]. Added new item for "radiation protection survey"
- Deleted "therapeutic facility and shielding design, area radiation survey or calibration." [Formerly item H]

4732.#### SERVICE PROVIDER REGISTRATION.

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

REGISTRATION

Subp. 2. **Registration.** A service company or a service provider 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, AZ, DE, FL, ID, IA, LA, MA, ME, MS, NM, ND, NC, RI, UT,
Similar to CRCPD: AZ, CO, HI, KY, 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, OR, RI, SC
Similar: FL, ID, IL

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

B. An applicant must provide all applicable information required by the commissioner as indicated on the forms 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 company or service provider to be registered;

(2) service company registration number and service provider registration number;

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

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

Commented [JC(4): 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 and the social security number of each service provider;

(6) the service categories under subpart 4 for which the applicant is registering;

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- (7) the training and experience of each service provider who provides services under subpart 4;
- (8) each type of x-ray system or x-ray imaging system the applicant is servicing;
- (9) the training and experience of each service provider for the types of x-ray systems and x-ray imaging systems under subitem (8);
- (10) the date of the application and the signature or electronic authorization of the responsible individual;
- (11) an attestation from the service company that each service provider understands the requirements of:
 - a. 21 CFR Chapter I, Subchapter J or successor requirements;
 - b. Minnesota Statutes, sections 144.121 and 144.1215; and
 - c. this chapter.

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

When the service company is the sole service provider, the responsible individual must submit an attestation under this subpart.

- (12) an attestation from a qualified expert or a qualified medical physicist for a service technician to perform:
 - 1) a shielding plan under subpart ##;
 - 2) a radiation protection survey under subpart ##; or
 - 3) a CT or interventional fluoroscopy equipment performance evaluation under subpart ##.

Commented [JC(6)]: NCRP 147 defines the term "qualified expert" under 1.5 General Concepts, p. 7. "Qualified expert" is a medical physicist or medical health physicist who is competent to design radiation shielding "shielding plan" for medical imaging facilities. The qualified expert is a person who is certified by the American board of Radiology, American Board of Medical Physics, American Board of Health Physics, or the Canadian College of Physicist in Medicine.

Commented [JC(7)]: Subpart reference: training for a service technician by a QE. (Forthcoming)

Commented [JC(8)]: Subpart reference: training for a service technician by a QE. (Forthcoming)

Commented [JC(9)]: Subpart reference: training for a service technician by a QMP. (Forthcoming)

The qualified expert or qualified medical physicist must be registered with the commissioner as a service provider.

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(13) any additional information the commissioner deems necessary for evaluation of the application for registration.

Subp. 4. Service categories. Service categories include:

- A. sale, lease, lend, transfer, or demonstration of x-ray systems and x-ray system components;
- B. installation, assembly, preventive maintenance, replacing, or servicing of x-ray systems, x-ray imaging systems, or x-ray system and x-ray imaging system components;
- C. disabling or disposing of x-ray systems;
- D. calibration or equipment performance evaluation of x-ray systems;
- E. extraoral, radiographic, fluoroscopic, CBCT, or CT shielding plan;
- F. shielding evaluation; and
- G. radiation protection survey.

Commented [SW(10): 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 [SW(11): 10A NCAC 15 .0205 – Items from NC
South Carolina 2.6.4- Items from SC

Commented [JC(12): TX, OR, PA, MD, ME

Commented [JC(13): CO 2.4.2.3-Reg. as a service company

Commented [JC(14): Advisory Committee: Discussion needed on industrial facilities.

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.

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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(15)]: Two years is consistent with variance time period.

Subp. 7. Notice of registration; expiration and renewal. A service company or 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 company or a service provider may continue to perform services under the expired notice of registration until the commissioner issues a new notice of registration or denies the renewal application.
- B. If a service company or 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 company or the service provider must terminate services.

Commented [SW(16)]: TX rule 289.226(p)(2)

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

Commented [SW(17)]: CRCPD
B13 Same: NM, ND, OH, OR
Similar: DE, FL, RI, OH, SC

Commented [JC(18)]: SC – 30 days

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Subp. 9. Prohibited services. A service company and 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(19): 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 in-house services under subpart 4 for x-ray systems and x-ray imaging systems is exempt from registering as a service provider if the individual:

Commented [JC(20): SC 2.6.1.1
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(21): SC Rule 2.6.1.1.1, 2.6.1.1.2, and 2.6.1.2

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