Radiation Control, X-ray Unit
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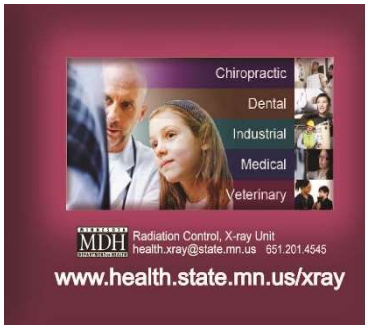
To: Minnesota Service Providers

From: Minnesota Department of Health, Radiation Control, X-ray Unit

RE: Service Provider Welcome Packet



Thank you for registering as a Service Provider with the Minnesota Department of Health (MDH). We would like you to consider the X-ray Unit a valuable resource and partner in radiation safety. Our mission is to protect and promote radiation safety through guidance and collaboration with the radiation community, and your role is instrumental in that collaborative effort.

Our goal is to be a resource to the regulated community and provide rule guidance, support, and resources to assist in compliance with Minnesota Ionizing Radiation Rules, Chapter 4732.

In addition to the Service Provider Guidance, Service Providers must follow the rules below.

- Minnesota Rules, Chapter 4732.0275, Service Provider Registration
- Minnesota Rules, Chapter 4732.0280, Service Provider Responsibilities
- Minnesota Rules, Chapter 4732.0710, Survey Equipment Calibrations

MDH has additional guidance and rule requirements available on our website that may be of interest to you and your Minnesota clients, including:

- Chiropractic Regulatory Guide
- Dental Regulatory Guide
- Veterinary Regulatory Guide
- X-ray Shielding Information
- Minnesota Rules, Chapter 4732.0220, General Shielding Documentation Requirements
- Minnesota Rules, Chapter 4732.0360, Shielding Plan Requirements
- Minnesota Rules, Chapter 4732.1100, Installation calibration tests and equipment performance tests

If you have any changes to your mailing address, employer, or email address, please email the current information to health.xray@state.mn.us. If you have not provided us with an email address, email that as well to the email above. This will ensure that you receive our email correspondences and other pertinent information regarding compliance with Minnesota Ionizing Radiation Rules, Chapter 4732.

For more information, please visit our website at www.health.state.mn.us/xray or contact us between the hours of 8:00 am – 4:30 pm at health.xray@state.mn.us or 651.201.4545. Thank you!

Minnesota Department of Health
Radiation Control, X-ray Unit

Service Provider Responsibilities

As a service provider, you may be the first point of contact with a facility acquiring x-ray equipment for the first time. The facility may have questions, and will look to you for answers for compliance with Minnesota Ionizing Radiation Rules, Chapter 4732. You will be instrumental in guiding the registrant to the Minnesota Department of Health (MDH). Please be aware of the following:.

- The faciilty is responsible for x-ray registration prior to first use. Service Provider notification requirements to MDH do not replace the facility's registration responsiblities.
- Registrants are required to maintain documentation of radiation shielding installed in their facility.

  1. Registrants that have x-ray rooms/areas constructed, remodeled, or placed into service after February 2008 must complete and submit a shielding plant to MDH prior to construction and first use.

  2. Registants that own or purchased facilities constructed before February 2008 must maintain doucmentation of radiation shielding installed in their facility. If documentation is not maintained, they must contact an individual qualified to complete shielding plans or radiation surveys to verify the existing shielding is adequate.
- The imaging of humans for the purpose of maintenance, demonstration, and training is prohibited. If you image for these purposes you must use a phantom.

Service Provider Registration

Service providers who are assembling, installing, repairing, or replacing one or more components in a radiation producing equipment system in Minnesota must apply for registration with MDH, renew annually, and comply with the requirements of Minnesota Ionizing Radiation Rules, Chapter 4732.0275 and 4732.0280, and perform calibrations and performance evaluations according to 4732.1100. Facilities will verify if a service provider is registered prior to an equipment installation, performance evaluation, and/or calibrations.

X-ray Equipment Notification

A service provider must meet the notification requirements in Minnesota Radiation Rules, Chapter 4732.0280. Service providers selling, leasing, or transferring radiation producing equipment must notify MDH in writing within 15 days of the sale, lease, or transfer. They must provide the following information on notifications:

- Purchaser registration number (if known), name, address and phone number
- Equipment manufacturer, model, serial number, and location in facility
- Contact name at facility
- Old console and x-ray tube serial number (if known), along with the manufacturer and serial numbers of the new x-ray console and x-ray tube

Installation calibrations and equipment performance test reports must be sent to the facility within 30 days of the tests. The service provider must keep copies of these test reports for four years after completion. The test reports must include written recommendations for necessary corrections or improvements.

X-ray Equipment Calibrations

At the time of installation or receipt, calibrations must be performed on all diagnostic and industrial radiation producing equipment, including mobile and portable equipment.

- Code of Federal Regulations, title 21, section 1020
- Manufacturer's specifications
- Minnesota Rules, Chapter 4732.1100 to 4732.1130

The service provider's written report must include:

- The facility's name, address and contact person
- The date of equipment performance tests
- The equipment serial number, room number and/or location or name
- The numerical results of the tests including any appropriate films
- Any written recommendations necessary for corrective actions to maintain compliance with Minnesota Rules, Chapter 4732
- The name and registration number of the service provider performing the testing

Service Provider Role in Registrants X-ray Quality Assurance Program

Calibrations	Calibrations and equipment performance testing must be performed at the time of installation, prior to first patient use, and at the required frequency thereafter
Notifications	Service providers selling, leasing, or transferring radiation producing equipment in Minnesota must notify MDH in writing within 15 days of sale, lease, or transfer
Phantom Use	The imaging of humans for the purpose of maintenance, demonstration, and training is prohibited. If you image for these purposes, you must use a phantom.
Registration	Service providers must register with MDH prior to assembling, installing, repairing, replacing radiation producing x-ray equipment, or completing shielding plans/ radiation surveys
Shielding Plan	Must be submitted to MDH prior to first patient use and maintained onsite. Shielding plans for Bone Densitometry, Dental Intraoral, Mammography, or Podiatry x-ray equipment are not required to be submitted to MDH

MINNESOTA MDH DEPARTMENT OF HEALTH

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4732.0275 REGISTRATION OF SERVICE PROVIDERS.

Subpart 1. **Application for service provider registration.**

A. A person who is engaged in the business of assembling, installing, repairing, or replacing one or more components in a radiation-producing equipment system or conducting equipment performance evaluations on diagnostic or industrial radiation-producing equipment must apply for registration with the commissioner within 30 days following the effective date of this chapter or prior to furnishing or offering to furnish any services. The services may include, but are not limited to:

(1) installing, replacing, or repairing radiation-producing equipment and associated components; and

(2) performing equipment performance evaluations on diagnostic or industrial radiation-producing equipment and associated components.

B. All applications for registration must be completed on forms furnished by the commissioner and must include all information specified by the commissioner.

C. A person applying for registration under this part must specify:

(1) the services for which they are applying for registration;

(2) the training and experience that qualify them to discharge the services for which they are applying for registration;

(3) the type of measurement instruments to be used, frequency of calibration, and calibration facility; and

(4) the type of individual monitoring devices worn, if applicable.

D. An individual shall not perform services that are not specifically stated for that individual.

Subp. 2. **Issuance of notice of registration.**

A. Upon a determination that an applicant meets the requirements of this chapter, the commissioner shall issue a notice of registration. Each notice of registration expires at the end of the specified day in the month and year stated in the notice.

B. The commissioner may incorporate in the notice of registration at the time of issuance or after by appropriate rule, or regulation, any additional requirements and conditions deemed appropriate or necessary by the commissioner.

Subp. 3. **Renewal of registration.** Renewal of the registration for service providers must be completed 30 days prior to the end of the month of the current registration.

Subp. 4. **Exemption.** An individual employed by a registrant to perform in-house calibrations, equipment performance evaluations, or repairs of diagnostic or industrial

radiation-producing equipment is exempt from registering as a service provider. An in-house employee may not perform these tasks elsewhere unless registered as a service provider.

Statutory Authority: *MS s 144.12*

History: *32 SR 777*

Published Electronically: *December 10, 2007*

4732.0280 SERVICE PROVIDER'S RESPONSIBILITY.

Subpart 1. **General requirements.** A person shall not make, sell, lease, transfer, lend, repair, or install radiation-producing equipment or the parts used in connection with this equipment unless the parts and equipment, when properly placed in operation, meet the federal requirements for the equipment manufacturer's specifications and the requirements of this chapter.

Subp. 2. **Notification requirements.** A registered service provider must meet the notification requirements in this subpart.

A. A person selling, leasing, or transferring radiation-producing equipment must notify the commissioner in writing within 15 days of the sale, lease, or transfer, and must supply the name and address of the purchaser and other pertinent information required by the commissioner.

B. Installation calibrations and equipment performance test reports must be sent to the facility within 30 days of the tests. The service provider must keep copies of these test reports for four years after completion.

C. The test reports must include written recommendations for necessary corrections or improvements.

Subp. 3. **Calibration reports at time of installation.** At the time of installation, calibrations must be performed on diagnostic or industrial radiation-producing equipment prior to first use on patients according to nationally recognized standards, such as:

A. Code of Federal Regulations, title 21, section 1020;

B. the manufacturer's specifications;

C. parts 4732.1100 to 4732.1130; and

D. the service provider's written report, which must include:

(1) the facility name, address, and contact person;

(2) the date of equipment performance tests;

(3) the serial number of the equipment, room number, or name if applicable;

(4) the numerical results of the tests including any appropriate films. If the result of the test is not a numerical answer, a pass or fail or "yes" or "no" answer is acceptable;

(5) any written recommendations necessary for corrective actions to maintain compliance with this chapter; and

(6) the name and registration information of the service provider performing the testing.

Subp. 4. **Equipment performance tests.** At the time of the equipment performance tests, the tests must be completed at intervals not to exceed 24 months. The tests must be performed over the clinical range on the equipment according to parts 4732.1100 to 4732.1130; Code of Federal Regulations, title 21, section 1020; or the manufacturer's specifications. The registered service provider must keep copies of these test reports for four years after completion. The service provider's written report to the facility must include:

A. the facility name, address, and contact person;

B. the date of equipment performance tests;

C. the serial number of the equipment, room number, or name if applicable;

D. the numerical results of the tests including any appropriate films. If the result of the test is not a numerical answer, a pass or fail or "yes" or "no" answer is acceptable;

E. any written recommendations necessary for corrective actions to maintain compliance with this chapter; and

F. the name and registration information of the service provider performing the testing.

Subp. 5. **Individual monitoring.** The vendor employing registered service providers must provide individual monitoring devices and reports for their occupational exposure according to part 4732.0440, where applicable.

Subp. 6. **Phantom use.** The use of humans is prohibited for maintenance, demonstration, and training. A phantom must be used for these purposes.

Statutory Authority: *MS s 144.12*

History: *32 SR 777*

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4732.1100 INSTALLATION CALIBRATION TESTS AND EQUIPMENT PERFORMANCE TESTS FOR A QUALITY ASSURANCE PROGRAM.

Subpart 1. **Tests required.**

A. Installation calibration tests must be conducted prior to any patient use. Any adjustments must be made to bring the equipment up to a nationally recognized standard such as Code of Federal Regulations, title 21, section 1020, or the manufacturer's specifications, and to ensure compliance with this chapter prior to first use.

B. Equipment performance tests must be conducted over all clinical ranges, when applicable. For equipment performance tests, any adjustments must be made to bring equipment to a nationally recognized standard or manufacturer's specifications; and to ensure compliance with this chapter prior to using the equipment again.

Subp. 2. **Frequency of tests.** The tests in this part are to be made at the time of installation and at the specified intervals thereafter.

Subp. 3. **Image receptors.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Screen-film contact	At intervals not to exceed 24 months	No significant areas of poor contact as measured by no less than: (1) 8 wires/inch mesh; or (2) 7 holes/inch for regular film; (3) 40 wires/inch mesh or greater for mammography film
B. Screen-film-cassette speed match	At intervals not to exceed 24 months	Densities within ± 0.10 O.D. for all cassettes of the same speed used for imaging
C. CR imaging plates	At intervals not to exceed three months or upon observation of image artifacts	Follow manufacturer's recommendations

Subp. 4. **Processing.**

	TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A.	Darkroom fog	At intervals not to exceed six months	< 0.08 O.D. increase in density (measured at approximately 1.00 O.D.) after 2 minutes using film exposed on-site at the time of test. For mammography the O.D. increase must be < 0.05
B.	Sensitometry and densitometry	Before processing first film of the day	Density difference ± 0.15 O.D. and base + fog + .05 O.D. using film exposed on-site at time of test. Veterinary facilities are not required to perform this test
C.	Temperature check	At the time of sensitometry	Follow manufacturer's recommendations

Subp. 5. **All diagnostic radiographic tubes; required when applicable.**

	TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A.	SID indicator accuracy	At intervals not to exceed 24 months	± 2% of indicated value
B.	X-ray and light field alignment	At intervals not to exceed 24 months	± 2% of SID any one direction, ± 3% of SID, both directions (total)
C.	X-ray and image receptor alignment	At intervals not to exceed 24 months	± 2% of SID
D.	Collimator dial accuracy	At intervals not to exceed 24 months	± 2% of SID
E.	Reproducibility	At intervals not to exceed 24 months	Coefficient of variation < 5%
F.	mR/mAs	At intervals not to exceed 24 months	± 10% of baseline

G. Linearity	At intervals not to exceed 24 months	± 10% over clinical range
H. Linearity - for mAs only units manufactured after May 3, 1994	At intervals not to exceed 24 months	Average ratios of exposure to the indicated mAs obtained in any two consecutive mAs settings must not differ by more than 0.10 times their sum, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection
I. Timer accuracy	At intervals not to exceed 24 months	Single Phase: ± 10% of setting. Three phase, high frequency, and constant potential: use ± 5% of selected time when measured > 100 milliseconds. At times shorter than 100 milliseconds, use manufacturers' specifications
J. Half-value layer	At intervals not to exceed 24 months	Must meet requirements in part 4732.0810
K. kVp accuracy	At intervals not to exceed 24 months	± 5% of indicated kVp
L. Phototimer reproducibility, if present	At intervals not to exceed 24 months	± 5% of average exposure
M. AEC (phototimer)	At intervals not to exceed 24 months	± 10% of manufacturer's state increments
N. Illuminance of collimator	At intervals not to exceed 24 months	> 15 footcandles
O. Film density vs. thickness change on AEC	At intervals not to exceed 24 months	± 0.30 O.D. of the averaged exposures over the range specified by the manufacturer

P. Film density vs. kVp change on AEC	At intervals not to exceed 24 months	± 0.30 O.D. of the averaged exposures when measured at > 1.2 O.D. and over the range as specified by the manufacturer
Q. Spot film reproducibility (fluoroscopy units with manual mode)	At intervals not to exceed 24 months	± 5% of average exposure
R. Phototimer back-up timer cut off	At time of installation	Terminates exposure at < 600 mAs
S. AEC density at normal or "0"	At intervals not to exceed 24 months	> 1.0 O.D.

Subp. 6. **For facilities with fluoroscopes and C-arm fluoroscopes, except radiation therapy simulators, manufactured before May 19, 1995.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Maximum output at tabletop or equivalent minimum SSD	At intervals not to exceed 12 months and every tube change	< 5 R (1.3 mC/kg) per minute for manual; < 10 R (2.6 mC/kg) per minute for automatic exposure rate control systems
B. High level control maximum output at tabletop or equivalent minimum SSD	At intervals not to exceed 12 months and every tube change	< 20 R (5.0 mC/kg^{-1}) per minute
C. Fluoroscopic image size	At intervals not to exceed 12 months and every tube change	Error between fluorographic beam size and observed image size must be no more than ± 3% of SID for all modes and at any tower height

D. Actual spot-film size vs. indicated	At intervals not to exceed 12 months	Error between actual fluorographic beam size at image receptor and indicated image size must be no more than ± 3% of SID for all modes and at any tower height
E. Spot-film reproducibility	At intervals not to exceed 12 months	± 5% of average exposure
F. Phototimer reproducibility, if present	At intervals not to exceed 12 months	± 5% of average exposure
G. Fluoroscopic high contrast resolution and distortion	At intervals not to exceed 12 months	Six inch (15 centimeter) intensifier: center 30 and edge 24 (wires per inch) copper mesh; nine inch (23 centimeter) intensifier
H. Half-value layer	At intervals not to exceed 12 months and after every tube change	± 5% for equipment manufactured before 1973. For equipment manufactured after 1973, follow manufacturer's specified limits

Subp. 7. **For facilities with fluoroscopes and C-arm fluoroscopes, except radiation therapy simulators, manufactured on or after May 19, 1995.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Maximum output at tabletop or equivalent minimum SSD	At intervals not to exceed 12 months and at every tube change	> 5 R/min must have automatic exposure rate control; > 10 R/min must have high level control; if not high level control maximum is < 10 R/min
B. High level control maximum output at tabletop or equivalent minimum SSD	At intervals not to exceed 12 months and at every tube change	< 20 R/min

C. All other tests as indicated in subpart 5	At intervals not to exceed 24 months	See criteria in subpart 5

Subp. 8. **For facilities with tomography systems other than computed tomography.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Section level	At intervals not to exceed 12 months	± 5 millimeters
B. Level incrementation	At intervals not to exceed 12 months	± 2 millimeters
C. Section thickness (slice width)	At intervals not to exceed 12 months	Follow manufacturer's specifications
D. All other tests in part 4732.1000 if applicable	At intervals not to exceed 24 months	See criteria in subpart 4
E. Spatial plane resolution	At intervals not to exceed 12 months	40 mesh screen or better

Subp. 9. **For facilities with computed tomography scanners.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Accuracy of scout localization view	At intervals not to exceed 12 months	± 1 millimeters
B. Accuracy of distance measurements	At intervals not to exceed 12 months	± 1 millimeters
C. CT dose index	At intervals not to exceed 12 months	± 20% from manufacturer's recommendations
D. CT number dependence on slice thickness	At intervals not to exceed 12 months	Mean ± 3 CT numbers averaged over 100 pixels

E. CT number calibration and noise	Daily	Water: 0 ± 5 CT numbers; Noise: ± 3 standard deviations of the mean of the baseline noise variance measurements
F. CT number uniformity and artifacts	Monthly for mobile units. At intervals not to exceed 12 months for fixed base units.	Variation ± 5 CT numbers between the mean values of measurements made at center and edge of phantom that is at least 20 cm. In diameter among a mean of 100 pixels. Artifacts: no noticeable artifacts
G. Hard copy output and visual display	Daily	Luminance and contrast not significantly different
H. Table indexing	At intervals not to exceed six months	± 0.5 millimeter for each increment
I. Table backlash	At intervals not to exceed six months	± one millimeter

Subp. 10. **For facilities with cinefluorographic and special procedure systems.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Cinefluorographic exposure rates	At intervals not to exceed 12 months	Approximately 10 to 20 μR (2.6 to 5.0 nC/kg) per frame at intensifier for nine inch (23 cm) mode; approximately 20 to 30 μR (5 to 8 nC/kg) per frame at intensifier for six inch (15 cm) mode
B. All tests in subparts 4, 5, and 6, if applicable	At intervals not to exceed 24 months	See criteria in subparts 4, 5, and 6

C. Film changer screen-film contact	At intervals not to exceed 24 months	No significant areas of poor contact as measured by no less than: (1) 8 wire per inch mesh; or (2) 7 holes per inch
D. High contrast resolution for cinefluorographic and digital systems	At intervals not to exceed 12 months	No significant difference between static and dynamic conditions
E. Optical density of films over duration of filming run	At intervals not to exceed 12 months	< ± 0.2 O.D. difference

Subp. 11. **For facilities with dental intraoral systems.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Film processing	Before the first film of the day	Between 0.75 and 1.05 O.D. on the test tool or follow test tool manufacturer's recommendations
B. Fog test	At intervals not to exceed six months	Unable to visualize coin edges
C. Filtration (HVL)	At intervals not to exceed 24 months	Meet requirements in part 4732.0800
D. Radiation exposure at the end of cone	At intervals not to exceed 24 months	Meet requirements in part 4732.0825
E. Timer reproducibility	At intervals not to exceed 24 months	± 10% of indicated timer setting
F. kVp accuracy	At intervals not to exceed 24 months	± 5% of indicated kVp for equipment manufactured before 1973. For equipment manufactured after 1973, follow manufacturer's specified limits

G. Exposure output reproducibility	At intervals not to exceed 24 months	Coefficient of variation < 5%
H. Dental mA linearity	At intervals not to exceed 24 months	± 10% over the clinical range

Subp. 12. **For facilities with dental extraoral systems including panoramic systems.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Film processing	Before the first film of the day	Use processing as specified in subpart 3. A step wedge may be used. ± one step from standard allowed
B. Fog test	At intervals not to exceed six months	Use criteria in subpart 3, item A, for automatic processing; subpart 4, item A, for manual processing
C. Same test types and minimum performance criteria as in diagnostic radiographic tubes in subpart 4	At intervals not to exceed 24 months	See criteria in subpart 4

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