

10A NCAC 15 .0205 SERVICE PROVIDER RESPONSIBILITIES

(a) Each person who is engaged in the business of furnishing or offering to furnish any services listed in Paragraph (e) of this Rule in this State, or any agency registrant, shall apply for registration of such services with the agency prior to furnishing or offering to furnish any of these services.

(b) Applications for registration shall be completed in accordance with Rule .0203 of this Section and contain all information required by the agency as indicated on the form and accompanying instructions.

(c) Each person applying for registration pursuant to Paragraph (a) of this Rule shall certify that he or she has read and understands the requirements of the rules in this Chapter by signing the Company Employee Services Application or Company Services Application form.

(d) Applicants for registration of services are subject to the requirements of Rules .0206 and .0207 of this Section.

(e) For purposes of this Section, services include:

- (1) Class I - direct sales, transfer, leasing, lending, demonstration, or manufacturer training for the use of radiation machines or radiation generating devices;
- (2) Class II - installation, repair, or service of the following:
 - (A) radiation machines and machine components, including the making of diagnostic radiation output measurements, and performance verification; or
 - (B) radiation generating devices to include equipment surveys.
- (3) Class III - shielding designs for diagnostic radiographic facilities;
- (4) Class IV - shielding designs for diagnostic fluoroscopy facilities;
- (5) Class V - area radiation surveys and shielding evaluations for diagnostic radiographic and fluoroscopy facilities;
- (6) Class VI - radiation survey equipment calibrations;
- (7) Class VII - therapeutic facility and shielding design, area radiation survey, or verification;
- (8) Class VIII - providing individual monitoring devices;
- (9) Class IX - general health and medical physics consulting to include the following services:
 - (A) equipment surveys and shielding designs for radiation generating devices;
 - (B) dose estimates;
 - (C) radiation output measurements;
 - (D) radiation safety program development; and
 - (E) radiation safety program training.

(f) Persons registered pursuant to Subparagraph (e)(1) as a Class I service provider to provide mobile radiation machines that are fixed in a vehicle or trailer for demonstration purposes or that provides leasing services shall meet the following requirements prior to use:

- (1) mobile radiation machines located and used in this State shall meet the requirements of Rules .0204(c)(1)(A) through (E) of this Section; and
- (2) mobile radiation machines located out of state and brought into this State for use shall meet the requirements of Rules .0204(c)(2)(A) and (B) of this Section.

(g) Report of installation

- (1) Persons registered pursuant to Paragraph (a) of this Rule who sell, install, transfer, lease, lend, or dispose of radiation machines in this State shall, within 15 days after each calendar quarter, notify the agency at XrayNORS@dhhs.nc.gov or the address, in accordance with Rule .0111 of this Chapter, of the following:
 - (A) whether any radiation machines were directly sold, disposed of, installed, leased, loaned, or transferred during the calendar quarter;
 - (B) the name and address of persons who received radiation machines during the calendar quarter;
 - (C) the manufacturer, model, and serial number of each radiation machine directly sold, disposed of, installed, leased, loaned, or transferred during the calendar quarter; and
 - (D) the date of disposition, installation, lease, loan, sale, or transfer of each radiation machine during the calendar quarter.
- (2) The information specified in Parts (g)(1)(A) through (D) of this Rule may be omitted from the quarterly reports when either of the following requirements are met:
 - (A) for any diagnostic x-ray system that contains certified components, when a copy of the assembler's report prepared in compliance with 21 CFR 1020.30(d) is received by the agency; or

- (B) for radiation machines for nonhuman use and radiation generating devices, when a Report of Sale and Installation Form prepared in accordance with Paragraph (i) of this Rule is received by the agency.

(h) A Report of Sale and Installation of radiation machines for nonhuman use or radiation generating devices can be found at <https://radiation.ncdhhs.gov/Xray/documents/rptofassembly.pdf> and shall include the following information:

- (1) facility registration number, street address, city, state, and telephone number;
- (2) service provider registration number, company name, street address, city, state, and telephone number;
- (3) identify if the radiation machine or the radiation generating device was sold or installed by checking the corresponding checkbox;
- (4) identify the system type by checking the corresponding checkbox;
- (5) room location;
- (6) date of sale or installation;
- (7) manufacturer, serial number, and control model number;
- (8) the seller's signature or signature of the individual responsible for installation; and
- (9) the date signed.

(i) No person registered pursuant to Paragraph (a) of this Rule for x-ray sales or installations shall make, sell, lease, transfer, lend, assemble, or install radiation machines, radiation machine components, or radiation machine generating devices unless such machines and devices when placed in operation shall meet the requirements of these Rules.

(j) No person registered pursuant to Rule .0205 of this Section shall install radiation machines that are subject to provisions of Section .0600 of this Chapter unless the registrant first determines that the agency has issued a written acknowledgment of a shielding design in accordance with Rule .0204(b) of this Section.

(k) Tests performed at the time of installation demonstrating the requirements of these Rules are met, shall be provided to the registrant for agency review during inspection for the following:

- (1) fluoroscopy machine output measurement; and
- (2) radiation generating devices equipment surveys.

(l) Records of any routine maintenance, repair, alterations, or reassembly of radiation machines or radiation generating devices shall:

- (1) include the date that the service was performed and a legible signature of the person performing the service; and
- (2) be provided to the registrant for agency review during inspection.

*History Note: Authority G.S. 104E-7; 104E-12; 104E-20;
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