

1 10A NCAC 15 .0205 is proposed for readoption with substantive changes as follows:

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3 **10A NCAC 15 .0205 ~~APPLICATION FOR REGISTRATION OF SERVICES~~ SERVICE PROVIDER**
4 **RESPONSIBILITIES**

5 (a) Each person who is engaged in the business of ~~installing or offering to install radiation machines and machine~~
6 ~~components or is engaged in the business of furnishing or offering to furnish any equipment~~ services listed in
7 Paragraph ~~(d)~~ (e) of this Rule in this state, ~~to any agency licensee or registrant, state or any agency registrant~~ shall
8 apply for registration of such services with the agency prior to furnishing or offering to furnish any of these services.

9 (b) ~~Application~~ Applications for registration shall be completed ~~on appropriate form(s) provided by the agency in~~
10 accordance with Rule .0203 of this Section and contain all information required by the agency as indicated on the
11 form and accompanying instructions. ~~This information shall include:~~

12 (1) ~~the name, address and telephone number of:~~

13 (A) ~~the individual or the company to be registered;~~

14 (B) ~~the owner(s) of the company;~~

15 (2) ~~the description of the services to be provided;~~

16 (3) ~~the name, training and experience of each person who provides services specified in Paragraph (d)~~
17 ~~of this Rule;~~

18 (4) ~~the date of the application and the signature of the person responsible for the company; and~~

19 (5) ~~any additional information the agency determines to be necessary for evaluation of the application~~
20 ~~for registration.~~

21 (c) Each person applying for registration ~~under~~ pursuant to Paragraph (a) of this Rule shall certify that he or she has
22 read and understands the requirements of the rules in this ~~Chapter. Chapter~~ by signing the company or employee
23 services application.

24 (d) ~~For the purpose of this Section, equipment services include:~~

25 (1) ~~direct sale and transfer of radiation machines and machine components to end users;~~

26 (2) ~~installation or servicing of radiation machines and associated radiation machine components;~~

27 (3) ~~diagnostic radiographic facility and shielding design;~~

28 (4) ~~diagnostic fluoroscopic facility and shielding design;~~

29 (5) ~~diagnostic area radiation survey, e.g., shielding evaluation;~~

30 (6) ~~radiation instrument calibration;~~

31 (7) ~~therapeutic facility and shielding design, area radiation survey or calibration;~~

32 (8) ~~personnel dosimetry services; and~~

33 (9) ~~general health physics consulting, e.g., independent diagnostic radiation output measurements,~~
34 ~~dose analysis, design of safety programs and radiation safety training programs, non-healing arts~~
35 ~~facility and shielding design and area radiation surveys.~~

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

1 ~~(e) Applicants for registration of services are subject to the applicable requirements of Rules .0213 and .0214 of this~~
 2 ~~Section.~~

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

- 4 (1) area radiation surveys and shielding evaluations for diagnostic radiographic and fluoroscopy
 5 facilities;
 6 (2) direct sales, transfer, leasing, lending, demonstration, or manufacturer training for the use of
 7 radiation machines or radiation generating devices;
 8 (3) general health and medical physics consulting to include the following services:
 9 (A) equipment surveys and shielding designs for radiation generating devices;
 10 (B) dose estimates;
 11 (C) radiation output measurements;
 12 (D) radiation safety program development; and
 13 (E) radiation safety program training.
 14 (4) installation or service repair to include the following:
 15 (A) radiation machines and machine components, including the making of diagnostic
 16 radiation output measurements; or
 17 (B) radiation generating devices to include equipment surveys.
 18 (5) manufacturer training for the use of radiation machines or radiation generating devices;
 19 (6) providing individual monitoring devices;
 20 (7) a radiation protection expert;
 21 (A) developing radiation safety programs;
 22 (B) performing output measurements; and
 23 (C) providing radiation safety program training.
 24 (8) radiation survey equipment calibrations;
 25 (9) shielding designs for diagnostic radiographic and fluoroscopy facilities; and
 26 (10) therapeutic facility and shielding design, area radiation survey, or calibration.

27 (f) Persons registered pursuant to Subparagraph(e)(7) of this Rule shall have all surveys, reports, or other work
 28 performed, reviewed and signed by a general health or medical physicist registered in accordance with this Rule.

29 (g) Report of installation

- 30 (1) Persons, registered pursuant to Paragraph (a) of this Rule, who sell, lease, transfer, lend, dispose
 31 of, or install radiation machines in this state shall, within 15 days after each calendar quarter,
 32 notify the agency at XrayNORS@dhhs.nc.gov or the address in accordance with Rule .0111 of
 33 this Chapter of the following:
 34 (A) whether any radiation machines were installed, transferred, or disposed of during the
 35 calendar quarter;
 36 (B) the name and address of persons who received radiation machines during the calendar
 37 quarter;

1 (C) the manufacturer, model, and serial number of each radiation machine transferred or
 2 disposed of; and

3 (D) the transfer date of each radiation machine.

4 (2) The information specified in Parts (g)(1)(A) through (D) of this Rule may be omitted from the
 5 quarterly reports when the following requirements are met:

6 (A) for any diagnostic x-ray system that contains certified components when a copy of the
 7 assembler's report prepared in compliance with 21 CFR 1020.30(d) is submitted to the
 8 agency; or

9 (B) for radiation machines for non-human use and radiation generating devices, when a
 10 report of sale and installation pursuant to Paragraph (h) of this Rule is submitted to the
 11 agency.

12 (h) A report of sale and installation of radiation generating devices shall include the following information:

13 (1) facility registration number, street address, city, state, and telephone number;

14 (2) service provider registration number, company name, street address, city, state, and telephone
 15 number;

16 (3) identify if the radiation machine or the radiation generating device was sold or installed by
 17 checking the corresponding checkbox;

18 (4) identify the system type by checking the corresponding checkbox;

19 (5) room location, date of sale or installation;

20 (6) manufacturer, serial number, and control model number;

21 (7) the seller's signature or signature of the individual responsible for installation; and

22 (8) the date signed.

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

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

29 (k) Tests performed at the time of installation for fluoroscopy machine output measurement and radiation
 30 generating devices equipment surveys, demonstrating the requirements of these Rules are met, shall be provided to
 31 the registrant at the time of installation.

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

34 (1) include the date that the service was performed and a legible signature of the person performing
 35 the service; and

36 (2) be provided to the registrant when the service is provided.

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1 *History Note: Authority G.S. 104E-7; 104E-12; 104E-20;*
2 *Eff. February 1, 1980;*
3 *Amended Eff. June 1, 1993; May 1, 1992; June 1, 1989;*
4 *Transferred and Recodified from 15A NCAC 11 .0205 Eff. February 1, ~~2015~~ 2015;*
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