

1 10A NCAC 15 .0205 is proposed for amendment as follows:

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3 **10A NCAC 15 .0205 SERVICE PROVIDER RESPONSIBILITES**

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

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

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

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

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

14 (1) Class I - direct sales, transfer, leasing, lending, demonstration, or manufacturer training for the use  
15 of ~~radiation~~ X-ray machines or radiation generating devices;

16 (2) Class II - installation, repair, or service of the following:

17 (A) ~~radiation~~ X-ray machines and machine components, including the making of diagnostic  
18 radiation output measurements, and performance verification; or

19 (B) radiation generating devices to include equipment surveys.

20 (3) Class III - shielding designs for ~~diagnostic radiographic facilities;~~ X-ray machines;

21 (4) Class IV - shielding designs for ~~diagnostic fluorosecopy facilities;~~ fluoroscopic X-ray machines;

22 (5) Class V - area radiation surveys and shielding evaluations for ~~diagnostic radiographic and~~  
23 ~~fluorosecopy facilities;~~ X-ray machines;

24 (6) Class VI - radiation survey equipment calibrations;

25 (7) Class VII - therapeutic ~~facility shielding design, area radiation survey, or verification;~~ verification  
26 and area surveys;

27 (8) Class VIII - providing individual monitoring devices;

28 (9) Class IX - general health and medical physics consulting to include the following services:

29 (A) equipment surveys and shielding designs for radiation generating devices;

30 (B) dose estimates;

31 (C) radiation output measurements;

32 (D) radiation safety program development; and

33 (E) radiation safety program training.

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

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

5 (g) Report of installation

- 6 (1) Persons registered pursuant to Paragraph (a) of this Rule who sell, install, transfer, lease, lend, or  
7 dispose of ~~radiation~~ X-ray machines or radiation generating devices in this State shall, within ~~15~~ 30  
8 days after each calendar quarter, notify the agency at ~~XrayNORS@dhhs.nc.gov~~  
9 fda2579@dhhs.nc.gov or the address, in accordance with Rule .0111 of this Chapter, of the  
10 following:

- 11 (A) whether any ~~radiation~~ X-ray machines or radiation generating devices were directly sold,  
12 disposed of, installed, leased, loaned, or transferred during the calendar quarter;
- 13 (B) the name and address of persons who received radiation machines during the calendar  
14 quarter;
- 15 (C) the manufacturer, model, and serial number of each ~~radiation~~ X-ray machine or radiation  
16 generating devices directly sold, disposed of, installed, leased, loaned, or transferred during  
17 the calendar quarter; and
- 18 (D) the date of disposition, installation, lease, loan, sale, or transfer of each ~~radiation~~ X-ray  
19 machine or radiation generating devices during the calendar quarter.

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

- 22 (A) for any diagnostic ~~x-ray~~ X-ray system that contains certified components, when a copy of  
23 the assembler's report prepared in compliance with 21 CFR 1020.30(d) is received by the  
24 agency; or
- 25 (B) for ~~radiation~~ X-ray machines for nonhuman use and radiation generating devices, when a  
26 Report of Sale and Installation Form prepared in accordance with Paragraph ~~(i)~~ (h) of this  
27 Rule is received by the agency.

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

- 31 (1) facility registration number, street address, city, state, and telephone number;
- 32 (2) service provider registration number, company name, street address, city, state, and telephone  
33 number;
- 34 (3) identify if the ~~radiation~~ X-ray machine or the radiation generating device was sold or installed by  
35 checking the corresponding checkbox;
- 36 (4) identify the system type by checking the corresponding checkbox;
- 37 (5) room location;

- 1 (6) date of sale or installation;
- 2 (7) manufacturer, serial number, and control model number;
- 3 (8) the seller's signature or the signature of the individual responsible for installation; and
- 4 (9) the date signed.

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

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

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

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

16 (l) Records of any routine maintenance, repair, alterations, or reassembly of ~~radiation~~ X-ray machines or radiation  
17 generating devices shall:

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

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

23 *Eff. February 1, 1980;*

24 *Amended Eff. June 1, 1993; May 1, 1992; June 1, 1989;*

25 *Transferred and Recodified from 15A NCAC 11 .0205 Eff. February 1, 2015;*

26 *Readopted Eff. October 1, ~~2025~~ 2025;*

27 *Amended Eff. October 1, 2026.*