

10A NCAC 15 .0203 is readopted as published in 39:22 NCR 1469-1480 as follows:

10A NCAC 15 .0203 ~~APPLICATION: REGISTRATION: RADIATION MACHINES: FACILITIES~~
APPLICATION FOR REGISTRATION PROCESS: GENERAL REQUIREMENTS
FOR ALL FACILITIES, RADIATION MACHINES, AND SERVICES PROVIDED

~~(a) Each person having an unregistered radiation machine or facility shall:~~

~~(1) apply for registration of such facility and each radiation machine within 30 days following initial operation of that facility and each radiation machine. Application for registration shall be completed on agency forms and shall contain all information required by the forms and accompanying instructions. The registration of the first radiation machine at a facility constitutes registration of the facility itself.~~

~~(2) designate on the application form an individual who shall be responsible for radiation protection.~~

~~(b) Agency forms described in Subparagraph (a)(1) of this Rule require the following and other information:~~

~~(1) name, address and telephone number of the radiation machine facility;~~

~~(2) name of the person responsible for radiation protection in the facility;~~

~~(3) name, training and experience of the person designated in Subparagraph (a)(2) of this Rule;~~

~~(4) the manufacturer, model number, serial number and type of each radiation machine located within the facility;~~

~~(5) the date of the application and the signatures of the persons specified in Subparagraphs (b)(2) and (3) of this Rule.~~

(a) A person with an unregistered facility, radiation machine, radiation generating device, or an unregistered service provider, shall apply for registration with the agency. After submitting the required application forms prescribed by the agency in this Rule, registration of the first radiation machine, radiation generating device, or registration of services provided, constitutes registration of the facility or service provider.

(b) All application forms in this Rule shall be completed by meeting the following requirements:

(1) An individual with administrative control and representative of the organization of a radiation machine, radiation generating device, or who is responsible for providing services, shall ensure application forms, required by the agency in this Rule, meet the following requirements:

(A) are accurate, complete, and contain all the information required by the application forms and accompanying instructions; and

(B) submitted to the agency at the e-mail address on the application for registration forms or mailed to the address in Rule .0111 of this Chapter.

(2) Incomplete application forms or application forms submitted without the requested documentation to provide services, will not be processed.

(3) The agency may require additional information at any time after submission of the application to determine if the notice of registration should be issued or denied.

1 (4) Application forms can be found at <https://radiation.ncdhhs.gov/Xray/applic.htm>.

2 (c) A Business Application form shall be submitted prior to the operation of a facility or providing services in this
3 State and the following additional requirements shall be met:

4 (1) The application shall be submitted by any person:

5 (A) with one or more radiation machines at a facility; or

6 (B) that plans to engage in services listed in Paragraphs (f) and (g) of this Rule.

7 (2) The application form requires the following:

8 (A) indication if the application is for a new facility, a change of ownership, relocation of a
9 facility, or to update information by marking the corresponding checkbox;

10 (B) the legal business name, facility physical address, phone number, type of business, days
11 and hours of operation;

12 (C) the name, title, mailing address, phone, and e-mail address of business manager;

13 (D) the name of the individual on-site who is responsible for radiation protection. The training
14 and experience qualifying him or her to perform the job duties and responsibilities in Rule
15 .0211 of this Section, shall be documented on the application;

16 (E) the name, title, mailing address, phone, and e-mail address for the invoice contact;

17 (F) description of facility use;

18 (G) description of service provider equipment;

19 (H) dated and signed by the owner or the individual with administrative control; and

20 (I) identify equipment forms included with the application form by marking the corresponding
21 checkbox.

22 (d) A Radiation Machine Application or Radiation Generating Devices Application form shall be submitted in
23 accordance with Rule .0204(c)(1) through (5) of this Section, for the type of radiation machine or radiation generating
24 device owned by the registrant or potential registrant or the service provided. The following additional requirements
25 shall be met:

26 (1) The application shall be submitted by any person:

27 (A) with one or more unregistered radiation machines or radiation generating devices at a
28 facility; or

29 (B) that is engaged in leasing or performing demonstrations using an unregistered radiation
30 machine or radiation generating device.

31 (2) The application requires the following information:

32 (A) registration number;

33 (B) machine or device location;

34 (C) manufacturer, model, serial number, number of tubes, install date, modality, application,
35 type, and use;

36 (D) location of machine or device not in use;

37 (E) installer information; and

(F) shall be dated and signed by the individual with administrative control. An individual with administrative control can delegate a responsible person or persons within the organization to sign when amendments are made to this form by notifying the agency in writing.

(e) A Disposal of a Radiation Machine or Radiation Generating Device Form shall be submitted when a facility disposes of a radiation machine or radiation generating device. The agency form requires the following information:

- (1) registration number, facility name, and physical address;
- (2) identify if the application is for a new facility, for a change of ownership, a facility relocates, or to update information;
- (3) radiation machine or radiation generating device location; manufacturer, model, serial number;
- (4) identify the reason for disposal of the radiation machine or radiation generating device;
- (5) the recipient of the radiation machine or radiation generating device, to the individual or business name, physical and e-mail address, and phone number; and
- (6) dated and signed by the owner or the individual with administrative control of the radiation machine or radiation generating device.

(f) A Company Service Application form shall be submitted prior to furnishing or offering to furnish services in Parts (A) through (C) of this Paragraph and the following additional requirements shall be met:

- (1) The application shall be submitted by any person engaged in:
 - (A) direct sales, demonstration, leasing, or transfer of radiation machines or radiation generating devices;
 - (B) providing individual monitoring devices; and
 - (C) radiation survey equipment calibrations, except when calibrations are performed by the manufacturer of the equipment.
- (2) The application requires the following information:
 - (A) registration number;
 - (B) business name, facility physical address;
 - (C) identify if the application is for a new service provider, for a change of ownership, relocation of the facility, or to update information;
 - (D) identify each class and modality of services requested to be provided in the State;
 - (E) submit the requirements listed on the agency form for each class and modality requesting to provide services in the State;
 - (F) list any class or modality not listed on this form;
 - (G) description of service provider equipment used for output measurements and surveys; and
 - (H) signature of the individual with administrative control.

(g) A Company Employee Services Application form shall be submitted prior to furnishing or offering to furnish services in Parts (A) through (H) of this Paragraph and the following additional requirements shall be met:

- (1) The application shall be submitted by any person engaged in providing the following services:
 - (A) area radiation surveys for diagnostic radiographic and fluoroscopy facilities;

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

(C) general health physics consulting services to perform dose estimates, radiation output measurements, radiation safety program development, and radiation safety program training;

(D) installation or service repair of radiation machines or radiation generating devices;

(E) qualified expert consulting services for CT and mammography radiation machines;

(F) radiation protection expert;

(G) shielding designs for diagnostic radiographic and fluoroscopy facilities; and

(H) therapeutic facility and shielding design, area radiation survey, or calibration.

(2) The application requires the following information:

(A) name of the employee to be registered;

(B) start date if the employee is being added and the stop date if the employee is being removed from the registration;

(C) business registration number, name, physical address, and contact e-mail;

(D) class identification and modality of services to be provided;

(E) training and experience to submit for each class of services to be provided;

(F) date and signature of the employee applying for registration;

(G) date and signature of the individual with administrative control; and

(H) additional information the agency determines is necessary for evaluating the application for registration.

(h) Owners of radiation imaging systems and in-house personnel employed by a facility or corporation shall be exempt from the registration requirements in this Rule to provide services in this State, provided such personnel:

(1) meets the education, or is supervised by an individual who meets the training and experience requirements of the Class for the services provided;

(2) provides services at one facility or corporation; and

(3) provides requirements in Subparagraph (1)(h) of this Rule for agency review during inspection.

(i) The following general requirements apply to all facilities and services provided in North Carolina.

(1) The registrant shall notify the agency when any change will render the information in an application for registration or notice of registration no longer accurate.

(2) A registrant that terminates all activities of radiation machines, radiation generating devices, or providing services shall meet the following requirements within 30 days:

(A) request termination of the notice of registration in writing by the owner or the individual with administrative control;

(B) submit to the agency, a Disposal of a Radiation Machine or Radiation Generating Device Form in accordance with Paragraph(e) of this Rule; and

(C) pay any outstanding fees pursuant to Section .1100 of this Chapter.

(3) A registrant shall not transfer the registration as part of a change of ownership.

1 (4) A person who takes possession of a radiation machine or radiation generating device because of
2 bankruptcy, foreclosure, or state auction may possess the machine or device when the following
3 additional requirements are met:

4 (A) The machine or device shall be posted with a visible sign stating that the new owner is
5 responsible for registering with the agency if used in this State; and

6 (B) If the machine or device is energized, it shall only be energized by someone registered in
7 accordance with this Section and only to demonstrate that it is operable for sale or transfer.

8 (5) No person shall in any advertisement refer to the fact that his or her facility is registered with the
9 agency pursuant to the provisions of Rule .0204 or .0205 of this Section, and no person shall state
10 or imply that under such registration any activities have been approved by the agency.

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

13 Eff. February 1, 1980;

14 Amended Eff. May 1, 1992;

15 Transferred and Recodified from 15A NCAC 11 .0203 Eff. February 1, ~~2015~~, 2015;

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