

10A NCAC 15 .0204 FACILITY RESPONSIBILITIES

(a) All forms in this Rule shall be completed in accordance with Rule .0203 of this Section and any accompanying instructions.

(b) Shielding design requirements:

- (1) Prior to construction for all new installations of radiation machines for human, non-human, or veterinary use and prior to structural modification of existing installations, an applicant, shall have the floor plans, shielding specifications, and equipment arrangement reviewed by a registered service provider.
- (2) The registrant shall submit the shielding design and the agency Shielding Design Review Form to the agency for review. The agency form shall include the following information:
 - (A) facility and service provider name, registration number, e-mail and physical address, and phone number;
 - (B) equipment location, manufacturer, status, kVp, mA, mA min per week, facility type; and
 - (C) proposed date of installation.
- (3) A radiation machine shall not be installed until the applicant has received acknowledgment of the shielding design from the agency.
- (4) A radiation machine shall not be replaced until the existing shielding design, acknowledged previously by the agency, is reviewed by a registered service provider in accordance with Rule .0205. The registrant shall have a service provider review the acknowledged shielding design for the proposed radiation machine replacement to assess if the existing shielding meets the requirements of this Chapter. The documentation provided to the registrant from the service provider shall be submitted to the agency and maintained for agency review during inspection.
- (5) The acknowledgment of such plans shall not preclude the requirement for additional modifications should a subsequent analysis of operating conditions indicate the possibility of a dose that exceeds the limits in Rule .1601 of this Chapter.
- (6) Shielding designs are not required to be submitted for the following radiation machines:
 - (A) dental handheld;
 - (B) dual x-ray absorptiometry (DEXA);
 - (C) mammography; or
 - (D) mobile or portable radiographic and fluoroscopic machines used in more than two locations.

(c) Facility registration

- (1) Mobile radiation machines located and used in this State that are fixed in a vehicle or trailer shall meet the following requirements prior to use:
 - (A) have a shielding design submitted in accordance with Paragraph (a) of this Rule;
 - (B) have a Radiation Machine Application or a Radiation Generating Devices Application form submitted in accordance with Rule .0203(d) of this Section. Radiation machines leased or on loan from a registered service provider shall register the radiation machine if used for more than 30 days;
 - (C) have a copy of the operating and safety procedures to protect patients, operators, and the public from radiation submitted to the agency;
 - (D) receive a notice of registration from the agency; and
 - (E) an individual with administrative control shall ensure that radiation machines are operated in accordance with Section .0600 of this Chapter.
- (2) Mobile radiation machines located out-of-state and brought into this State for use, that are fixed in a vehicle or trailer, shall meet the following requirements prior to use:
 - (A) have the requirements in Parts (c)(1)(A) through (c)(1)(C) of this Rule submitted as a complete document for agency review; and
 - (B) have a written notice submitted, in accordance with Rule .0208 of this Section, and maintain it for agency review during inspection.
- (3) Radiation machines for human, non-human, or veterinary use shall meet the following additional requirements:
 - (A) have a shielding design acknowledged by the agency in accordance with Paragraph (b) of this Rule; and
 - (B) submit a Radiation Machine Application form in accordance with Rule .0203 (d) of this Section within 30 days of use.

- (4) Radiation generating devices in Section .0800 of this Chapter shall meet the following additional requirements prior to use:
 - (A) submit a Radiation Generation Device Application in accordance with Rule .0203(d) of this Section; and
 - (B) an individual with administrative control shall ensure operators are qualified in accordance with Rule .0800 of this Chapter to use the radiation generating device indicated on the application.
- (5) Industrial radiography radiation machines in Section .0500 of this Chapter shall meet the following additional requirements prior to use:
 - (A) submit a Radiation Generating Device Application in accordance with Rule .0203(d) of this Section; and
 - (B) an individual with administrative control shall ensure operators are qualified in accordance with Section .0500 of this Chapter to use the machines indicated on the application.

(d) Persons registered pursuant to Paragraph (c) of this Rule shall notify the agency, using the Disposal of a Radiation Machine or Radiation Generating Device Form, prior to disposition or the transfer of a registered radiation machine or radiation generating device to another person required to be registered pursuant to Paragraph (c) of this Rule.

(e) Persons registered pursuant to Paragraph(c) of this Rule shall prohibit any person from furnishing services described in Rule .0205(d) of this Section, at his or her facility, until such person provides evidence they are currently registered with the agency as a provider of such services in accordance with Rule .0205 of this Section.

(f) No person registered pursuant to the provisions of Paragraph (c) of this Rule shall perform any services listed in Rule .0205(d) of this Section in his or her facility unless such person meets the requirements in Rules .0205 and .0206 of this Section and has received written authorization from the agency to perform such services.

*History Note: Authority G.S. 104E-7; 104E-9(a)(3); 104E-12;
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0204 Eff. February 1, 2015;
Readopted Eff. October 1, 2025.*