

1 10A NCAC 15 .0204 is proposed for readoption with substantive changes as follows:

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3 **10A NCAC 15 .0204     ~~PROHIBITED~~     ~~SERVICES~~     ~~AND~~     ~~INSTALLATION~~     FACILITY**  
4                                    RESPONSIBILITIES

5 ~~(a) Except as provided in Paragraph (b) of this Rule or otherwise authorized in writing by the agency, each person~~  
6 ~~registered pursuant to Rule .0203 of this Section shall prohibit any person from furnishing equipment services~~  
7 ~~described in Rule .0205(d) of this Section to his facility until such person provides evidence that he is currently~~  
8 ~~registered with the agency as a provider of such services in accordance with Rule .0205 of this Section.~~

9 ~~(b) No person registered pursuant to the provisions of Rule .0203 of this Section shall perform any services listed in~~  
10 ~~Rule .0205(d) of this Section in his facility unless such person satisfies the applicable requirements in Rules .0205,~~  
11 ~~.0213, and .0214 of this Section and has received written authorization from the agency to perform such services.~~

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

14 (b) Shielding design requirements:

15           (1) Prior to construction for all new installations of radiation machines for human or veterinary use  
16 and prior to structural modification of existing installations, an applicant, shall have the floor  
17 plans, shielding specifications, and equipment arrangement reviewed by a registered service  
18 provider.

19           (2) The registrant shall submit the shielding design and the agency shielding design review form to  
20 the agency for review. The agency form shall include the following information:

21                   (A) facility and service provider name, registration number, e-mail and physical address, and  
22                   phone number;

23                   (B) equipment location, manufacturer, status, kVp, mA, mA min per week, facility type; and

24                   (C) proposed date of installation.

25           (3) A radiation machine shall not be installed until the applicant has received acknowledgment of the  
26 shielding design from the agency.

27           (4) A radiation machine shall not be replaced until the existing shielding design, acknowledged  
28 previously by the agency, is reviewed by a service provider. The registrant shall have a service  
29 provider review the acknowledged shielding design for the proposed radiation machine  
30 replacement to assess if the existing shielding meets the requirements of this Chapter. The  
31 documentation provided to the registrant from the service provider shall be submitted to the  
32 agency and maintained for agency review during inspection.

33           (5) The acknowledgment of such plans shall not preclude the requirement for additional modifications  
34 should a subsequent analysis of operating conditions indicate the possibility of a dose that exceeds  
35 the limits in Rule .1601 of this Chapter.

36           (6) Shielding designs are not required to be submitted for the following radiation machines:

37                   (A) bone densitometry;

- 1           (B) dental handheld;  
2           (C) mammography; or  
3           (D) mobile or portable radiographic machines used in more than two locations.

4 (c) Facility registration

5           (1) Mobile radiation machines that are fixed in a vehicle or trailer shall meet the following  
6           requirements prior to use:

7           (A) submit a shielding design in accordance with Paragraph (a) of this Rule, except out-of-  
8           state fixed radiation machines used in a vehicle or trailer shall submit a shielding design  
9           with the Equipment Form application in Part (B) of this Subparagraph and maintain  
10           documentation for agency review during inspection;

11           (B) submit an Equipment Form application in accordance with Rule .0203 (d) of this Section.  
12           Radiation machines leased or on loan from a registered service provider shall register the  
13           radiation machine if used for more than 30 days;

14           (C) submit a copy of the operating and safety procedures to protect patients, operators, and  
15           the public from radiation that exceeds doses in Rule .1601 of this Chapter;

16           (D) receive a notice of registration from the agency;

17           (E) the individual with administrative control shall ensure that radiation machines are  
18           operated in accordance with Part (c)(4)(B) or (c)(5)(B) of this Section; and

19           (F) in addition to the requirements of this Rule, out of state mobile radiation machines shall  
20           have a notice submitted to the agency in accordance with Rule .0208 of this Section.

21           (2) Radiation machines for human or veterinary use shall meet the following additional requirements:

22           (A) have a shielding design acknowledged by the agency in accordance with Paragraph (b) of  
23           this Rule; and

24           (B) submit an Equipment Form application in accordance with Rule .0203 (d) of this Section  
25           within 30 days of use.

26           (3) Radiation machines for clinical studies, research, and screenings shall meet the following  
27           additional requirements prior to use:

28           (A) submit a request in accordance with Rule .0213 of this Section; and

29           (B) receive a notice of acknowledgment and conditions for use from the agency to conduct  
30           the study.

31           (4) Radiation generating devices in Section .0800 of this Chapter shall meet the following additional  
32           requirements prior to use:

33           (A) submit an Equipment Form application in accordance with Rule .0203(d) of this Section;  
34           and

35           (B) the individual with administrative control shall ensure operators are qualified in  
36           accordance with Rule .0800 of this Chapter to use the radiation generating device  
37           indicated on the equipment application.

1           (5) Industrial radiography radiation machines in Section .0500 of this Chapter shall meet the  
2           following additional requirements prior to use:

3           (A) submit an Equipment Form application in accordance with Rule .0203(d) of this Section;

4           and

5           (B) the individual with administrative control shall ensure operators are qualified in  
6           accordance with Section .0500 of this Chapter to use the machines indicated on the  
7           equipment application.

8           (d) Persons registered pursuant to Paragraph (c) of this Rule shall notify the agency, using the Delete Radiation  
9           Machine or Radiation Generating Devices form, prior to disposition or the transfer of a registered radiation machine  
10           or radiation generating device to another person required to be registered pursuant to Paragraph (c) of this Rule.

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

14           (f) No person registered pursuant to the provisions of Paragraph (c) of this Rule shall perform any services listed in  
15           Rule .0205(d) of this Section in his or her facility unless such person meets the requirements in Rules .0205 and  
16           .0206 of this Section and has received written authorization from the agency to perform such services.

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18           *History Note: Authority G.S. 104E-7; 104E-9(a)(3); 104E-12;*

19           *Eff. February 1, 1980;*

20           *Amended Eff. June 1, 1989;*

21           *Transferred and Recodified from 15A NCAC 11 .0204 Eff. February 1, ~~2015~~ 2015;*

22           *Readopted Eff. May 1, 2025.*