

1 10A NCAC 15 .0204 is proposed for amendment as follows:

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3 **10A NCAC 15 .0204 FACILITY RESPONSIBILITIES**

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

6 (b) Shielding design requirements:

7 (1) Prior to construction for all new installations of ~~radiation~~ X-ray machines for human, non-human,  
8 or veterinary use and prior to structural modification of existing installations, an ~~applicant~~, applicant  
9 shall have the floor plans, shielding specifications, and equipment arrangement reviewed by a  
10 registered service provider.

11 (2) The registrant shall submit ~~the a~~ shielding design and the agency Shielding Design Review Form to  
12 the agency for review. Shielding design drawings shall include a scaled drawing. The ~~agency form~~  
13 Shielding Design Review Form shall include the following information:

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

16 (B) ~~equipment~~ machine location, manufacturer, status, kVp, mA, mA min per week, facility  
17 type; and

18 (C) proposed date of installation.

19 (3) ~~A radiation~~ An X-ray machine shall not be installed until the applicant has received  
20 acknowledgment of the shielding design from the agency.

21 (4) ~~A radiation~~ An X-ray machine shall not be replaced until the existing shielding design,  
22 acknowledged previously by the agency, is reviewed by a registered service provider in accordance  
23 with Rule .0205. The registrant shall have a service provider review the acknowledged shielding  
24 design for the proposed ~~radiation~~ X-Ray machine replacement to assess if the existing shielding  
25 meets the requirements of this Chapter. The documentation provided to the registrant from the  
26 service provider shall be submitted to the agency and maintained for agency review during  
27 inspection.

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

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

32 (A) dental handheld;

33 (B) dual ~~x-ray~~ X-ray absorptiometry (DEXA);

34 (C) mammography; or

35 (D) mobile or portable radiographic and fluoroscopic machines used in more than two  
36 locations.

37 (c) Facility registration

- 1 (1) Mobile ~~radiation X-ray~~ machines located and used in this State ~~that are fixed in~~ State, and  
2 permanently affixed within a vehicle or ~~trailer trailer~~, shall meet the following requirements prior to  
3 use:
- 4 (A) have a shielding design ~~submitted~~ acknowledged by the agency in accordance with  
5 Paragraph ~~(a)~~ (b) of this Rule;
- 6 (B) have a ~~Radiation~~ an X-ray Machine Application or a ~~Radiation Generating Devices~~  
7 ~~Application~~ form submitted in accordance with Rule .0203(d) of this Section. ~~Radiation X-~~  
8 ray machines leased or on loan from a registered service provider shall ~~register the radiation~~  
9 machine be registered with the agency if ~~used~~ maintained for more than 30 days;
- 10 (C) have a copy of the operating and safety procedures describing how to protect patients,  
11 operators, and the public from radiation submitted to the ~~agency; agency; and~~
- 12 ~~(D) receive a notice of registration from the agency; and~~
- 13 ~~(E)(D)~~ an individual ~~with administrative control~~ responsible for business operations shall ensure  
14 that ~~radiation X-ray~~ machines are operated in accordance with Section .0600 of this  
15 Chapter.
- 16 (2) Mobile ~~radiation X-ray~~ machines located out-of-state and brought into this State for use, ~~that are~~  
17 fixed in and permanently affixed within a vehicle or trailer, shall meet the following ~~requirements~~  
18 prior to use: requirements:
- 19 (A) have the requirements in Parts (c)(1)(A) through (c)(1)(C) of this Rule submitted as a  
20 complete document for agency ~~review; and~~ review;
- 21 (B) have a written notice submitted, in accordance with Rule .0208 of this Section, and  
22 maintain it for agency review during ~~inspection.~~ inspection; and
- 23 ~~(C) an individual responsible for business operations shall ensure that X-ray machines are~~  
24 operated in accordance with Section .0600 of this Chapter.
- 25 (3) Mobile radiation generating devices located out-of-state and brought into this State for use shall  
26 meet the following requirements prior to use:
- 27 ~~(A) have a Radiation Generating Devices Application form submitted in accordance with Rule~~  
28 .0203(d) of this Section. Radiation generating devices leased or on loan from a registered  
29 service provider shall be registered with the agency if maintained for use for more than 30  
30 days;
- 31 ~~(B) have a copy of the operating and safety procedures describing how to protect operators and~~  
32 the public from radiation submitted to the agency;
- 33 ~~(C) submit a written notice, in accordance with Rule .0208 of this Section, and maintain it for~~  
34 agency review during inspection; and
- 35 ~~(D) an individual with administrative control responsible for business operations shall ensure~~  
36 operators are qualified in accordance with Rule .0800 of this Chapter to use the radiation  
37 generating device indicated on the application.

1           ~~(3)~~(4) ~~Radiation X-ray machines for human, non-human, diagnostic imaging, non-diagnostic imaging,~~  
2           ~~clinical studies, or veterinary use use, or by service providers for demonstration purposes~~ shall meet  
3           the following additional requirements:

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

6           (B)     submit a ~~Radiation~~ an X-ray Machine Application form in accordance with Rule .0203 (d)  
7           of this Section within 30 days of ~~use.~~ use; and

8           ~~(C)     an individual with administrative control responsible for business operations shall ensure~~  
9           that X-ray machines are operated in accordance with Section .0600 of this Chapter.

10          ~~(4)~~(5) Radiation generating devices in Section .0800 of this Chapter shall meet the following additional  
11          requirements prior to use:

12          (A)     submit a Radiation Generation Device Application form in accordance with Rule .0203(d)  
13          of this Section; and

14          (B)     an individual ~~with administrative control~~ responsible for business operations shall ensure  
15          operators are qualified in accordance with Rule .0800 of this Chapter to use the radiation  
16          generating device indicated on the application.

17          ~~(5)~~(6) Industrial radiography ~~radiation~~ X-ray machines in Section .0500 of this Chapter shall meet the  
18          following additional requirements prior to use:

19          (A)     submit a Radiation Generating Device Application form in accordance with Rule .0203(d)  
20          of this Section; and

21          (B)     an individual ~~with administrative control~~ responsible for business operations shall ensure  
22          operators are qualified in accordance with Section .0500 of this Chapter to use the machines  
23          indicated on the application.

24          (d) Persons registered pursuant to Paragraph (c) of this Rule shall notify the agency, using the Disposal of a ~~Radiation~~  
25          an X-Ray Machine or Radiation Generating Device Form, prior to the disposition or the transfer of a registered  
26          ~~radiation X-ray~~ machine or radiation generating device to another person required to be registered pursuant to  
27          Paragraph (c) of this Rule.

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

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

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35          History Note:     Authority G.S. 104E-7; 104E-9(a)(3); 104E-12;  
36                             Eff. February 1, 1980;  
37                             Amended Eff. June 1, 1989;

1                    *Transferred and Recodified from 15A NCAC 11 .0204 Eff. February 1, 2015;*  
2                    *Readopted Eff. October 1, ~~2025~~ 2025;*  
3                    *Amended Eff. October 1, 2026.*