

1 10A NCAC 15 .0212 is proposed for amendment as follows:

2  
3 **10A NCAC 15 .0212 EMERGING TECHNOLOGIES NOT MEETING EXISTING EQUIPMENT**  
4 **REQUIREMENTS**

5 (a) ~~Radiation X-ray~~ machines or radiation generating devices that do not meet the ~~radiation X-ray machine or radiation~~  
6 ~~generating device~~ requirements in Section .0600 of this Chapter or radiation generating devices in Rule .0807 of this  
7 Chapter shall not be sold, installed, or used prior to the agency completing a review of information regarding the  
8 ~~radiation X-ray machine or radiation generating device~~ and determining if the use of the ~~radiation X-ray machine or~~  
9 ~~radiation generating device~~ is allowed. ~~The user or manufacturer of the radiation machine shall submit the following~~  
10 ~~to the agency for review:~~

- 11 (1) ~~an application form in accordance with Rule .0203(d) of this Section;~~  
12 (2) ~~the manufacturer manual;~~  
13 (3) ~~description of intended use;~~  
14 (4) ~~operator training provided to the end user;~~  
15 (5) ~~an independent equipment survey to include the following:~~  
16 (A) ~~all equipment settings available to the operator;~~  
17 (B) ~~output at the highest setting; and~~  
18 (C) ~~leakage radiation around the radiation machine.~~  
19 (6) ~~an area survey to include the following:~~  
20 (A) ~~radiation levels in adjacent areas, the operator location, and annual exposure to an operator;~~  
21 (B) ~~the survey instrument used; and~~  
22 (C) ~~the name and legible signature of the person who performed the survey.~~  
23 (7) ~~the hazard level associated with the use of the radiation machine.~~  
24 (8) ~~means to achieve radiation protection equivalent to the rules of this Section.~~

25 (b) The user or manufacturer of the X-ray machine shall submit the following to the agency for review:

- 26 (1) an application form in accordance with Rule .0203(d) of this Section;  
27 (2) the manufacturer's manual;  
28 (3) description of intended use;  
29 (4) operator training provided to the end user;  
30 (5) an independent equipment survey to include the following:  
31 (A) all equipment settings available to the operator;  
32 (B) output at the highest setting; and  
33 (C) leakage radiation around the X-ray machine.  
34 (6) an area survey to include the following:  
35 (A) radiation levels in adjacent areas, the operator location, and annual exposure to an operator;  
36 (B) the survey instrument used; and  
37 (C) the name and legible signature of the person who performed the survey.

1           (7) the hazard level associated with the use of the X-ray machine.

2           (8) means to achieve radiation protection equivalent to the rules of this Section.

3 (c) The user or manufacturer of the radiation generating device shall submit the requirements in Rule .0808 of this  
4 Chapter for review.

5 ~~(b)~~(d) After receiving the information in ~~Paragraph (a)~~ Paragraphs (b) and (c) of this Rule, the agency will respond  
6 to the applicant in writing within 90 calendar days. Upon review, the agency may require additional information to  
7 determine if the ~~radiation~~ X-ray machine or radiation generating device is allowed for use.

8  
9 *History Note: Authority G.S. 104E-7; 104E-20;*

10 *Eff. June 1, 1989;*

11 *Amended Eff. June 1, 1993;*

12 *Transferred and Recodified from 15A NCAC 11 .0212 Eff. February 1, 2015;*

13 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22,*  
14 *2019;*

15 *Amended Eff. October 1, ~~2025~~; 2025; October 1, 2026.*