10A NCAC 15 .0204 is readopted with changes as published in 39:10 NCR 629-642 as follows:

10A NCAC 15 .0204 ~~PROHIBITED SERVICES AND INSTALLATION~~ FACILITY responsibilities

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

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

(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~~ 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~~ 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.~~ 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) bonedensitometry~~;]

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

(B) [~~submit~~]have an Equipment Form application 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) [~~submit]~~ have a copy of the operating and safety procedures to protect patients, operators, and the public from radiation ~~[that exceeds doses in Rule .1601 of this Chapter;]~~submitted to the agency;

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

(E) the individual with administrative control shall ensure that radiation machines are operated in accordance with [~~Part (c)(4)(B) or (c)(5)(B) of this Section; and]~~ Section .0600 of this Chapter.

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

(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)(D) of this Rule submitted as a complete document for agency review; and

(B) have a notice in submitted accordance with Rule .0208 of this Section and maintained for agency review during inspection.

(3)(~~2~~) Radiation machines for ~~human~~ 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 an Equipment Form application in accordance with Rule .0203 (d) of this Section within 30 days of use.

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

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

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

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

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

(B) the 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 equipment application.

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

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

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

(d) Persons registered pursuant to Paragraph (c) of this Rule shall notify the agency, using the Delete Radiation Machine or Radiation Generating Devices 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;

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