1	10A NCAC 15 .0204 is	proposed for readopti	on with substantive	e changes as	follows:	
2						
3	10A NCAC 15 .0204	<b>PROHIBITED</b>	SERVICES	AND	INSTALLATION	<b>FACILITY</b>
4		RESPONSIBILIT	<u> FIES</u>			
5	(a) Except as provided	in Paragraph (b) of the	his Rule or otherwi	<del>se authorize</del>	d in writing by the age	acy, each person
6	registered pursuant to	Rule .0203 of this S	ection shall prohib	oit any perso	on from furnishing equ	<del>iipment services</del>
7	described in Rule .020	5(d) of this Section to	o his facility until	such person	provides evidence that	t he is currently
8	registered with the agen	ey as a provider of su	<del>ch services in acco</del> i	rdance with	Rule .0205 of this Section	<del>on.</del>
9	(b) No person registere	d pursuant to the prov	risions of Rule .020	3 of this Sec	ction shall perform any	services listed in
10	Rule .0205(d) of this Se	ection in his facility u	nless such person s	satisfies the	applicable requirements	in Rules .0205,
11	.0213, and .0214 of this	Section and has received	ved written authori	zation from	the agency to perform s	uch services.
12	(a) All forms in this R	ule shall be completed	l in accordance wit	h Rule .0202	3 of this Section and an	y accompanying
13	instructions.					
14	(b) Shielding design re-	quirements:				
15	(1) <u>Prior</u>	to construction for a	ll new installations	of radiatio	n machines for human	<u>, non-human, or</u>
16	<u>veteri</u>	nary use and prior to s	structural modificat	tion of existi	ng installations, an appl	icant, shall have
17	the fl	oor plans, shielding	specifications, and	equipment	arrangement reviewed	by a registered
18	servic	ce provider.				
19	(2) The re	egistrant shall submit	the shielding desig	n and the ag	ency Shielding Design	Review Form to
20	the ag	gency for review. The	agency form shall i	nclude the f	ollowing information:	
21	<u>(A)</u>	facility and service	e provider name, re	gistration n	umber, e-mail and phys	ical address, and
22		phone number;				
23	<u>(B)</u>	equipment location	n, manufacturer, sta	tus, kVp, m	A, mA min per week, fa	cility type; and
24	<u>(C)</u>	proposed date of in	nstallation.			
25	(3) A rad	iation machine shall r	not be installed unti	il the applica	ant has received acknow	rledgment of the
26	shield	ling design from the ag	gency.			
27	(4) A rac	liation machine shall	not be replaced	until the ex	isting shielding design	, acknowledged
28	previo	ously by the agency,	is reviewed by a r	egistered se	rvice provider in accor-	dance with Rule
29	<u>.0205</u>	. The registrant shall	have a service prov	vider review	the acknowledged shie	lding design for
30	the p	roposed radiation m	achine replacemen	nt to assess	s if the existing shiel	ding meets the
31	<u>requi</u>	rements of this Chapter	r. The documentation	on provided 1	to the registrant from the	service provider
32	shall l	be submitted to the ago	ency and maintaine	ed for agency	review during inspecti	on.
33	(5) The a	cknowledgment of suc	ch plans shall not p	reclude the	requirement for addition	al modifications
34	shoul	d a subsequent analysi	is of operating cond	ditions indic	ate the possibility of a d	ose that exceeds
35	the lin	mits in Rule .1601 of t	his Chapter.			
36	(6) Shield	ding designs are not re	equired to be submit	tted for the f	ollowing radiation mac	nines:
37	(A)	dental handheld;				

1		(B)	dual x-ray absorptiometry (DEXA);
2		(C)	mammography; or
3		<u>(D)</u>	mobile or portable radiographic and fluoroscopic machines used in more than two
4			locations.
5	(c) Facility regi	istration	
6	<u>(1)</u>	Mobile	e radiation machines located and used in this State that are fixed in a vehicle or trailer shall
7		meet tl	ne following requirements prior to use:
8		(A)	have a shielding design submitted in accordance with Paragraph (a) of this Rule;
9		<u>(B)</u>	have a Radiation Machine Application or a Radiation Generating Devices Application form
10			submitted in accordance with Rule .0203(d) of this Section. Radiation machines leased or
11			on loan from a registered service provider shall register the radiation machine if used for
12			more than 30 days;
13		(C)	have a copy of the operating and safety procedures to protect patients, operators, and the
14			public from radiation submitted to the agency;
15		(D)	receive a notice of registration from the agency; and
16		<u>(E)</u>	an individual with administrative control shall ensure that radiation machines are operated
17			in accordance with Section .0600 of this Chapter.
18	(2)	Mobile	e radiation machines located out-of-state and brought into this State for use, that are fixed in
19		a vehic	cle or trailer, shall meet the following requirements prior to use:
20		(A)	have the requirements in Parts (c)(1)(A) through (c)(1)(C) of this Rule submitted as a
21			complete document for agency review; and
22		(B)	have a written notice submitted, in accordance with Rule .0208 of this Section, and
23			maintain it for agency review during inspection.
24	(3)	Radiat	ion machines for human, non-human, or veterinary use shall meet the following additional
25		require	ements:
26		(A)	have a shielding design acknowledged by the agency in accordance with Paragraph (b) of
27			this Rule; and
28		(B)	submit a Radiation Machine Application form in accordance with Rule .0203 (d) of this
29			Section within 30 days of use.
30	<u>(4)</u>	Radiat	ion generating devices in Section .0800 of this Chapter shall meet the following additional
31		require	ements prior to use:
32		<u>(A)</u>	submit a Radiation Generation Device Application in accordance with Rule .0203(d) of
33			this Section; and
34		<u>(B)</u>	an individual with administrative control shall ensure operators are qualified in accordance
35			with Rule .0800 of this Chapter to use the radiation generating device indicated on the
36			application.

	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 reg	stered pursuant to Paragraph (c) of this Rule shall notify the agency, using the Disposal of a Radiation
Machine or Rac	liation Generating Device Form, prior to disposition or the transfer of a registered radiation machine
or radiation gen	erating device to another person required to be registered pursuant to Paragraph (c) of this Rule.
(e) Persons re	gistered pursuant to Paragraph(c) of this Rule shall prohibit any person from furnishing services
described in Ru	le .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 r	egistered pursuant to the provisions of Paragraph (c) of this Rule shall perform any services listed in
Rule .0205(d) o	f this Section in his or her facility unless such person meets the requirements in Rules .0205 and .0206
of this Section a	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, <del>2015.</del> 2015;
	Readopted Eff. October 1, 2025.
	Machine or Rador radiation gen  (e) Persons reg described in Rul registered with the (f) No person regular (f)