| 1 | 10A NCAC 15 .0203 is pr | coposed for readoption | n <u>with subst</u> | antive changes as follow | s: | |
|----|-----------------------------|-------------------------------------|--------------------------|-----------------------------|-------------------------------|--------------------|
| 2 | | | | | | |
| 3 | 10A NCAC 15 .0203 | APPLICATION: | REGISTR. | ATION: RADIATION | MACHINES: | FACILITIES |
| 4 | | APPLICATION | FOR | REGISTRATION | PROCESS: | GENERAL |
| 5 | | REQUIREMENTS | FOR AL | L FACILITIES, RAI | DIATION MAC | HINES, AND |
| 6 | | SERVICES PROV | <u>IDED</u> | | | |
| 7 | | | | | | |
| 8 | (a) Each person having as | n unregistered radiation | on machine | or facility shall: | | |
| 9 | (1) apply for | or registration of such | facility and | l each radiation machine | e within 30 days f | Collowing initial |
| 10 | operation | on of that facility as | nd each rac | liation machine. Appl | ication for regist | ration shall be |
| 11 | complet | ed on agency form | s and shal | l contain all informati | on required by | the forms and |
| 12 | accomp | anying instructions. | The registra | tion of the first radiation | r machine at a fac | vility constitutes |
| 13 | registra | tion of the facility itse | lf. | | | |
| 14 | (2) designa | t e on the application f | form an indi | vidual who shall be resp | onsible for radiati | on protection. |
| 15 | (b) Agency forms describ | ed in Subparagraph (| a)(1) of this | Rule require the followi | ng and other infor | mation: |
| 16 | (1) name, a | ddress and telephone | number of t | he radiation machine fac | ility; | |
| 17 | (2) name of | the person responsib | le for radiat | ion protection in the faci | lity; | |
| 18 | (3) name, tr | aining and experience | e of the pers | on designated in Subpar | agraph (a)(2) of th | nis Rule; |
| 19 | (4) the man | ufacturer, model num | nber, serial 1 | number and type of each | radiation machine | e located within |
| 20 | the facil | lity; | | | | |
| 21 | (5) the date | of the application an | d the signat | ures of the persons spec | ified in Subparagı | raphs (b)(2) and |
| 22 | (3) of th | is Rule. | | | | |
| 23 | (a) A person with an unre | egistered facility, radi | ation machi | ne, radiation generating | device, or an unre | gistered service |
| 24 | provider, shall apply for a | egistration with the a | gency. Afte | r submitting the required | d application form | s prescribed by |
| 25 | the agency in this Rule, | registration of the fir | rst radiation | machine, radiation gen | erating device, or | registration of |
| 26 | services provided, constitu | utes registration of the | e facility or | service provider. | | |
| 27 | (b) All application forms | in this Rule shall be c | completed b | y meeting the following | requirements: | |
| 28 | (1) The ind | ividual with administ | trative contr | ol of a radiation machin | e, radiation gener | ating device, or |
| 29 | that is re | esponsible for provid | ing services | shall ensure application | forms, required b | y the agency in |
| 30 | this Rul | e, meet the following | requiremen | <u>ts:</u> | | |
| 31 | (A) | are accurate, comple | ete, and con | tain all the information i | required by the ap | plication forms |
| 32 | | and accompanying in | nstructions; | <u>and</u> | | |
| 33 | <u>(B)</u> | submitted to the age | ency at the e | e-mail address on the app | olication for regis | tration forms or |
| 34 | | mailed to the address | s in Rule .0 | 111 of this Chapter. | | |
| 35 | (2) Incomp | lete application forms | s or applicat | ion forms submitted with | nout the requested | documentation |
| 36 | <u>to provi</u> | de services, will not b | oe processed | l <u>.</u> | | |

| 1 | (3) | The ag | ency may require additional information at any time after submission of the application to |
|----|--------------------|------------|--|
| 2 | | determ | ine if the notice of registration should be issued or denied. |
| 3 | <u>(4)</u> | Applica | ation forms can be found at https://radiation.ncdhhs.gov/Xray/applic.htm. |
| 4 | (c) A Business | Applicat | ion form shall be submitted prior to the operation of a facility or providing services in this |
| 5 | state and the foll | owing ac | dditional requirements shall be met: |
| 6 | <u>(1)</u> | The ap | plication shall be submitted by any person: |
| 7 | | (A) | with one or more radiation machines at a facility; or |
| 8 | | <u>(B)</u> | that plans to engage in services listed in Paragraphs (f) and (g) of this Rule. |
| 9 | (2) | The ap | plication form requires the following: |
| 10 | | (A) | indication if the application is for a new facility, a change of ownership, when a facility |
| 11 | | | moves, or to update information by marking the corresponding checkbox; |
| 12 | | <u>(B)</u> | the legal business name, facility physical address, phone number, type of business, days |
| 13 | | | and hours of operation; |
| 14 | | <u>(C)</u> | the name, title, mailing address, phone, and e-mail address of business manager; |
| 15 | | (D) | the name of the individual on-site who is responsible for radiation protection. The |
| 16 | | | training and experience qualifying him or her to perform the job duties and |
| 17 | | | responsibilities in Rule .0211 of this Section, shall be documented on the application; |
| 18 | | <u>(E)</u> | the name, title, mailing address, phone, and e-mail address for the invoice contact; |
| 19 | | <u>(F)</u> | description of facility use; |
| 20 | | <u>(G)</u> | description of service provider equipment; |
| 21 | | <u>(H)</u> | dated and signed by the owner or the individual with administrative control; and |
| 22 | | <u>(I)</u> | identify equipment forms included with the application form by marking the |
| 23 | | | corresponding checkbox. |
| 24 | (d) Equipment a | pplication | on forms shall be submitted in accordance with Rule .0204(c)(1) through (5) of this Section, |
| 25 | for the type of ra | idiation 1 | nachine or radiation generating device owned by the registrant or potential registrant or the |
| 26 | service provided | . The fol | lowing additional requirements shall be met: |
| 27 | (1) | The ap | plication shall be submitted by any person: |
| 28 | | (A) | with one or more unregistered radiation machines or radiation generating devices at a |
| 29 | | | facility; or |
| 30 | | (B) | that is engaged in leasing or performing demonstrations using an unregistered radiation |
| 31 | | | machine or radiation generating device. |
| 32 | (2) | The ap | plication requires the following information: |
| 33 | | (A) | registration number; |
| 34 | | <u>(B)</u> | equipment location; |
| 35 | | <u>(C)</u> | manufacturer, model, serial number, number of tubes, install date, modality, application, |
| 36 | | | type, and use; |
| 37 | | (D) | location of equipment not in use; |

| 1 | <u>(E</u>) | installer information; and |
|----|-----------------------|---|
| 2 | <u>(F)</u> | shall be dated and signed by the individual with administrative control. The individual |
| 3 | | with administrative control can delegate a responsible person or persons within the |
| 4 | | organization to sign when amendments are made to this form by notifying the agency in |
| 5 | | writing. |
| 6 | (e) A Delete X-Ray | Equipment form shall be submitted when a facility disposes of a radiation machine or radiation |
| 7 | generating device. T | he agency form requires the following information: |
| 8 | <u>(1) reg</u> | gistration number, facility name, and physical address; |
| 9 | <u>(2)</u> ide | entify if the application is for a new facility, for a change of ownership, a facility moves, or to |
| 10 | <u>up</u> | date information; |
| 11 | <u>(3)</u> eq | uipment location; manufacturer, model, serial number; |
| 12 | <u>(4)</u> ide | entify the reason for deleting the equipment; |
| 13 | <u>(5)</u> the | recipient of the equipment, to the individual or business name, physical and e-mail address, |
| 14 | <u>an</u> | d phone number; and |
| 15 | <u>(6)</u> dat | ted and signed by the owner or the individual with administrative control of the radiation |
| 16 | <u>ma</u> | schine or radiation generating device. |
| 17 | (f) A Company Ser | vice application form shall be submitted prior to furnishing or offering to furnish services in |
| 18 | Parts (A) through (C |) of this Paragraph and the following additional requirements shall be met: |
| 19 | <u>(1) Th</u> | e application shall be submitted by any person engaged in: |
| 20 | <u>(A</u> | direct sales, demonstration, leasing, or transfer of radiation machines or radiation |
| 21 | | generating devices; |
| 22 | <u>(B</u> | providing individual monitoring devices; and |
| 23 | <u>(C</u> | radiation survey equipment calibration. |
| 24 | <u>(2) Th</u> | e application requires the following information: |
| 25 | <u>(A</u> | registration number; |
| 26 | <u>(B</u> | business name, facility physical address; |
| 27 | <u>(C</u> | identify if the application is for a new service provider, for a change of ownership, if a |
| 28 | | facility moves, or to update information; |
| 29 | <u>(D</u> | identify each class and modality of services requested to be provided in the state; |
| 30 | <u>(E</u> | submit the requirements listed on the agency form for each class and modality requesting |
| 31 | | to provide services in the state; |
| 32 | <u>(F)</u> | list any class or modality not listed on this form; |
| 33 | <u>(G</u> | description of service provider equipment used for output measurements and surveys; and |
| 34 | <u>(H</u> | signature of the individual with administrative control. |
| 35 | (g) A Company En | aployee Services application form shall be submitted prior to furnishing or offering to furnish |
| 36 | services in Parts (A) | through (H) of this Paragraph and the following additional requirements shall be met: |
| 37 | <u>(1) Th</u> | e application shall be submitted by any person engaged in providing the following services: |

| 1 | | (A) area radiation surveys for diagnostic radiographic and fluoroscopy facilities; |
|----|------------------|---|
| 2 | | (B) equipment surveys and shielding designs for radiation generating devices; |
| 3 | | (C) general health physics consulting services to perform dose estimates, radiation output |
| 4 | | measurements, radiation safety program development, and radiation safety program |
| 5 | | training; |
| 6 | | (D) installation or service repair of radiation machines or radiation generating devices; |
| 7 | | (E) qualified expert consulting services for CT and mammography radiation machines; |
| 8 | | (F) radiation protection expert; |
| 9 | | (G) shielding designs for diagnostic radiographic and fluoroscopy facilities; and |
| 10 | | (H) therapeutic facility and shielding design, area radiation survey, or calibration. |
| 11 | <u>(2)</u> | The application requires the following information: |
| 12 | | (A) name of the employee to be registered; |
| 13 | | (B) start date if the employee is being added and the stop date if the employee is being |
| 14 | | removed from the registration; |
| 15 | | (C) business registration number, name, physical address, and contact e-mail; |
| 16 | | (D) identify class and modality of services to be provided; |
| 17 | | (E) training and experience to submit for each class of services to be provided; |
| 18 | | (F) the date and signature of the employee applying for registration; |
| 19 | | (G) the date and signature of the individual with administrative control; and |
| 20 | | (H) any additional information the agency determines to be necessary for evaluation of the |
| 21 | | application for registration. |
| 22 | (h) The followin | g general requirements apply to all facilities and services provided in North Carolina. |
| 23 | <u>(1)</u> | The registrant shall notify the agency when any change will render the information in an |
| 24 | | application for registration or notice of registration no longer accurate. |
| 25 | <u>(2)</u> | A registrant that terminates all activities of radiation machines, radiation generating devices, or |
| 26 | | providing services shall meet the following requirements within 30 days: |
| 27 | | (A) request termination of the notice of registration in writing by the owner or the individual |
| 28 | | with administrative control; |
| 29 | | (B) submit to the agency, a delete a radiation machine or radiation generation device form, in |
| 30 | | accordance with Paragraph(e) of this Rule; and |
| 31 | | (C) pay any outstanding fees pursuant to Section .1100 of this Chapter. |
| 32 | (3) | A registrant shall not transfer the registration as part of a change of ownership. |
| 33 | <u>(4)</u> | A person who takes possession of a radiation machine or radiation generating device because of |
| 34 | | bankruptcy, foreclosure, or state auction may possess the machine or device when the following |
| 35 | | additional requirements are met: |
| 36 | | (A) The machine or device shall be posted stating that the new owner is responsible for |
| 37 | | registering with the agency if used in this state. |

| 1 | | (B) If the machine or device is energized, it shall only be energized by someone registered in |
|----|---------------|--|
| 2 | | accordance with this Section and only to demonstrate that it is operable for sale or |
| 3 | | transfer. |
| 4 | <u>(5)</u> | No person shall in any advertisement refer to the fact that his or her facility is registered with the |
| 5 | | agency pursuant to the provisions of Rule .0204 or .0205 of this Section, and no person shall state |
| 6 | | or imply that under such registration any activities have been approved by the agency. |
| 7 | | |
| 8 | History Note: | Authority G.S. 104E-7; <u>104E-12; 104E-20;</u> |
| 9 | | Eff. February 1, 1980; |
| 10 | | Amended Eff. May 1, 1992; |
| 11 | | Transferred and Recodified from 15A NCAC 11 .0203 Eff. February 1, 2015; |
| 12 | | Readopted Eff. May 1, 2025. |