CHAPTER 15 – RADIATION PROTECTION

SECTION .0100 – GENERAL PROVISIONS

10A NCAC 15 .0101 SCOPE
(a) Except as otherwise specifically provided these Rules apply to all persons who receive, possess, use, transfer, own or acquire any source of radiation within the State of North Carolina.
(b) Nothing in these Rules shall apply to any person to the extent any person is subject to regulation by the United States Nuclear Regulatory Commission.
(c) Regulation by the State of North Carolina of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the "Agreement Between the United States Atomic Energy Commission and the State of North Carolina for Discontinuance of Certain Commission Regulatory and Responsibility within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended" under provisions of Public Law 86-373, as amended, and 10 CFR Part 150.

History Note: Authority G.S. 104E-2; 104E-7, 104E-10104E-7(a)(2); 104E-12(a);
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2201 Eff. January 4, 1990;
Amended Eff. June 1, 1993;

10A NCAC 15 .0102 COMPLIANCE WITH LAWS
Nothing in these Rules shall relieve any person of responsibility for complying with other pertinent North Carolina laws and rules.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0102 Eff. February 1, 2015.

10A NCAC 15 .0103 INTENTIONAL EXPOSURE
Nothing in Sections .0100 to .1000 of this Chapter shall be interpreted as limiting the intentional exposure of patients to radiation for the purposes of medical diagnosis and therapy.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2203 Eff. January 4, 1990;
Transferred and Recodified from 15A NCAC 11 .0103 Eff. February 1, 2015.

10A NCAC 15 .0104 DEFINITIONS
As used in these Rules, the following definitions apply.

1. "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).
2. "Accelerator produced material" means any material made radioactive by use of a particle accelerator.
4. "Activity" is the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).
5. "Adult" means an individual 18 or more years of age.
6. "Agency" means the, North Carolina Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section.
7. "Agreement state" has the meaning as defined in G.S. 104E-5(2).
8. "Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.
9. "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.
"Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed radioactive material, exist in concentrations:
(a) in excess of the derived air concentrations specified in Appendix B to 10 CFR 20.1001 - 20.2401; or
(b) to such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake or 12 DAC-hours.

"ALARA" (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in the rules of this Chapter as is practical consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of sources of radiation in the public interest.

"Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in an effective dose equivalent of five rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue. The ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table 1, Columns 1 and 2, of Appendix B to 10 CFR 20.1001 - 20.2401.

"Annually" means either:
(a) at intervals not to exceed 12 consecutive months; or
(b) once per year at the same time each year (completed during the same month each year over a period of multiple years).

"Assigned protection factor (APF)" means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. APF can be divided into the ambient airborne concentrations to estimate inhaled air concentrations.

"Atmosphere-supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere and includes supplied-air respirators and self-contained breathing apparatus units.

"Authorized representative" means an employee of the agency, or an individual outside the agency when the individual is so designated by the agency under Rule .0112 of this Section.

"Authorized user" means an individual who is authorized by license or registration condition to use a source of radiation.

"Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that are not under the control of the licensee or registrant. "Background radiation" does not include sources of radiation regulated by the agency.

"Becquerel" is the SI unit of radioactivity. One becquerel is equal to one disintegration per second (s-1).

"Bioassay" or "radiobioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.

"Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal or interstitial application.

"Brachytherapy source" means a radioactive source or a manufacturer assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

"Byproduct material" has the meaning as defined in G.S. 104E-5(4), and in addition includes:
(a) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by
these solution extraction operations do not constitute "byproduct material" within this definition;

(b) Any discrete source of Radium-226 that is produced, extracted, or converted after extraction, for use for a commercial, medical, or research activity;

(c) Any material that:
   (i) has been made radioactive by use of a particle accelerator; or
   (ii) is produced, extracted, or converted after extraction, for use for a commercial, medical, or research activity; and

(d) Any discrete source of naturally occurring radioactive material, other than source material, that:
   (i) the US Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would poses a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and
   (ii) is extracted or converted after extraction for use in a commercial, medical, or research activity.

(24) "Class", "lung class" or "inhalation class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times as follows:

<table>
<thead>
<tr>
<th>CLASSIFICATION OF INHALED MATERIAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class</td>
</tr>
<tr>
<td>Class D (Day)</td>
</tr>
<tr>
<td>Class W (Weeks)</td>
</tr>
<tr>
<td>Class Y (Years)</td>
</tr>
</tbody>
</table>

(25) "Clinical procedures manual" means a collection of procedures governing the medical use of radioactive material not requiring a written directive that describes each method by which the licensee performs clinical procedures and includes other instructions and precautions. Each clinical procedure, including the radiopharmaceutical dosage and route of administration, shall be approved in writing by an authorized user prior to inclusion in the manual. The radiation safety officer shall ensure that the manual includes the approved procedure(s) for all clinical procedures using radioactive material not requiring a written directive performed at the facility.

(26) "Collective dose" is the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

(27) "Commission" has the meaning as defined in G.S. 104E-5(5).

(28) "Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

(29) "Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \sum w_T H_{T,50}$).

(30) "Consortium" means an association of medical use licensees and a PET radionuclide production facility that jointly own or share in the operation and maintenance costs of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The consortium's PET radionuclide production facility must be located at an educational institution, federal or medical facility.

(31) "Constraint" or "dose constraint" means a value above which specified licensee actions are required.

(32) "Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee or registrant for any reason.

(33) "Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

(34) "Curie" is the special unit of radioactivity. One curie is equal to $3.7 \times 10^{10}$ disintegrations per second = $3.7 \times 10^{10}$ bequerels = $2.22 \times 10^{12}$ disintegrations per minute.
"Declared pregnant woman" means a woman who has voluntarily informed the licensee or registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

"Decommission" means to remove (as a facility) safely from service and reduce residual radioactivity to a level that permits release of the property for either unrestricted use and termination of the license or for restricted use and termination of the license.

"Deep-dose equivalent" (H\text{\textsubscript{\text{d}}}), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of one cm (1000 mg/cm\textsuperscript{2}).

"Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

"Department" has the meaning as defined in G.S. 104E-5(6).

"Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

"Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour), results in an intake of ALI. DAC values are given in Table 1, Column 3, of Appendix B to 10 CFR 20.1001 - 20.2401).

"Derived air concentration-hour" (DAC-hour) is the product of the concentration of radioactive material in air (expressed as a fraction or multiple of the derived air concentration for each radionuclide) and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of five rems (0.05 Sv).

"Discrete source" means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

"Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

"Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using measurement technology, survey and statistical techniques as defined in 10 CFR 20.1003.

"Dose" or "radiation dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in other Items of this Rule.

"Dose equivalent" (H\text{\textsubscript{\text{t}}}) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

"Dose limits" (see "Limits" defined in this Rule).

"Dosimetry processor" means an individual or organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment.

"Effective dose equivalent" (H\text{\textsubscript{\text{e}}}) is the sum of the products of the dose equivalent to the organ or tissue (H\text{\textsubscript{\text{t}}}) and the weighting factors (w\textsubscript{T}) applicable to each of the body organs or tissues that are irradiated (H\text{\textsubscript{\text{e}}} = \Sigma w\textsubscript{T}H\text{\textsubscript{\text{t}}}).

"Embryo/fetus" means the developing human organism from conception until the time of birth.

"Entrance or access point" means any location through which an individual could gain access to radiation areas or to a source of radiation. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

"Equipment services" means the selling, installation, rebuilding, conversion, repair, inspection, testing, survey or calibration of equipment which can affect compliance with these Rules by a licensee or registrant.

"Exposure" means being exposed to ionizing radiation or to radioactive material.

"Exposure rate" means the exposure per unit of time, such as R/min and mR/h.

"Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.
"Eye dose equivalent" (See "Lens dose equivalent" as defined in this Rule).

"Filtering facepiece" or "dust mask" means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

"Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

"Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

"Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.), as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using sources of radiation.

"Gray" (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule/kilogram (100 rads).

"Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

"High dose-rate remote afterloader" (HDR) means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

"High radiation area" means an area, accessible to individuals, in which radiation levels from sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

"Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

"Hospital" means a facility that provides as its primary functions diagnostic services and intensive medical and nursing care in the treatment of acute stages of illness.

"Human use" means the internal or external administration of radiation or radioactive materials to human beings.

"Individual" means any human being.

"Individual monitoring" means:

(a) the assessment of dose equivalent by the use of devices designed to be worn by an individual;
(b) the assessment of committed effective dose equivalent by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours;
(c) the assessment of dose equivalent by the use of survey data.

"Individual monitoring devices" or "individual monitoring equipment" means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

"Inhalation class" (see "Class" defined in this Rule).

"Inspection" means an examination or observation by the agency to determine compliance with rules, orders, requirements and conditions of the agency or the Commission.

"Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

"Lens dose equivalent" (LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 cm (300 mg/cm²).

"License," except where otherwise specified, means a license issued pursuant to Section .0300 of this Chapter.

"Licensee" means any person who is licensed by the agency pursuant to Section .0300 of this Chapter.

"Licensing state" means any state designated as such by the Conference of Radiation Control Program Directors, Inc. Unless the context indicates otherwise, use of the term Agreement State in this Chapter includes licensing state with respect to naturally occurring and accelerator produced radioactive material (NARM).

"Limits" or "dose limits" means the permissible upper bounds of radiation doses.
"Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

"Lost or missing licensed radioactive material" means licensed radioactive material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

"Low-dose-rate remote afterloader" (LDR) means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

"Lung class" (see "Class" as defined in this Rule).

"Manual brachytherapy" means a type of brachytherapy in which the brachytherapy seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

"Medical event" means an event that meets the criteria in Rule .0364 of this Chapter.

"Medical use" means the intentional internal or external administration of radioactive material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user.

"Medium dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

"Member of the public" means any individual except when that individual is receiving an occupational dose.

"Minor" means an individual less than 18 years of age.

"Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

"Monitoring," "radiation monitoring" or "radiation protection monitoring" means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

"Natural radioactivity" means radioactivity of naturally occurring nuclides.

"Negative pressure respirator" means a tight-fitting respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside of the respirator.

"Nonstochastic effect" or "deterministic effect" means health effects, the severity of which vary with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect.

"NRC" means the United States Nuclear Regulatory Commission or its authorized representatives.

"Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or registrant or other person. Occupational dose does not include doses received from background radiation, as a patient from medical practices, from exposure to individuals administered radioactive material and released in accordance with Rule .0358 of this Chapter, from voluntary participation in medical research programs, or as a member of the public.

"Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles, in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one megaelectron volt. For purposes of this definition, "accelerator" is an equivalent term.

"Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

"Person" has the meaning as defined in G.S. 104E-5(11).

"Personnel monitoring equipment" means devices, such as film badges, pocket dosimeters, and thermoluminescent dosimeters, designed to be worn or carried by an individual for the purpose of estimating the dose of radiation received by the individual.

"Pharmacist" means a person licensed to practice pharmacy in North Carolina pursuant to G.S. Chapter 90, Article 4A.

"Physician" means a person licensed to practice medicine in North Carolina pursuant to G.S. Chapter 90, Article 1.
"Planned special exposure” means an infrequent exposure to radiation, separate from and in addition to the annual dose limits as defined in Rule .1608 of this Chapter.

"Positive pressure respirator” means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

"Positron Emission Tomography (PET) radionuclide production facility” means a facility operating an accelerator or a cyclotron for the purpose of producing PET radionuclides.

"Powered air-purifying respirator (PAPR)” means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

"Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented:
(a) In a written directive; or
(b) In accordance with the directions of an authorized user.

"Prescribed dose” means:
(a) for teletherapy or accelerator radiation:
   (i) the total dose; and
   (ii) the dose per fraction as documented in the written directive;
(b) for brachytherapy:
   (i) the total source strength and exposure time; or
   (ii) the total dose, as documented in the written directive;
(c) for gamma stereotactic radiosurgery, the total dose as documented in the written directive; or
(d) for remote brachytherapy afterloaders, the total dose and dose per fraction as documented in a written directive.

"Pressure demand respirator” means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

"Public dose” means the dose received by a member of the public from exposure to radiation or radioactive material released by a licensee or registrant, or another source of radiation within a licensee's or registrant's control. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, from exposure to individuals administered radioactive material and released in accordance with Rule .0358 of this Chapter, or from voluntary participation in medical research programs.

"Pulsed dose-rate remote afterloader” means a type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate” range, but:
(a) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and
(b) Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

"Qualitative fit test” (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

"Quality factor” (Q) means the modifying factor that is used to derive dose equivalent from absorbed dose. Quality factors are provided in the definition of rem in this Rule.

"Quantitative fit test” (QNF) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

"Quarter” means a period of time equal to one-fourth of the year observed by the licensee or registrant (approximately 13 consecutive weeks), providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

"Quarterly” means either:
(a) at intervals not to exceed 13 weeks; or
(b) once per 13 weeks at about the same time during each 13 week period (completed during the same month of the quarter (first month, second month or third month) each quarter over a time period of several quarters.

"Rad” is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 gray).

"Radiation”, except as otherwise defined in Section .1400 of this Chapter, has the meaning as defined in G.S. 104E-5(12).
"Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

"Radiation dose" means dose.

"Radiation machine" has the meaning as defined in G.S. 104E-5(13).

"Radiation safety officer" means one who has the knowledge and responsibility to apply appropriate radiation protection rules.

"Radioactive material" has the meaning as defined in G.S. 104E-5(14).

"Radioactive waste disposal facility" means any low-level radioactive waste disposal facility, as defined in G.S. 104E-5(9c), established for the purpose of receiving low-level radioactive waste, as defined in Rule .1202 of this Chapter, generated by another licensee for the purpose of disposal.

"Radioactive waste processing facility" means any low-level radioactive waste facility, as defined in G.S. 104E-5(9b), established for the purpose of receiving waste, as defined in this Rule, generated by another licensee to be stored, compacted, incinerated or treated.

"Radioactivity" means the disintegration of unstable atomic nuclei by emission of radiation.

"Radioassay" means bioassay.

"Reference man" means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus as published by the International Commission on Radiological Protection. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

"Registrant" means any person who is registered with the agency as required by provisions of these Rules or the Act.

"Registration" means registration with the agency in accordance with these Rules.

"Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189.

"Rem" is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert). As used in this Chapter, the quality factors for converting absorbed dose to dose equivalent are as follows:

<table>
<thead>
<tr>
<th>TYPE OF RADIATION</th>
<th>Quality Factor (Q)</th>
<th>Absorbed Dose Equivalent to a Unit Dose Equivalent*</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-, gamma, or beta radiation</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Alpha particles, multiple-charged particles,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>fission fragments and heavy particles of</td>
<td></td>
<td></td>
</tr>
<tr>
<td>unknown charge</td>
<td>20</td>
<td>0.05</td>
</tr>
<tr>
<td>Neutrons of unknown energy</td>
<td>10</td>
<td>0.1</td>
</tr>
<tr>
<td>High-energy protons</td>
<td>10</td>
<td>0.1</td>
</tr>
</tbody>
</table>

* Absorbed dose in rad equal to one rem or the absorbed dose in gray equal to one sievert.

If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, one rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of the rules of this Chapter, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body.

If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from the following table to convert a measured tissue dose in rads to dose equivalent in rems:

<table>
<thead>
<tr>
<th>MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>X-, gamma, or beta radiation</td>
<td>1</td>
</tr>
<tr>
<td>Alpha particles, multiple-charged particles, fission fragments and heavy particles of</td>
<td>20</td>
</tr>
<tr>
<td>unknown charge</td>
<td></td>
</tr>
<tr>
<td>Neutrons of unknown energy</td>
<td>10</td>
</tr>
<tr>
<td>High-energy protons</td>
<td>10</td>
</tr>
<tr>
<td>Neutron Energy (MeV)</td>
<td>Quality Factor(^a) (Q)</td>
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<tr>
<td>----------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>(thermal)</td>
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</tr>
<tr>
<td>2.5 x 10(^{-8})</td>
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<td>1 x 10(^{-2})</td>
<td>7.5</td>
</tr>
<tr>
<td>5 x 10(^{-1})</td>
<td>11</td>
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<tr>
<td>5</td>
<td>9</td>
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<td>7</td>
<td>8</td>
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<td>10</td>
<td>6.5</td>
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<tr>
<td>14</td>
<td>7.5</td>
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<tr>
<td>20</td>
<td>8</td>
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<tr>
<td>40</td>
<td>7</td>
</tr>
<tr>
<td>60</td>
<td>5.5</td>
</tr>
<tr>
<td>1 x 10(^2)</td>
<td>4</td>
</tr>
<tr>
<td>2 x 10(^2)</td>
<td>3.5</td>
</tr>
<tr>
<td>3 x 10(^2)</td>
<td>3.5</td>
</tr>
<tr>
<td>4 x 10(^2)</td>
<td>3.5</td>
</tr>
</tbody>
</table>

\(^a\) Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-cm diameter cylinder tissue-equivalent phantom.

\(^b\) Monoenergetic neutrons incident normally on a 30-cm diameter cylinder tissue-equivalent phantom.
"Sealed source" means radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

"Sealed source and device registry" means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

"Self-contained breathing apparatus (SCBA)" means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

"Semiannually" means either:
(a) at intervals not to exceed six months; or
(b) once per six months at about the same time during each six month period (completed during the sixth month of each six month period over multiple six month periods).

"Shallow-dose equivalent" (Hs), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm²).

"SI unit" means a unit of measure from the International System of Units as established by the General Conference of Weights and Measures.

"Sievert" is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems).

"Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

"Source material" has the meaning as defined in G.S. 104E-5(15).

"Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.

"Special form radioactive material" means radioactive material which satisfies the following conditions:
(a) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
(b) The piece or capsule has at least one dimension not less than five millimeters (0.197 inch); and
(c) It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission, Subpart F of 10 CFR Part 71, and the tests prescribed in Rule .0114 of this Section. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements, Subpart F of 10 CFR Part 71, in effect on June 30, 1984, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.

"Special nuclear material" has the meaning as defined in G.S. 104E-5(16).

"Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope uranium-235 in quantities not exceeding 350 grams of contained uranium-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of uranium-235, uranium enriched in uranium-235 and plutonium in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified in this Rule for the same kind of special nuclear material. The sum of these ratios for all the kinds of special nuclear material in combination shall not exceed one. For example, the following quantities in combination would not exceed the limitations and are within the formula, as follows:

\[
\frac{175 \text{ (gram contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} \quad \text{is} \quad \leq 1
\]

"State" means the State of North Carolina.

"Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to precisely deliver a therapeutic dose to a tissue volume.
"Stochastic effects" means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

"Supplied-air respirator" (SAR) or "airline respirator" means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

"Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of sources of radiation and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

"Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

"These Rules" means Chapter 11 of this Title.

"Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

"To the extent practicable" means to the extent feasible or capable of being done or carried out with reasonable effort, taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations.

"Total effective dose equivalent" (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

"Toxic or hazardous constituent of the waste" means the nonradioactive content of waste which, notwithstanding the radioactive content, would be classified as "hazardous waste" as defined in G.S. 130A-290(8).

"Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

"Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A₁ for special form radioactive material or A₂ for normal form radioactive material, where A₁ and A₂ are given in Rule .0113 of this Section or may be determined by procedures described in that Rule. All quantities of radioactive material greater than a Type A quantity are Type B.

"Unit dosage" means a dosage intended for medical use in an individual that has been obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent agreement state requirements.

"Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

"Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant.

"User seal check" or "fit check" means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

"Very high radiation area" means an area, accessible to individuals, in which radiation levels from sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in one hour at one meter from a radiation source or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts).

"Waste" means low-level radioactive waste as defined in G.S. 104E-5(9a) and includes those low-level radioactive wastes containing source, special nuclear, or radioactive material that are acceptable for disposal in a land disposal facility. For purposes of this definition, low-level waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in this Rule, and licensed naturally occurring and accelerator produced radioactive material which is not subject to regulation by the U.S. Nuclear Regulatory Commission under the Atomic Energy Act of 1954, as amended, except as defined differently in Rule .1202 of this Chapter.

"Week" means seven consecutive days.

"Weighting factor", w_T, for an organ or tissue (T) is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS
<table>
<thead>
<tr>
<th>Organ or Tissue</th>
<th>( w_T )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gonads</td>
<td>0.25</td>
</tr>
<tr>
<td>Breast</td>
<td>0.15</td>
</tr>
<tr>
<td>Red bone marrow</td>
<td>0.12</td>
</tr>
<tr>
<td>Lung</td>
<td>0.12</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.03</td>
</tr>
<tr>
<td>Bone surfaces</td>
<td>0.03</td>
</tr>
<tr>
<td>Remainder</td>
<td>0.30 (^a)</td>
</tr>
<tr>
<td>Whole body</td>
<td>1.00 (^b)</td>
</tr>
</tbody>
</table>

\(^a\) 0.30 results from 0.06 for each of 5 "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.

\(^b\) For the purpose of weighting the external whole body dose (for adding it to the internal dose), a single weighting factor, \( w_T = 1.0 \), has been specified.

(174) "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

(175) "Worker" means an individual engaged in work under a license or registration issued by the agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

(176) "Working level" (WL) is any combination of short-lived radon daughters (for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212) in one liter of air that will result in the ultimate emission of 1.3 x 105 MeV of potential alpha particle energy.

(177) "Working level month" (WLM) means an exposure to one working level for 170 hours.

(178) "Written directive" means an order in writing for a specific patient or human research subject dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation from a licensed source, except as specified in Sub-item (e) of this definition, containing the patient or human research subject's name and the following information:

(a) for the administration of greater than 30 microcuries (1.11 Megabecquerels (MBq)) of sodium iodide I-131, the dosage;

(b) for the therapeutic administration of a radiopharmaceutical other than sodium iodide I-131:

(i) radionuclide;

(ii) dosage; and

(iii) route of administration;

(c) for teletherapy or accelerator radiation therapy:

(i) total dose;

(ii) dose per fraction;

(iii) treatment site; and

(iv) number of fractions;

(d) for high-dose-rate remote afterloading brachytherapy:

(i) radionuclide;

(ii) treatment site;

(iii) dose per fraction

(iv) number of fractions; and

(v) total dose;

(e) for all other brachytherapy:

(i) prior to implantation:

(A) radionuclide;

(B) treatment site; and

(C) dose; and

(ii) after implantation:

(A) radionuclide;

(B) treatment site;
(C) number of sources;
(D) total source strength and exposure time; and
(E) total dose; and

(f) for gamma stereotactic radiosurgery:
   (i) the total dose;
   (ii) treatment site; and
   (iii) values for the target coordinate settings per treatment for each anatomically distinct treatment site.

"Year" means the period of time beginning in January used to determine compliance with the provisions of Section .1600 of this Chapter. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

History Note: Authority G.S. 104E-7(a)(2); 10 CFR 20.1003;
Eff. February 1, 1980;
Amended Eff. November 1, 1989; June 1, 1989; October 1, 1984;
Transferred and Recodified from 10 NCAC 03G .2204 Eff. January 4, 1990;
Amended Eff. January 1, 1994; May 1, 1992;
Temporary Amendment Eff. August 20, 1994, for a Period of 180 Days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. October 1, 2013; November 1, 2007; May 1, 2006; January 1, 2005; August 1, 2002;
April 1, 1999; August 1, 1998; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0104 Eff. February 1, 2015.

10A NCAC 15 .0105 OTHER DEFINITIONS
Definitions of certain other words and phrases as used in these Rules are set forth in Sections .0300, .0500, .0600, .0800, .1200, .1300, .1400, and .1500 of this Chapter. Waste class is defined in Rule .1650 of this Chapter.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Transferred and Recodified from 10 NCAC 03G .2205 Eff. January 4, 1990;
Amended Eff. October 1, 2013; May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0105 Eff. February 1, 2015.

10A NCAC 15 .0106 EXEMPTIONS
(a) The agency may, upon application therefore, grant individual exemptions or exceptions from the requirements of these Rules if it will not result in radiation dose or contamination in excess of the limits prescribed in these Rules for the protection of public health, safety or property.

(b) Except as otherwise provided in this Rule, common and contract or other carriers, freight forwarders, and warehousemen, who are subject to the regulations of the U.S. Postal Service (39 CFR Parts 14 and 15), are exempt from these Rules to the extent that they transport or store sources of radiation in the regular course of their carriage for another or storage incident thereto. Common, contract, or other carriers who are not exempt pursuant to this Rule are subject to the provisions of Rule .0316 of this Chapter. Notwithstanding these exemptions, common, contract or other carriers are required to comply with the provisions of Rule .0316(c) of this Chapter to the extent that these carriers are transporting spent nuclear fuel, as defined in Rule .0316(c) of this Chapter, upon the highways of North Carolina.

(c) Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this state is exempt from these Rules to the extent that the contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

(1) prime contractors performing work for the U.S. Department of Energy at U.S. government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

(2) prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;
(3) prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel; and
(4) any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the agency and the U.S. Nuclear Regulatory Commission jointly determine that:
(A) the exemption of the prime contractor or subcontractor in Subparagraph (c)(4) of this Rule is authorized by law, and
(B) that under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.


10A NCAC 15 .0107 INSPECTIONS
Each licensee and registrant shall, upon reasonable notice, make available to the agency for inspection records maintained pursuant to provisions of these Rules.


10A NCAC 15 .0108 ADDITIONAL REQUIREMENTS
(a) The agency may, by license condition, registration condition, or order, when not in conflict with any law, waive any requirement in these Rules or impose additional requirements in accordance with 46 FR 7540 as it deems appropriate or necessary to minimize danger to public health, safety or property. Such additional requirements are subject to appeal procedures contained in Section 15A NCAC 1B .0200.
(b) The Commission may by rule require radioactive material licensees to procure and file with the department such bond, insurance or other security as the Commission deems necessary to protect the state from costs for emergency response and perpetual maintenance.


10A NCAC 15 .0109 IMPOUNDING
Sources of radiation are subject to impounding by authorized representatives of the agency pursuant to provisions of the Act.


10A NCAC 15 .0110 PROHIBITED USES
(a) Hand-held fluoroscopic screens shall not be used.
(b) Shoe-fitting fluoroscopic devices shall not be used.
(c) Effective February 1, 1981, plastic pointed position indicating devices on intraoral dental systems shall not be used.
(d) Effective February 1, 1983, mechanical timers on intraoral dental machines shall not be used.
(e) Dental fluoroscopy without image intensification shall not be used.
(f) Non-intensified photofluorographic equipment shall not be used.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Transferred and Recodified from 10 NCAC 3G .2211 Eff. January 4, 1990;
Transferred and Recodified from 15A NCAC 11 .0110 Eff. February 1, 2015.

10A NCAC 15 .0111 COMMUNICATIONS
(a) Except as provided in Paragraph (b) of this Rule, all communications and reports concerning these Rules and applications filed thereunder shall be mailed to the agency at Radiation Protection Section, 1645 Mail Service Center, Raleigh, North Carolina 27699-1600 or delivered to the agency at its office located at 5505 Creedmoor Road, Suite 100, Raleigh, North Carolina 27612.
(b) Except as specifically instructed otherwise by the agency, immediate telephone notification and reports required by the rules in this Chapter shall be directed to (919) 814-2250 from 8:00 a.m. to 5:30 p.m. on business days.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Transferred and Recodified from 10 NCAC 3G .2212 Eff. January 4, 1990;
Amended Eff. August 1, 2002; April 1, 1999; May 1, 1993; May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0805 Eff. February 1, 2015;
Amended Eff. January 1, 2016;

10A NCAC 15 .0112 DESIGNATION OF AUTHORIZED REPRESENTATIVE OF THE AGENCY
(a) When an employee of the agency is qualified and is specifically designated by the agency, the employee shall be an authorized representative of the agency to conduct inspections, or tests, or surveys.
(b) When a public employee of other than the agency is determined by the agency to be qualified, the agency may designate the employee as an authorized representative of the agency to conduct specified inspections, or tests, or surveys.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. November 1, 1989;
Transferred and Recodified from 10 NCAC 3G .2213 Eff. January 4, 1990;
Transferred and Recodified from 15A NCAC 11 .0112 Eff. February 1, 2015;

10A NCAC 15 .0113 CLASSIFICATION OF RADIOACTIVE MATERIAL

History Note: Authority G.S. 104E-15;
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Transferred and Recodified from 10 NCAC 3G .2214 Eff. January 4, 1990;
Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0113 Eff. February 1, 2015;

10A NCAC 15 .0114 TESTS FOR SPECIAL FORM
Special form radioactive material as defined in Rule .0104 of this Section must satisfactorily pass the following tests:
(1) a free drop through a distance of 30 feet onto a flat essentially unyielding horizontal surface, striking the surface in such a position as to suffer maximum damage:
impact of the flat circular end of a one-inch diameter steel rod weighing three pounds, dropped through a distance on a sheet of lead, of hardness number 3.5 to 4.5 on the Vickers scale, and not more than one inch thick supported by a smooth essentially unyielding surface;

(3) heating in air to a temperature of 1,475 °F. and remaining at that temperature for a period of ten minutes;

(4) immersion for 24 hours in water at room temperature at pH 6 to pH 8, with a maximum conductivity of ten micromhos per centimeter.


10A NCAC 15 .0115 RECORDS
Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these Rules.

History Note: Authority G.S. 104E-7; 104E-12(a); Eff. February 1, 1980; Transferred and Recodified from 10 NCAC 3G .2216 Eff. January 4, 1990; Amended Eff. May 1, 1993; Transferred and Recodified from 15A NCAC 11 .0115 Eff. February 1, 2015.

10A NCAC 15 .0116 TESTS
Each licensee and registrant shall perform upon instructions from the agency, or shall permit the agency to perform, such reasonable tests as the agency deems appropriate or necessary including, but not limited to, tests of:

(1) sources of radiation;
(2) facilities wherein sources of radiation are used or stored;
(3) radiation detection and monitoring instruments; and
(4) other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

History Note: Authority G.S. 104E-7; 104E-7(2); 104E-11(a); Eff. February 1, 1980; Transferred and Recodified from 10 NCAC 3G .2217 Eff. January 4, 1990; Transferred and Recodified from 15A NCAC 11 .0116 Eff. February 1, 2015.

10A NCAC 15 .0117 INCORPORATION BY REFERENCE
(a) For the purpose of the rules in this Chapter, the following rules, standards and other requirements are hereby incorporated by reference including any subsequent amendments and editions:

(1) Appendix A, Appendix B, Appendix C, and Appendix G to 10 CFR Parts 20.1001 - 20.2401;

(2) The following parts of 10 CFR:
(A) Part 21;
(B) Parts 30.1, 30.4 and 30.10;
(C) Part 31, except 31.5;
(D) Parts 32.2, 32.13, 32.24, 32.110, 32.201, 32.210;
(E) Subpart J of 10 CFR Part 35, Parts 35.50, 35.51, 35.55, 35.57, 35.59, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.432, 35.433, 35.457, 35.490, 35.491, 35.500, 35.590, Subpart H of 10 CFR Part 35, 35.1000;
(F) Part 36;
(G) Part 40, except 40.12(b), 40.23, 40.27, 40.28, 40.31 (j through m), 40.32(d) and portions of (e) pertaining to uranium enrichment, and 40.32(g), 40.33, 40.38, 40.41(d), 40.41(e)(1), 40.41(e)(3), 40.41(g), 40.41(h), 40.51(b)(6), 40.64, 40.66, 40.67;
(H) Part 61 except 61.16, 61.23(i) and (j);
(I) Part 70, except 70.1 (c), (d), (e), 70.13, 70.14, 70.20(a), (b), 70.21(a)(1), (c), (f through h), 70.22(b), (c), (f through h), 70.23 (a)(6 through 12), (b), 70.23a, 70.24, 70.25(a)(1), 70.31(c through e), 70.32(a)(1), (a)(4 through 7), (b)(1), (b)(3), (b)(4)(c through k), 70.37, 70.40, 70.42(b)(6), 70.44, 70.51(c), 70.52, 70.55(c), 70.59-62, 70.64, 70.65, 70.66, 70.72, 70.73, 70.74, 70.76, 70.82; (J) Parts 71.0, 71.1, 71.2, 71.3, 71.4, 71.5, 71.8, 71.14(a), 71.15, 71.17(a) through (e), 71.20, 71.21, 71.22, 71.23, 71.47, Subpart G of 10 CFR Part 71, 10 CFR 71.101(a) through (c)(1), 71.101(f), 71.101(g), 71.103, 71.105, 71.127, 71.129, 71.131, 71.133, 71.135, 71.137, Appendix A to 10 CFR Part 71; and (K) Part 150 except 150.3 Definition: Foreign Obligations, 150.7, 150.10, 150.14, 150.15, 150.15a, 150.16-17, 150.17a, 150.19, 150.21. (3) 21 CFR Part 1010, 21 CFR Part 1020 and 21 CFR Part 1040; (4) 39 CFR Part 14 and 39 CFR Part 15; (5) Postal Service Manual (Domestic Mail Manual) Section 124.3 [incorporated by reference in 39 CFR Section 111.11]; (6) 40 CFR Part 261; (7) 49 CFR Parts 100-189; (8) "Agreement Between the United States Atomic Energy Commission and the State of North Carolina for Discontinuance of Certain Commission Regulatory Authority and Responsibility within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended," signed July 21, 1964; (9) "Standards and Specifications for Geodetic Control Networks" (September 1984); (10) "Geometric Geodetic Survey Accuracy Standards and Specifications for Geodetic Surveys Using GPS Relative Positioning Techniques"; (11) "Reference Man: Anatomical, Physiological and Metabolic Characteristics" (ICRP Publication No. 23) of the International Commission on Radiological Protection; (12) "10 CFR, Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 FR 7540"; and (13) American National Standard N43.9 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography". (b) The rules, standards and other requirements incorporated by reference in Paragraph (a) of this Rule are available for inspection at the Agency at the address listed in Rule .0111 of this Section. Except as noted in the Subparagraphs of this Paragraph, copies of the rules, standards and other requirements incorporated by reference in Paragraph (a) of this Rule may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 at a cost as follows: (1) Three dollars ($3.00) for the appendixes listed in Subparagraph (a)(1) of this Rule, available from the Agency; (2) Sixty-Seven dollars ($67.00) for the regulations listed in Subparagraph (a)(2) of this Rule in a volume containing 10 CFR Parts 1-50; (3) Sixty-Four dollars ($64.00) for the regulations listed in Subparagraph (a)(3) of this Rule in a volume containing 10 CFR Parts 51-199; (4) Sixty-Six dollars ($66.00) for the regulations listed in Subparagraph (a)(4) of this Rule in a volume containing 21 CFR Parts 800-1299; (5) Forty-Seven dollars ($47.00) for the regulations listed in Subparagraph (a)(5) of this Rule in a volume containing 39 CFR; (6) Thirty-six dollars ($36.00) for the manual listed in Subparagraph (a)(6) of this Rule; http://pe.usps.gov/text/dmm300/dmm300_landing.htm; (7) Fifty-Six dollars ($56.00) for the regulations listed in Subparagraph (a)(7) of this Rule in a volume containing 40 CFR Parts 260-299; (8) For the regulations listed in Subparagraph (a)(8) of this Rule: (A) Seventy dollars ($70.00) for a volume containing 49 CFR Parts 100-177; and (B) Seventy dollars ($70.00) for a volume containing 49 CFR Parts 178-199; (9) One dollar ($1.00) for the agreement in Subparagraph (a)(9) of this Rule, available from the Agency; (10) Two dollars and eighty-five cents ($2.85) for the standards and specifications in Subparagraph (a)(10) of this Rule, available from the National Geodetic Information Center, N/CG174, Rockwall Building, Room 24, National Geodetic Survey, NOAA, Rockville, MD 20852;
(11) Two dollars and eighty-five cents ($2.85) for the standards and specifications in Subparagraph (a)(11) of this Rule, available from the National Geodetic Information Center, NCG174, Rockwall Building, Room 24, National Geodetic Survey, NOAA, Rockville, MD 20852;

(12) Two Hundred Eighteen dollars ($218.00) for the ICRP Publication No. 23 in Subparagraph (a)(12) of this Rule, available from Pergamon Press, Inc., Maxwell House, Fairview Park, Elmsford, NY 10523;

(13) Two dollars ($2.00) for the document in Subparagraph (a)(13) of this Rule, available from the Agency; and

(14) Twenty-Five dollars plus five dollars shipping and handling ($30.00) for the American National Standard N43.9 in Subparagraph (a)(14) of this Rule, available from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018, telephone number (212) 642-4900.


(c) Nothing in this incorporation by reference of 10 CFR Part 61 in Subparagraph (a)(3) of this Rule shall limit or affect the continued applicability of G.S. 104E-7(a)(2); 104E-12(a)

**10A NCAC 15 .0118  OPTIONAL EARLY COMPLIANCE WITH SECTION .1600**

Any licensee or registrant may choose to implement the rules in Section .1600 of this Chapter prior to the January 1, 1994 effective date of that Section, in lieu of the rules in Section .0400 of this Chapter, provided such licensee or registrant shall:

(1) implement all rules in Section .1600 of this Chapter, except as exempted by the provisions of Rule .1602(c) of this Chapter;

(2) comply with the rules in Section .1600 of this Chapter in lieu of any rule in Section .0400 of this Chapter that is cited in license or registration conditions, except as otherwise provided in Rule .1602 of this Chapter; and

(3) provide written notification of implementation to the agency at the address in Rule .0111 of this Section.

**History Note:** Authority G.S. 104E-7(a)(2); 104E-12(a); Eff. May 1, 1993; Transferred and Recodified from 15A NCAC 11 .0117 Eff. February 1, 2015.

**SECTION .0200 - REGISTRATION OF RADIATION MACHINES: FACILITIES AND SERVICES**

Codifier's Note: 10 NCAC 03G .2300 was transferred to 15A NCAC 11 .0200 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

**10A NCAC 15 .0201  PURPOSE AND SCOPE**

(a) This Section provides for the registration of radiation machines, radiation machine facilities and persons who provide other radiological services.

(b) For purposes of this Section, "facility" means the location at which one or more radiation machines are installed or located within one building, vehicle, or under one roof and are under the same administrative control.

(c) In addition to the requirements of this Section, all registrants are subject to the provisions of the other sections of this Chapter.

(d) Special requirements for registration of particle accelerators are provided in Section .0900 of this Chapter and are in addition to the requirements of this Section.

(e) In addition to the requirements of this Section, all registrants are subject to the annual fee provisions contained in Section .1100 of this Chapter.
10A NCAC 15 .0202 EXEMPTIONS
(a) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this Section provided that the dose equivalent rate average over an area of ten square centimeters does not exceed 0.5 mrem per hour at five centimeters from any accessible surface of the equipment when any external shielding is removed. The production, testing, or factory servicing of such equipment are not exempt.
(b) Radiation machines while in transit or storage incident thereto are exempt from the requirements of this Section.
(c) Domestic television receivers are exempt from the requirements of this Section.

10A NCAC 15 .0203 APPLICATION; REGISTRATION; RADIATION MACHINES; FACILITIES
(a) Each person having an unregistered radiation machine or facility shall:
   (1) apply for registration of such facility and each radiation machine within 30 days following initial operation of that facility and each radiation machine. Application for registration shall be completed on agency forms and shall contain all information required by the forms and accompanying instructions. The registration of the first radiation machine at a facility constitutes registration of the facility itself.
   (2) designate on the application form an individual who shall be responsible for radiation protection.
(b) Agency forms described in Subparagraph (a)(1) of this Rule require the following and other information:
   (1) name, address and telephone number of the radiation machine facility;
   (2) name of the person responsible for radiation protection in the facility;
   (3) name, training and experience of the person designated in Subparagraph (a)(2) of this Rule;
   (4) the manufacturer, model number, serial number and type of each radiation machine located within the facility;
   (5) the date of the application and the signatures of the persons specified in Subparagraphs (b)(2) and (3) of this Rule.

10A NCAC 15 .0204 PROHIBITED SERVICES AND INSTALLATION
(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.

10A NCAC 15 .0205 APPLICATION FOR REGISTRATION OF SERVICES
(a) Each person who is engaged in the business of installing or offering to install radiation machines and machine components or is engaged in the business of furnishing or offering to furnish any equipment services listed in Paragraph (d) of this Rule in this state, to any agency licensee or registrant, shall apply for registration of such services with the agency prior to furnishing or offering to furnish any of these services.

(b) Application for registration shall be completed on appropriate form(s) provided by the agency and shall contain all information required by the agency as indicated on the form and accompanying instructions. This information shall include:

1. the name, address and telephone number of:
   A. the individual or the company to be registered;
   B. the owner(s) of the company;
2. the description of the services to be provided;
3. the name, training and experience of each person who provides services specified in Paragraph (d) of this Rule;
4. the date of the application and the signature of the person responsible for the company; and
5. any additional information the agency determines to be necessary for evaluation of the application for registration.

(c) Each person applying for registration under Paragraph (a) of this Rule shall certify that he has read and understands the requirements of the rules in this Chapter.

(d) For the purpose of this Section, equipment services include:

1. direct sale and transfer of radiation machines and machine components to end users;
2. installation or servicing of radiation machines and associated radiation machine components;
3. diagnostic radiographic facility and shielding design;
4. diagnostic fluoroscopic facility and shielding design;
5. diagnostic area radiation survey, e.g., shielding evaluation;
6. radiation instrument calibration;
7. therapeutic facility and shielding design, area radiation survey or calibration;
8. personnel dosimetry services; and
9. general health physics consulting, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs and radiation safety training programs, non-healing arts facility and shielding design and area radiation surveys.

(e) Applicants for registration of services are subject to the applicable requirements of Rules .0213 and .0214 of this Section.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. June 1, 1993; May 1, 1992; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0205 Eff. February 1, 2015.

10A NCAC 15 .0206 REPORTS OF INSTALLATION
(a) Persons, registered pursuant to Rule .0205 of this Section, who sell, lease, transfer, lend, dispose of, assemble or install radiation machines in this state shall, within 30 days after each calendar quarter, notify the agency at the address in Rule .0111 of this Chapter, of:

1. whether any radiation machines were installed, transferred, or disposed of during the calendar quarter;
2. the name and address of persons who received radiation machines during the calendar quarter;
3. the manufacturer, model and serial number of each radiation machine transferred or disposed of;
4. the date of transfer of each radiation machine.

(b) The information specified in Subparagraphs (a)(2), (3) and (4) of this Rule may be omitted from the quarterly reports required in (a) of this Rule for any diagnostic x-ray system which contains certified components when a copy of the assembler's report prepared in compliance with 21 CFR 1020.30(d) is submitted to the agency.

History Note: Authority G.S. 104E-7; 104E-12;
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0206 Eff. February 1, 2015.

10A NCAC 15 .0207 ISSUANCE OF NOTICE OF REGISTRATION
(a) The agency shall issue a notice of registration upon a determination that an applicant:
is qualified by reason of education, training or experience in the use and hazards of radiation sources
described in the application for registration;
(2) has facilities and equipment which meet the requirements in these Rules;
(3) has established a radiation protection program, appropriate to the registered activities, which assures
compliance with radiation protection requirements in these Rules; and
(4) meets the applicable requirements in this Chapter.

(b) The agency may, by registration condition or order, when not in conflict with any law, waive any requirement in
these Rules or impose requirements with respect to the registrant's receipt, possession, use and transfer of radiation
machines as the agency deems appropriate or necessary for compliance with the rules in this Chapter. Such additional
requirements are subject to appeal under 15A NCAC 1B .0200.

(c) The agency may refuse to grant a registration required in Rules .0203 and .0205 of this Section to any applicant who
does not possess adequate qualifications or equipment or satisfy the applicable requirements in this Chapter; provided
that, before any order is entered denying an application for registration, the agency shall give notice and grant a hearing
as provided in G.S. 150B.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. June 1, 1993; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0207 Eff. February 1, 2015.

10A NCAC 15 .0208 PRIOR NOTIFICATION OF TRANSFER

(a) Persons registered pursuant to Rule .0203 of this Section shall notify the agency in writing prior to transfer of a
registered radiation machine to another person required to be registered pursuant to Rule .0203(a) of this Section. This
Rule does not prohibit transfer without prior notification to sales and service companies registered pursuant to Rule
.0205 of this Section.

(b) The notification shall include:
(1) the name and address of the transferee, and
(2) the manufacturer, model number and serial number of the radiation machine to be transferred.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0208 Eff. February 1, 2015;

10A NCAC 15 .0209 REPORT OF CHANGES

Any registrant shall notify the agency in writing when any change will render the information contained in the
application for registration or notice of registration no longer accurate.

History Note: Authority G.S. 104E-7; 104E-12;
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0209 Eff. February 1, 2015.

10A NCAC 15 .0210 OTHER PROHIBITED ACTIVITIES

(a) No person registered pursuant to Rule .0205 of this Section for x-ray sales or installations shall make, sell, lease,
transfer, lend, assemble, or install radiation machines or equipment used in connection with such machines unless such
machines and equipment when placed in operation shall meet the applicable requirements of these Rules.

(b) No person, in any advertisement, shall refer to the fact that he or his facility is registered with the agency pursuant to
the provisions of Rule .0203 or .0205 of this Section and no person shall state or imply that any activity under such
registration has been approved by the agency.

(c) No person registered pursuant to Rule .0205 of this Section shall install radiation machines which are subject to
provisions of Section .0600 of this Chapter unless the registrant first determines that the agency has issued written
acknowledgement of receipt of any facility and shielding design required in Rule .0603 of this Chapter.

History Note: Authority G.S. 104E-7; 104E-20;
Eff. February 1, 1980;
Amended Eff. May 1, 1993; June 1, 1989;
10A NCAC 15 .0211 OUT-OF-STATE RADIATION MACHINES  
(a) No person shall bring any radiation machine into the state, for any temporary use, unless such person has given a written notice to the agency at least five working days before the machine is to be used in the state. The notice shall include the type of radiation machine; the nature, duration, and scope of use; and the exact location(s) where the radiation machine is to be used. If, for a specific case, the five working day period would impose an undue hardship on the person, he may, upon application to the agency, obtain permission to proceed sooner.  
(b) The person in Paragraph (a) of this Rule shall:  
   (1) comply with all applicable rules in this Chapter, including registration pursuant to Rule .0203 of this Section; and  
   (2) supply the agency with such other information as the agency may reasonably request.  

History Note:  Authority G.S. 104E-7;  
Eff. February 1, 1980;  
Amended Eff. June 1, 1989;  
Transferred and Recodified from 15A NCAC 11 .0211 Eff. February 1, 2015;  

10A NCAC 15 .0212 MODIFICATIONS: REVOCATION: TERMINATION OF REGISTRANTS  
(a) The terms and conditions of all registrations are subject to amendment, revision or modification and all registrations are subject to suspension or revocation by reason of:  
   (1) rules adopted pursuant to provisions of the Act; or  
   (2) orders issued by the agency pursuant to provisions of the Act and rules adopted pursuant to provisions of the Act.  
(b) Any registration may be revoked, suspended or modified in whole or in part:  
   (1) for any material false statement in the application or in any statement of fact required by provisions of this Section;  
   (2) because of conditions which would warrant the agency to refuse to grant a registration on original application revealed by:  
      (A) the application;  
      (B) any statement of fact;  
      (C) any report, record, inspection or other means; or  
   (3) for violations of, or failure to observe any of the terms and conditions of the Act, the registration, the rules of this Chapter, or order of the agency.  
(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, prior to the institution of proceedings for modification, revocation or suspension of a registrant, the agency shall:  
   (1) call to the attention of the registrant in writing the facts or conduct which may warrant these actions, and  
   (2) provide an opportunity for the registrant to demonstrate or achieve compliance with all lawful requirements.  
(d) Before any order is entered suspending, revoking or modifying a registration, the agency shall give notice and grant a hearing as provided in Chapter 150B of the North Carolina General Statutes.  
(e) The agency may terminate a registration upon written request submitted by the registrant to the agency.  

History Note:  Authority G.S. 104E-7; 104E-13;  
Eff. June 1, 1989;  
Amended Eff. June 1, 1993;  
Transferred and Recodified from 15A NCAC 11 .0212 Eff. February 1, 2015;  

10A NCAC 15 .0213 ADDITIONAL REQUIREMENTS: REGISTERED SERVICES  
(a) An applicant for registration of diagnostic area radiation survey, diagnostic radiation output measurements or therapeutic calibration services pursuant to Rule .0205 of this Section shall meet the following additional requirements:  
   (1) The applicant shall have adequate radiation survey and radiation measurement equipment appropriate to the services requested for authorization.
(2) The applicant shall ensure that the equipment in Subparagraph (a)(1) of this Rule is calibrated at least every 12 months by persons registered to provide such services pursuant to Rule .0205 of this Section, except as provided in Subparagraph (a)(3) of this Rule. The agency may approve less frequent calibration of equipment used for therapy calibration, provided the applicant satisfies the agency that the proposed frequency and procedures will provide equivalent or better assurance of proper calibration.

(3) The applicant may perform the equipment calibrations required in Subparagraph (a)(2) of this Rule provided that:
   (A) such calibrations are currently traceable to the National Institute of Standards and Technology;
   (B) the calibration procedures are approved by the agency;
   (C) the radiation sources used for such calibration are licensed or registered as required by the rules in this Chapter; and
   (D) the equipment is labeled to indicate the date of calibration and records of the calibration are maintained.

(4) The applicant shall submit:
   (A) a description of the procedures that will be used in performing area radiation surveys including a list of all guides and references to the employed;
   (B) a copy of all forms, reports and documents that will be supplied to customers;
   (C) samples of three different types of surveys;
   (D) samples of three reports of diagnostic radiation output measurements; and
   (E) samples of three therapeutic calibration reports.

(b) An applicant for registration of services pursuant to Rule .0205 of this Section who proposes to provide diagnostic radiographic, fluoroscopic and therapeutic facility and shielding design services shall meet the following additional requirements:
   (1) The applicant shall submit examples of the facility and shielding design which will be provided to clients.
   (2) The applicant shall submit examples of the calculations which will be performed as part of the facility and shielding design along with any guides, occupancy factor rationales, and workload estimation rationales which will be used.
   (3) The applicant shall ensure that the facility and shielding design services provided to licensees and registrants of the agency satisfy the applicable requirements in this Chapter.

History Note: Authority G.S. 104E-7;
Eff. June 1, 1989;
Amended Eff. June 1, 1993;

10A NCAC 15 .0214 TRAINING AND EDUCATIONAL REQUIREMENTS FOR EQUIPMENT SERVICES

(a) Each person registered pursuant to Rule .0205 of this Section shall be qualified by reason of education, training and experience to provide the services for which registration is requested. The following are minimum qualifications for specific types of services:

   (1) Class I - sales of radiation machines and machine components to end users: The applicant must certify knowledge of familiarity with the rules which govern the possession, installation and use of radiation machines in North Carolina.

   (2) Class II - installation and service of radiation machines and machine components including the making of diagnostic radiation output measurements to verify performance associated with the installation or service:
      (A) manufacturer's equipment school for service, maintenance and installation for the type of machine use (e.g. dental intraoral, medical diagnostic or medical fluoroscopic) or equivalent training;
      (B) training in principles of radiation protection; and
      (C) three months of experience in installation and service of radiation machines and machine components.

   (3) Class III - diagnostic radiographic facility and shielding design:
      (A) training in principles of radiation protection;
(B) training in shielding design; and
(C) one year of experience in diagnostic radiographic facility and shielding design for the specific type of machine application.

(4) Class IV - diagnostic fluoroscopic facility and shielding design:
(A) training in principles of radiation protection;
(B) training in shielding design; and
(C) one year of experience in diagnostic fluoroscopic facility and shielding design for the specific type of machine application.

(5) Class V - diagnostic area radiation survey, e.g., shielding evaluation:
(A) training in basic radiological health;
(B) training in shielding evaluation; and
(C) one year of experience performing area radiation surveys.

(6) Class VI - radiation instrument calibration: The applicant must possess a current radioactive materials license or registration authorizing radiation instrument calibration.

(7) Class VII - therapeutic facility and shielding design, area radiation survey, or calibration:
(A) certification by the American Board of Radiology in therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, or x-ray and radium physics; or certification by the American Board of Medical Physics; or
(B) having the following minimum training and experience:
   (i) a master's degree in physics, biophysics, radiological physics or health physics;
   (ii) one year of full-time training in therapeutic radiological physics
   (iii) one year of full-time experience in a therapeutic facility including personal calibration and spot-check of at least one machine;
(C) shall submit a description of the procedures that will be utilized in performing therapeutic calibrations including a list of all guides and references to be employed;
(D) shall submit a copy of all forms, reports and documents that will be supplied to customers; and
(E) shall submit one sample of each specific type, e.g., teletherapy, accelerator.

(8) Class VIII - personnel dosimetry service: The applicant must hold current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology or use NVLAP accredited dosimetry.

(9) Class IX - general health physics consulting, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs, and radiation safety training programs, non-healing arts facility and shielding design, and area radiation surveys:
(A) baccalaureate degree in a physical science (e.g. physics, chemistry or radiologic science), engineering or related field and two years of progressive experience in medical or health physics; graduate training in medical or health physics may be substituted on a year for year basis; or
(B) certification by the American Board of Radiology in therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, or x-ray and radium physics; certification by the American Board of Health Physics in health physics or certification by the American Board of Medical Physics.

(b) Any person not meeting the requirements in Paragraph (a) of this Rule may apply to the agency for registration, provided such person demonstrates education, training and experience which is equivalent to that required in Paragraph (a) of this Rule.

(c) Any person registered prior to the effective date of this Rule to provide equipment services pursuant to Rule .0205 of this Section shall meet the education, training and experience requirements in Paragraph (a) or (b) of this Rule no later than 24 months after the effective date of this Rule.

(d) The agency shall initiate action to terminate the registration of any person who fails to comply with the requirements of Paragraph (c) of this Rule.

History Note: Authority G.S. 104E-7; 104E-13;
Eff. June 1, 1989;
Amended Eff. June 1, 1993;
SECTION .0300 - LICENSING OF RADIOACTIVE MATERIAL

Codifier's Note: 10 NCAC 03G .2400 was transferred to 15A NCAC 11 .0300 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .0301 PURPOSE AND SCOPE
(a) This Section provides for the licensing of radioactive material. No person shall receive, possess, use, transfer, own, transport, manufacture and produce, or acquire radioactive material except as authorized in a specific or general license issued pursuant to, or as otherwise provided in, this Section.
(b) In addition to the requirements of this Section:
   (1) All licensees are subject to the requirements of Sections .1000, .1100 and .1600 of this Chapter, except as otherwise provided in the rules of this Section;
   (2) Licensees engaged in industrial radiographic operations are subject to the requirements of Section .0500 of this Chapter;
   (3) Licensees using sealed sources in the healing arts are subject to the requirements of Section .0700 of this Chapter;
   (4) Licensees engaged in the operation of radioactive waste disposal facilities are subject to the requirements of Section .1200 of this Chapter; and
   (5) Licensees engaged in well-logging operations are subject to the requirements of Section .1300 of this Chapter.
(c) The rules in this Section do not apply to persons licensed pursuant to the rules in Section .1200 of this Chapter except as specifically provided otherwise in Section .1200.

History Note: Authority G.S. 104E-7; 104E-9(8); 104E-10(b);
            Eff. February 1, 1980;
            Amended Eff. October 1, 2013; August 1, 1998; January 1, 1994; May 1, 1992; June 1, 1989; July 1, 1982;

10A NCAC 15 .0302 EXEMPTIONS FOR SOURCE MATERIAL
(a) Any person possessing source material, or devices containing source material, in quantities not exceeding the limits of 10 CFR 40.13(a) through (c)(8) shall be exempt from the requirement for a radioactive materials license and shall comply with the provisions of 10 CFR 40.13.
(b) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beecece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

History Note: Authority G.S. 104E-7; 104E-10(b);
            Eff. February 1, 1980;
            Amended Eff. June 1, 1989; October 1, 1984; October 1, 1980;
            Transferred and Recodified from 15A NCAC 11 .0302 Eff. February 1, 2015;

10A NCAC 15 .0303 EXEMPT CONCENTRATIONS: OTHER THAN SOURCE MATERIAL
(a) No person shall introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under Paragraph (d) of this Rule or equivalent regulations of the U.S. Nuclear Regulatory Commission or any agreement state, except in accordance with a specific license issued by the Nuclear Regulatory Commission pursuant to 10 CFR 32.11.
(b) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in the rules of this Section to the extent that this person transfers radioactive material contained in a product or material in concentrations not in excess of those specified in Paragraph (d) of this Rule, and introduced into the product or material by a licensee holding a specific license issued by the U.S. Nuclear Regulatory Commission expressly authorizing such introduction. This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being.
(c) This Rule shall not be deemed to authorize the import of radioactive material or products containing radioactive material.

(d) Except as provided in Paragraph (a) and (b) of this Rule, any person is exempt from these Rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires products or materials containing radioactive material in concentrations not in excess of those listed in the following table:

<table>
<thead>
<tr>
<th>Element (atomic number)</th>
<th>Isotope</th>
<th>Column I Gas concentration microcurie/ml</th>
<th>Column II Liquid and solid concentration microcurie/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antimony (51)</td>
<td>Sb 122</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sb 124</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Sb 125</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Argon (18)</td>
<td>Ar 37</td>
<td>$1 \times 10^{-3}$</td>
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<tr>
<td></td>
<td>Ar 41</td>
<td>$4 \times 10^{-7}$</td>
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<tr>
<td>Arsenic (33)</td>
<td>As 73</td>
<td></td>
<td>$5 \times 10^{-3}$</td>
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<tr>
<td></td>
<td>As 74</td>
<td></td>
<td>$5 \times 10^{-4}$</td>
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<td></td>
<td>As 76</td>
<td></td>
<td>$2 \times 10^{-4}$</td>
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<tr>
<td></td>
<td>As 77</td>
<td></td>
<td>$8 \times 10^{-4}$</td>
</tr>
<tr>
<td>Barium (56)</td>
<td>Ba 131</td>
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<td></td>
<td>Ba 140</td>
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<tr>
<td>Beryllium (4)</td>
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<td>Bismuth (83)</td>
<td>Bi 206</td>
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<tr>
<td>Bromine (35)</td>
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<td>Cadmium (48)</td>
<td>Cd 109</td>
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<td>Cd 115m</td>
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<td>Calcium (20)</td>
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<td></td>
<td>Ca 47</td>
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<tr>
<td>Carbon (6)</td>
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<tr>
<td>Cerium (58)</td>
<td>Ce 141</td>
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<td>$9 \times 10^{-4}$</td>
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<td></td>
<td>Ce 143</td>
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<td>$4 \times 10^{-4}$</td>
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<td></td>
<td>Ce 144</td>
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<td>$1 \times 10^{-4}$</td>
</tr>
<tr>
<td>Cesium (55)</td>
<td>Cs 131</td>
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<tr>
<td></td>
<td>Cs 134m</td>
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<td></td>
<td>Cs 134</td>
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<tr>
<td>Chlorine (17)</td>
<td>Cl 38</td>
<td>$9 \times 10^{-7}$</td>
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<tr>
<td>Chromium (24)</td>
<td>Cr 51</td>
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<td>Cobalt (27)</td>
<td>Co 57</td>
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<td>Co 58</td>
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<tr>
<td>Dysprosium (66)</td>
<td>Dy 165</td>
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<td></td>
<td>Dy 166</td>
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<tr>
<td>Erbium (68)</td>
<td>Er 169</td>
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<td></td>
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<tr>
<td></td>
<td>Er 171</td>
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</tr>
<tr>
<td>Europium (63)</td>
<td>Eu 152</td>
<td>(Half-life = 9.2 Hrs.)</td>
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<td>Fluorine (9)</td>
<td>F 18</td>
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<td>Gd 159</td>
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<td>S 35</td>
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<td>Thulium (69)</td>
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<td>Tm 171</td>
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<td>Xe 131m</td>
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<td>Xe 133</td>
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<td>Zr 97</td>
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</table>
Beta or gamma emitting radioactive material not listed above with half-life less than 3 years

\[1 \times 10^{-10} \rightarrow 1 \times 10^{-6}\]

(e) In Column I of the table, in Paragraph (d) of this Rule, values are given only for those materials normally used as gases.

(f) In Column II of the table, in Paragraph (d) of this Rule, the units, microcuries per gram, are used for solids.

(g) Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Paragraph (d) of this Rule, the activity stated is that of the parent isotope and takes into account the daughters.

(h) For purposes of this Rule, where a combination of isotopes is involved, the limit for the combination shall be derived as follows: Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Paragraph (d) of this Rule for the specific isotope when not in combination. The sum of the ratios shall not exceed unity. An example of this is:

\[
\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} \leq 1
\]

History Note: Authority G.S. 104E-7; 104E-10; 104E-20; 10 CFR 30.70; Eff. February 1, 1980; Amended Eff. October 1, 2013; May 1, 1993; June 1, 1989; Transferred and Recodified from 15A NCAC 11 .0303 Eff. February 1, 2015.

10A NCAC 15 .0304 EXEMPT QUANTITIES: OTHER THAN SOURCE MATERIAL

(a) Any person possessing radioactive material in individual quantities specified in 10 CFR 30.18(a) or (b) shall be exempt from the requirements for a radioactive materials license and shall comply with the provisions of 10 CFR 30.18(c) through (e).

(b) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/textidx?SID=2beeece594411a03e50b2468ae31f89b&ptid=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

History Note: Authority G.S. 104E-7; 104E-10(b); 104E-20; 10 CFR 30.71; Eff. February 1, 1980; Amended Eff. October 1, 2013; May 1, 1993; Transferred and Recodified from 15A NCAC 11 .0304 Eff. February 1, 2015; Amended Eff. March 1, 2017.

10A NCAC 15 .0305 EXEMPT ITEM CONTAINING OTHER THAN SOURCE MATERIAL

(a) Any person possessing items containing radioactive material listed in 10 CFR 30.15(a)(1) through (9) shall be exempt from the requirements for a radioactive materials license and shall comply with the provisions of 10 CFR 30.15.

(b) Any person possessing self-luminous products listed in 10 CFR 30.19(a) shall be exempt from the requirements for a radioactive materials license and shall comply with the provisions of 10 CFR 30.19.

(c) Any person possessing gas and aerosol detectors listed in 10 CFR 30.20(a) shall be exempt from the requirements for a radioactive materials license and shall comply with the provisions of 10 CFR 30.20.

(d) Any person possessing radioactive drugs containing carbon-14 urea for diagnostic use in humans listed in 10 CFR 30.21(a) shall be exempt from the requirements for a radioactive materials license and shall comply with the provisions of 10 CFR 30.21.

(e) Any person possessing industrial devices listed in 10 CFR 30.22(a) shall be exempt from the requirements for a radioactive materials license and shall comply with the provisions of 10 CFR 30.22.

(f) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are
10A NCAC 15 .0306    TYPES OF LICENSES: GENERAL AND SPECIFIC
(a) General licenses provided in this Section are effective without the filing of applications with the agency or the issuance of licensing documents to the general licensee, although registration with the agency may be required by the particular general license. The general license is subject to all other applicable rules in this Chapter and any limitations contained in a general license document, if issued.
(b) Specific licenses require the submission of an application to the agency and the issuance of a licensing document by the agency. The licensee is subject to all applicable rules of this Chapter as well as any limitations and requirements specified in the licensing document.

10A NCAC 15 .0307    GENERAL LICENSES: SOURCE MATERIAL
(a) Any person possessing source material in quantities equal to or less than the quantities shown in 10 CFR 40.22(a) shall be issued a general license in accordance with Rule .0306(a) of this Section, and shall comply with the provisions of 10 CFR 40.22(b) through (e).
(b) Any person possessing depleted uranium for the purpose authorized in 10 CFR 40.25(a) shall be issued a general license in accordance with Rule .0306(a) of this Section, and shall comply with the provisions of 10 CFR 40.25(b) through (e).
(c) Reports required by 10 CFR 40.22(b)(4) or 40.25(c) shall be sent to the agency at the address shown in Rule .0111 of this Chapter.
(d) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beeece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

10A NCAC 15 .0308    GENERAL LICENSES: OTHER THAN SOURCE MATERIAL
Any person possessing static elimination devices, or ion generating tubes containing 500 microcuries or less of Polonium-210, or ion generating tubes containing 50 millicuries or less of tritium, shall comply with Rule .0305(a) of this Section.

10A NCAC 15 .0309    GENERAL LICENSES: MEASURING GAUGING: CONTROLLING DEVICES
(a) Any person possessing devices listed in 10 CFR 31.5(a) meeting the requirements of 10 CFR 31.5(b) shall be issued a general license in accordance with Rule .0306(a) of this Section, and shall comply with the provisions of 10 CFR 31.5(c) and (d), except that the fees specified in 10 CFR 31.5(c)(13)(ii) shall not apply to persons issued a general license under this Rule.

(b) Requests, reports for prior approval to transfer devices authorized under this Rule, and any other correspondence required by 10 CFR 31.5 shall be sent to the agency at the address listed in Rule .0111 of this Chapter.

(c) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beece594411a03e50b2468ae31f89b&pidd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

**History Note:** Authority G.S. 104E-7; 104E-10(b); Eff. February 1, 1980; Amended Eff. October 1, 2013; January 1, 2005; January 1, 1994; June 1, 1989; Transferred and Recodified from 15A NCAC 11 .0309 Eff. February 1, 2015; Amended Eff. March 1, 2017.

10A NCAC 15 .0310 GENERAL LICENSES: MANUFACTURE, TRANSFER, INSTALL GENERALLY LICENSED DEVICES

(a) Any person possessing a specific license issued by the agency, the U.S. Nuclear Regulatory Commission, or another Agreement State authorizing the manufacture, installation, or servicing of a device described in Rule .0309 of this Section shall be authorized to install, service, and uninstall these devices in accordance with the provisions of 10 CFR 31.6.

(b) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beece594411a03e50b2468ae31f89b&pidd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

**History Note:** Authority G.S. 104E-7; 104E-10(b); Eff. February 1, 1980; Amended Eff. January 1, 2005; Transferred and Recodified from 15A NCAC 11 .0310 Eff. February 1, 2015; Amended Eff. March 1, 2017.

10A NCAC 15 .0311 GENERAL LICENSES: LUMINOUS SAFETY DEVICES

(a) A general license shall be issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

1. each device contains not more than ten curies of tritium or 300 millicuries of promethium-147; and
2. each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the agency or an agreement state to the manufacturer or assembler of the device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.

(b) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in Paragraph (a) of this Rule are exempt from the requirements of Sections .1000 and .1600 of this Chapter except for Rules .1645 and .1646 of this Chapter.

(c) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

(d) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

(e) The general license provided in Paragraphs (a) and (b) of this Rule are subject to the provisions of Rules .0107 to .0111, .0303(a), .0338, .0343, .0344 and .0346 of this Chapter.

**History Note:** Authority G.S. 104E-7; 104E-10(b); Eff. February 1, 1980;
10A NCAC 15 .0312 GENERAL LICENSES: CALIBRATION AND REFERENCE

(a) A general license shall be issued to those persons listed below to own, receive, acquire, possess, use and transfer, in accordance with the provisions in Paragraphs (c) and (d) of this Rule, americium-241 in the form of calibration or reference sources:

1. any person who holds a specific license issued by the agency which authorizes receipt, possession, use, and transfer of radioactive material; and
2. any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes receipt, possession, use, and transfer of special nuclear material.

(b) A general license to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions in Paragraphs (c) and (d) of this Rule is hereby issued to any person who holds a specific license which is issued by the agency and which authorizes receipt, possession, use, and transfer of radioactive material.

(c) The general licenses in Paragraphs (a) and (b) of this Rule apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the agency or an agreement state pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 of the regulations of the U.S. Nuclear Regulatory Commission.

(d) The general license provided in Paragraphs (a) and (b) of this Rule are subject to the provisions of Rules .0107 to .0111, .0303(a), .0337, .0342, .0343 and .0345 of this Chapter and Sections .1000 and .1600 of this Chapter. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to this Rule:

1. shall not possess at any one time, at any one location of storage or use, more than five microcuries of americium-241 and five microcuries of plutonium in the calibration and reference sources;
2. shall not receive, possess, use, or transfer a calibration or reference source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement:

   The receipt, possession, use and transfer of this source, Model _________________, Serial No. _________________, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

   CAUTION - RADIOACTIVE MATERIAL
   THIS SOURCE CONTAINS
   (name of appropriate radioisotope)

   DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

   (Name of manufacturer or importer)

3. shall not transfer, abandon, or dispose of a calibration or reference source except by transfer to a person authorized by a license issued by the agency, the U.S. Nuclear Regulatory Commission, or an agreement state and authorizing receipt of the source;
4. shall store each source, except when being used, in a closed container adequately designed and constructed to contain americium-241 or plutonium which might otherwise escape during storage; and
5. shall not use a calibration or reference source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(e) The general licenses in Paragraphs (a) and (b) of this Rule do not authorize the manufacture or calibration of reference sources containing americium-241 or plutonium.

History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. January 1, 1994;
10A NCAC 15 .0313 OWNERSHIP OF RADIOACTIVE MATERIAL

A general license shall be issued to own radioactive material without regard to quantity. This general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

History Note: Authority G.S. 104E-7; 104E-10(b); Eff. February 1, 1980; Transferred and Recodified from 15A NCAC 11 .0313 Eff. February 1, 2015.

10A NCAC 15 .0314 GENERAL LICENSES: IN VITRO CLINICAL OR LABORATORY TESTING

(a) A general license shall be issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer or use the following radioactive materials for IN VITRO clinical or laboratory tests not involving internal or external administration of radioactive material, or radiation therefrom, to human beings or animals:

1. iodine-125 in units not exceeding ten microcuries each;
2. iodine-131 in units not exceeding ten microcuries each;
3. carbon-14 in units not exceeding ten microcuries each;
4. hydrogen-3 (tritium) in units not exceeding 50 microcuries each;
5. iron-59 in units not exceeding 20 microcuries each;
6. cobalt-57 in units not exceeding ten microcuries each;
7. selenium-75 in units not exceeding ten microcuries each;
8. mock iodine-125 reference or calibration sources in units not exceeding 0.05 microcuries of iodine-129 and 0.005 microcurie of americium-241 each. This general license is subject to the provisions of Paragraphs (b) to (f) of this Rule.

(b) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established in Paragraph (a) of this Rule until he has filed agency form “Certificate IN VITRO Testing with Radioactive Material Under General License”, with the agency and received from the agency a validated copy of the agency form with certification number assigned. The physician, clinical laboratory or hospital shall furnish on the agency form the following information and such other information as may be required by the form:

1. name and address of the physician, clinical laboratory or hospital;
2. the location of use;
3. a statement that the physician, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out IN VITRO clinical or laboratory tests with radioactive material as authorized under the general license in Paragraph (a) of this Rule and that these tests will be performed only by personnel competent in the use of the instruments and in the handling of the radioactive material.

(c) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established in Paragraph (a) of this Rule:

1. shall not possess at any one time, pursuant to the general license in Paragraph (a) of this Rule at any one location of storage or use a total amount of iodine-125, iodine-131, and iron-59 in excess of 200 microcuries;
2. shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection;
3. shall use the radioactive material only for the uses authorized in Paragraph (a) of this Rule;
4. shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the agency, the U.S. Nuclear Regulatory Commission, or an agreement state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier; and
5. shall dispose of the mock iodine-125 reference or calibration sources described in Subparagraph (a)(8) of this Rule as required by Rule .1628 of this Chapter.

(d) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to Paragraph (a) of this Rule:

1. except as prepackaged units which are labeled in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, or an agreement state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75,
mock iodine-125 (of iodine-129 and americium-241), or iron-59 for distribution to persons generally licensed under Paragraph (a) of this Rule or its equivalent; and

(2) unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(A) This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories, or hospitals and only for IN VITRO clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals.

(B) Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the United States Nuclear Regulatory Commission, or, of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. (Name of Manufacturer).

(e) The physician, clinical laboratory or hospital possessing or using radioactive material under the general license in Paragraph (a) of this Rule shall report in writing to the agency, any changes in the information furnished in the "Certificate IN VITRO Testing with Radioactive Material Under General License" agency form within 30 days after the effective date of the changes.

(f) Any person using radioactive material pursuant to the general license in Paragraph (a) of this Rule is exempt from the requirements of Sections .1000 and .1600 of these Rules with respect to radioactive material covered by the general license. The new drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. January 1, 1994;
Transfered and Recodified from 15A NCAC 11 .0314 Eff. February 1, 2015.

10A NCAC 15 .0315 GENERAL LICENSES: ICE DETECTION DEVICES

(a) A general license shall be issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries of strontium-90 and each device has been manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or in accordance with the specifications contained in a specific license issued by the agency or an agreement state to the manufacturer of the device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.

(b) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in Paragraph (a) of this Rule:

(1) shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an agreement state authorizing manufacture or servicing of the devices; or shall dispose of the device pursuant to the provisions of Rule .1628 of this Chapter;

(2) shall assure that all labels affixed to the device at the time of receipt, and bearing a statement which prohibits removal of the labels, are maintained thereon; and

(3) are exempt from the requirements of Sections .1000 and .1600 of this Chapter except that such persons shall comply with the provisions of Rules .1628, .1645 and .1646 of this Chapter.

(c) This general license does not authorize the manufacture, assembly, disassembly or repair of ice detection devices containing strontium-90.

(d) This general license is subject to the provisions of Rules .0107 to .0111 of this Chapter and Rules .0303(a), .0337, .0342, .0343, and .0345 of this Section.

History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. January 1, 1994;

10A NCAC 15 .0316 GENERAL LICENSES: TRANSPORTATION
(a) Any person transporting or storing byproduct material for transportation shall be exempt as authorized by 10 CFR 30.13.
(b) Any person transporting or storing source material for transportation shall be exempt as authorized by 10 CFR 40.12. Any person not exempt under 10 CFR 40.12 shall be issued a general license in accordance with Rule .0306(a) of this Section.
(c) Any person transporting or storing special nuclear material for transportation shall be exempt as authorized by 10 CFR 70.12. Any person not exempt shall be issued a general license in accordance with Rule .0306(a) of this Section.
(d) Any person preparing radioactive material for shipment or transporting radioactive material shall be subject to the provisions of 10 CFR Part 71 as applicable to the shipment and mode of transportation. Notwithstanding Rule .0117(a)(2)(J) of this Chapter, 10 CFR 71.85(a) through (c), and 71.91(b) are excluded from incorporation by reference for the purposes of this Rule.
(e) Notifications required by 10 CFR 71.97 and 10 CFR 73.37(b)(2) shall be made to the Governor's designee as follows:
   (1) designee: N.C. Highway Patrol Headquarters, Operations Officer;
   (2) mailing address: P.O. Box 27687, Raleigh, North Carolina 27611-7687;
   (3) telephone: (919) 733-4030 from 8 a.m. to 5 p.m. Monday through Friday except State holidays, and (919) 733-3861 at all other times.
(f) Transportation of special nuclear material by aircraft shall be prohibited in accordance with 10 CFR 150.21.
(g) Notifications of incidents, accidents, or the loss of control of radioactive material while in transit or while being stored for transportation shall be made to the agency in accordance with Rule .0357 of this Section. Notification of the theft, or loss of radioactive material while in transit, or while being stored for transportation shall be made to the agency in accordance with Rule .1645 of this Chapter.
(h) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beeece594411a03e50b2468ae31f89b&p=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

History Note: Authority G.S. 20-167.1; 104E-7; 104E-10(b); 104E-15(a);
Eff. February 1, 1980;
Amended Eff. January 1, 1994; May 1, 1992; October 1, 1982;
Transferred and Recodified from 15A NCAC 11 .0316 Eff. February 1, 2015;

10A NCAC 15 .0317 SPECIFIC LICENSES: FILING APPLICATION AND GENERAL REQUIREMENT
(a) Applications for specific licenses shall be filed on an agency form in accordance with G.S. 104E-10(b) in lieu of NRC Form 313, and shall meet the requirements of 10 CFR 30.32, 30.37, or 30.38 as applicable for the type of licensing action, except that:
   (1) 10 CFR 30.32(e), 35.18(a)(2), the portions of 36.11 and 39.11 pertaining to payment of fees, 40.31(e), 61.20(c) and 70.21(e) are not incorporated by reference;
   (2) the agency may require an applicant to submit an environmental impact statement to the agency in accordance with Rule .0108 of this Chapter in lieu of the requirements of 10 CFR 30.32(f), 40.31(f), 40.32(e), 61.10, or 70.23(a); and
   (3) applications for activities listed in 10 CFR 150.7 or excepted activities listed in 10 CFR 150.10 shall be filed on NRC Form 313 and submitted to the U.S. Nuclear Regulatory Commission at the address shown in 10 CFR 150.4 in lieu of the agency. The NRC Form 313 may be found online at https://www.nrc.gov/reading-rm/doc-collections/forms/nrc313.pdf.
(b) In addition to Paragraph (a) of this Rule, applications for a specific license to:
   (1) manufacture items containing exempt quantities of radioactive material or to manufacture exempt quantities of radioactive material that is not incorporated into a manufactured item shall meet the applicable requirements of 10 CFR Part 32, Subpart A;
   (2) manufacture or initially transfer generally licensed devices containing byproduct material shall meet the applicable requirements of 10 CFR Part 32, Subpart B;
   (3) manufacture radioactive drugs, sources, or devices not containing exempt quantities of radioactive material for medical use shall meet the applicable requirements of 10 CFR Part 32, Subpart C;
   (4) conduct broad scope activities shall meet the requirements of 10 CFR 33.12 and 33.16, as applicable to licensed activities. Broad scope medical licensees meeting the criteria of 10 CFR 33.13(a) shall be
exempt from certain licensing and regulatory requirements as specified in 10 CFR 35.15. 10 CFR 33.11 is not incorporated by reference;
(5) perform industrial radiography shall meet the requirements of 10 CFR 34.11;
(6) administer radioactive material or radiation from a licensed source to humans for medical use when a license is required by 10 CFR 35.11 shall meet the requirements of 10 CFR 35.12 and 35.13, as applicable to licensed activities. Notifications required by 10 CFR 35.14 shall be sent to the agency at the address shown in Rule .0111 of this Chapter;
(7) irradiate material using gamma radiation from sealed sources in facilities listed in 10 CFR 36.1(b) shall meet the requirements of 10 CFR 36.1;
(8) conduct well logging activities shall meet the requirements of 10 CFR 39.11;
(9) possess, use, or transfer source material shall meet the requirements of 10 CFR 40.31;
(10) dispose of radioactive waste received from another person shall meet the requirements of Section .1200 of this Chapter;
(11) receive, possess, or use special nuclear material shall meet the requirements of 10 CFR 70.22(a), 70.22(d), and 70.22(e), 70.33, or 70.34 as applicable to licensed activities; or
(12) manufacture or initially transfer calibration or reference sources containing plutonium to persons generally licensed under Rule .0312 of this Section shall meet the requirements of 10 CFR 70.39.

(c) Applications for sealed source and device registration certification, amendment of sealed source and device registration certificates, and inactivation of previously issued sealed source and device registration certificates shall comply with the provisions of 10 CFR Part 32, Subpart D.

(d) Completed applications shall be sent to the agency at the address shown in Rule .0111 of this Chapter.

(e) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beece594411a03e50b24668ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. October 1, 2013; April 1, 1999; May 1, 1992; November 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0317 Eff. February 1, 2015;

10A NCAC 15 .0318 SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE

(a) For the purposes of this Rule, "Authorized medical physicist" means an individual who:
(1) Meets the requirements in 10 CFR 35.51(a) and 35.59; or
(2) Is identified as an authorized medical physicist or teletherapy physicist on:
(A) A specific medical use license issued by the U.S. Nuclear Regulatory Commission or Agreement State;
(B) A medical use permit issued by the U.S. Nuclear Regulatory Commission master material licensee;
(C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; or
(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee.

(b) For the purposes of this Rule, "Authorized nuclear pharmacist" means a pharmacist who:
(1) Meets the requirements in 10 CFR 35.55(a) and 35.59; or
(2) Is identified as an authorized nuclear pharmacist on:
(A) A specific license issued by the U.S. Nuclear Regulatory Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;
(B) A permit issued by the U.S. Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;
(C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use license that authorizes medical use or the practice of nuclear pharmacy; or
(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy;
(3) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized by the U.S. Nuclear Regulatory Commission or Agreement State to identify authorized nuclear pharmacists; or

(4) Is designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(4).

(c) For the purposes of this Rule, "Authorized user" means a physician, dentist, or podiatrist who:

(1) Meets the requirements in 10 CFR 35.59 and either 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.396(a), 35.490(a), 35.590(a), or 35.690(a); or

(2) Is identified as an authorized user on:
   (A) A U.S. Nuclear Regulatory Commission or Agreement State license that authorizes medical use of radioactive material;
   (B) A permit issued by a U.S. Nuclear Regulatory Commission master material licensee that is authorized to permit the medical use of radioactive material;
   (C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State specific license of broad scope that is authorized to permit the medical use of radioactive material; or
   (D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

(d) For the purposes of this Section, "Radiation safety officer" means an individual who:

(1) Meets the requirements in 10 CFR 35.50(a) or (c)(1) and 10 CFR 35.59; or

(2) Is identified as a Radiation Safety Officer on:
   (A) A specific medical use license issued by the U.S. Nuclear Regulatory Commission, or an Agreement State; or
   (B) A medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee.

(e) License required:

(1) A person shall not manufacture, produce, acquire, receive, possess, use or transfer radioactive material for medical use except in accordance with a specific license issued by the agency or as allowed pursuant to Subparagraphs (e)(2) and (e)(3) of this Rule.

(2) An individual may receive, possess, use, or transfer radioactive material in accordance with the rules of this Section under the supervision of an authorized user as provided in this Section unless prohibited by license condition.

(3) An individual may prepare unsealed radioactive material for medical use in accordance with the rules of this Section under the supervision of a pharmacist who is an authorized nuclear pharmacist or physician who is an authorized user as provided in this Section unless prohibited by license condition.

(f) A license application for human use of radioactive material shall be approved if the agency determines that:

(1) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these Rules;

(2) The applicant's proposed equipment, facilities, and procedures are adequate to protect public health from radiation hazards and minimize radiological danger to life or property;

(3) The issuance of the license will not be inimical to the health and safety of the public;

(4) The following training and supervisory relationship are adhered to:
   (A) The user of radioisotopes applied to humans for diagnostic, therapeutic, or investigational purposes shall be a physician authorized by a condition of a specific license, including a specific license of broad scope.
   (B) An authorized physician may delegate the following only to persons who are physicians under the supervision of the authorized physician:
      (i) The approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radioisotope sources;
      (ii) The prescription of the radiopharmaceutical or source of radiation and the dose or exposure to be administered;
      (iii) The determination of the route of administration; and
      (iv) The interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered.
   (C) The authorized physician shall review the work of the supervised individual as it pertains to the delegated work in Subparagraph (f)(4) of this Rule and the records kept reflecting that work; and
(5) the applicant satisfies any applicable requirements in Rules .0319 to .0322 of this Section.

(g) Subject to the provisions of Subparagraph (f)(4) and Paragraphs (h) through (k) of this Rule, an authorized physician may permit technicians and other paramedic personnel to perform the following activities:

(1) Preparation and quality control testing of radiopharmaceuticals and sources of radiation;
(2) Measurement of radiopharmaceutical doses prior to administration;
(3) Use of instrumentation for the collection of data to be used by the physician;
(4) Administration of radiopharmaceuticals and radiation from radioisotope sources to patients.

(h) Authorized physicians who permit activities to be performed by technicians and other paramedical personnel pursuant to Paragraph (g) of this Rule shall:

(1) Prior to giving permission, determine that the technicians and other paramedical personnel have been properly trained to perform their duties with training in the following subjects, as applicable to the duties assigned:
   (A) General characteristics of radiation and radioactive materials;
   (B) Physical, chemical, and pharmaceutical characteristics of each radiopharmaceutical to be used;
   (C) Mathematics and calculations basic to the use and measurement of radioactivity, Radioactivity, including units of radiation dose and radiation exposure;
   (D) Use of radiation instrumentation for measurements and monitoring including operating procedures, calibration of instruments, and limitations of instruments;
   (E) Principles and practices of radiation protection; and
   (F) Additional training in the above subjects, as appropriate, when new duties are added;
(2) Assure that the technicians and other paramedical personnel receive retraining in the subjects listed in Subparagraph (h)(1) of this Rule to maintain proficiency and to keep abreast of developments in the field of nuclear medical technology;
(3) Keep records showing the bases for the determinations of proper training;
(4) Retain responsibility as licensee or authorized user for the satisfactory performance of the activities; and
(5) Review the work of the supervised individual and the records kept reflecting that work.

(i) Certification in nuclear medicine technology by the American Registry of Radiologic Technologists or in nuclear medicine technology by the Nuclear Medicine Technologist Certification Board or the Society of Nuclear Medicine shall be deemed to satisfy the training requirements in Subparagraphs (h)(1) and (2) of this Rule.

(j) An applicant for an initial, amended or renewed license shall state whether he desires to permit technicians or other paramedical personnel to perform activities pursuant to Paragraph (g) of this Rule. If the applicant intends to do so, the application shall include a statement of the activities to be so performed and a description of an adequate program for training the personnel, including retraining as required to keep abreast of developments in technology, or for otherwise determining that the personnel are properly trained to perform their duties.

(k) Whenever a technician or other paramedical person administers a radiopharmaceutical to a patient by injection, a physician shall be accessible. That physician is not required to be authorized by the agency to be a user of radioisotopes.

(l) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user shall:

(1) In addition to the requirements in Rule .1003 of this Chapter, instruct the supervised individual in the licensee’s written radiation protection procedures, written directive procedures, this Chapter, and license conditions with respect to the use of radioactive material; and
(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, rules of this Chapter, and license conditions with respect to the medical use of radioactive material.

(m) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user shall:

(1) In addition to the requirements in Paragraph (h) of this Rule and Rule .1003 of this Chapter, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and
(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the rules of this Chapter, and license conditions.
(n) A licensee that permits supervised activities under Paragraphs (g) and (h) of this Rule is responsible for the acts and omissions of the supervised individual.

(o) A licensee's management shall appoint a Radiation Safety Officer (RSO) who agrees in writing to be responsible for implementing the radiation safety program. The licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

(p) A licensee shall establish in writing the authority, duties and responsibilities of the Radiation Safety Officer.

(q) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, and management prerogative to:
   (1) Identify radiation safety problems;
   (2) Investigate radiation safety problems such as overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, medical events, and other deviations from approved radiation safety procedures and implement corrective actions as necessary;
   (3) Initiate, recommend or provide corrective actions for radiation safety problems;
   (4) Verify implementation of corrective actions; and
   (5) Retain records of items required by this Paragraph.

(r) In addition to the requirements in Rule .1003 of this Chapter, the licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released in accordance with the requirements of Rule .0358 of this Section. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:
   (1) Patient or human research subject control;
   (2) Visitor control, including:
      (A) Routine visitation to hospitalized individuals in accordance with the provisions of Rule .1611(a)(1) of this Chapter; and
      (B) Visitation authorized by Rule .1611(e) of this Chapter;
   (3) Contamination control;
   (4) Waste control; and
   (5) Notification of the Radiation Safety Officer, or his designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(s) The licensee shall retain records of the radiation safety instructions required by Paragraphs (l), (m), and (r) for three years. The record must include:
   (1) A list of topics covered;
   (2) The date of the instruction;
   (3) The name(s) of the attendee(s); and
   (4) The name(s) of the individual(s) who provided the instruction.

History Note: Authority G.S. 104E-7; 104E-10(b); 10 CFR 35.2; Eff. February 1, 1980; Amended Eff. October 1, 2013; November 1, 2007; April 1, 1999; May 1, 1993; November 1, 1989; Transferred and Recodified from 15A NCAC 11 .0318 Eff. February 1, 2015.

10A NCAC 15 .0319 SPECIFIC LICENSES: HUMAN USE IN HOSPITALS

(a) Except as provided in Rules .0302 to .0315 and .0320 of this Section, all receipt, possession, use, storage and disposal of radioactive material in a hospital shall be pursuant to the provisions of a specific license issued to the hospital.

(b) An application by a hospital for a specific license for human use of radioactive material in a hospital shall be pursuant to the provisions of a specific license issued to the hospital.

(1) the applicant satisfies the general requirements in Rule .0318 of this Section;
(2) the applicant has appointed a medical isotopes committee of at least three members to evaluate all proposals for research, diagnostic and therapeutic use of radioisotopes within the hospital;
(3) membership of the committee required in Subparagraph (b)(2) of this Rule includes an authorized user from each department where radioactive material is used, a representative of the nursing staff, a representative of the institution's management and a person trained in radiation safety;
(4) the applicant possesses adequate facilities for the clinical care of patients;
(5) the physician designated on the application as the individual user has substantial experience in the proposed use, handling and administration of radioisotopes and, where applicable, the clinical management of radioactive patients; and
when the application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant has previously received a reasonable number of licenses for a variety of radioactive materials for a variety of human uses.

History Note: Authority G.S. 104E-7(2);
Eff. February 1, 1980;
Amended Eff. October 1, 1984;
Transferred and Recodified from 15A NCAC 11 .0319 Eff. February 1, 2015.

10A NCAC 15 .0320 SPECIFIC LICENSES: HUMAN USE BY INDIVIDUAL PHYSICIANS
(a) An application by an individual physician or a group of physicians for a specific license for human use of radioactive material shall be approved if:

(1) the applicant satisfies the general requirements in Rule .0318 of this Section;
(2) The application is for use in the applicant's practice in an office(s) outside a medical institution;
(3) the applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable;
(4) the applicant has experience, which meets the requirements of the applicable sections of 10 CFR Part 35, in the proposed use, the handling and administration of radioisotopes, and where applicable, the clinical management of radioactive patients; and
(5) the physician(s) furnishes suitable evidence of experience along with the application, except that a statement from the medical isotope committee in the hospital where the applicant acquired experience, indicating its amount and nature, may be submitted as evidence of experience. 10 CFR Part 35 provides the requirements that meet the test for suitable evidence of experience.

(b) The agency shall not approve an application by an individual physician or group of physicians for a specific license to receive, possess or use radioactive material on the premises of a hospital unless:

(1) The use of radioactive material is limited to:
   (A) the administration of radiopharmaceuticals for diagnostic or therapeutic purposes;
   (B) the performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered;
   (C) the performance of IN VITRO diagnostic studies; or
   (D) the calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation and diagnostic instrumentation;
(2) The physician brings the radioactive material with him and removes the radioactive material when he departs;
(3) No radioactive material is received, possessed or stored in the hospital other than the amount of material remaining in the patient; and
(4) The hospital does not hold a radioactive material license under Rule .0319 of this Section.

History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. November 1, 2007; August 1, 2002; November 1, 1989;

10A NCAC 15 .0321 SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE OF UNSEALED RADIOACTIVE MATERIALS
(a) An application for a specific license pursuant to Rule .0318 of this Section for any diagnostic or therapeutic use of unsealed radioactive material shall be approved if:

(1) the applicant satisfies the requirements in Rule .0319 or Rule .0320 of this Section;
(2) the applicant's proposed radiation detection instrumentation is adequate for conducting the diagnostic or therapeutic procedure(s) requested;
(3) the physicians designated in the application as individual users have clinical experience as required by Rule .0117(a)(2) of this Chapter;
(4) the physicians and all other personnel who will be involved in the preparation and use of radioactive material have training and experience in the handling of unsealed radioactive material appropriate to their use of radioactive material and as required by Rule .0117(a)(2) of this Chapter;
(5) the applicant has radiation safety operating procedures for handling and disposal of the radioactive material that provide protection to the workers, the public and the environment from radiation exposure and radioactive contamination; and

(6) the applicant has a clinical procedures manual appropriate for the licensed activities.

(b) Any person authorized by Rules .0318, .0319, .0320, .0322, or .0324 of this Section for medical use of radioactive material may receive, possess and use any of the following radioactive material for check, calibration, transmission and reference use:

(1) Sealed sources not exceeding 30 millicuries (mCi) (1.11 Gigabecquerel (GBq)) each, manufactured and distributed by a person licensed under 10 CFR 32.74 or equivalent Agreement State regulations;

(2) Sealed sources, not exceeding 30 mCi (1.11 GBq) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under 10 CFR 32.74, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

(3) Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 15 mCi (0.56 GBq);

(4) Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed the smaller of 200 microcuries (µCi) (7.4 Megabecquerel (MBq)) or 1000 times the quantities in Appendix C of 10 CFR Part 20; and

(5) Technetium-99m in amounts as needed.

(c) Any licensee who possesses sealed sources as calibration and reference sources pursuant to Paragraph (b) of this Rule shall test each source for leakage and contamination prior to initial use and at intervals not to exceed six months or at longer intervals as approved by the U.S. Nuclear Regulatory Commission or an Agreement State in the source specific Sealed Source and Device Registry sheet. If there is reason for the licensee to suspect that a sealed source may have been damaged, or might be leaking, it shall be tested for leakage before further use.

(d) Leak test results shall be recorded in units of microcuries and maintained for inspection by the agency.

(e) Any licensee who possesses and uses calibration and reference sources pursuant to Paragraph (b) of this Rule shall:

(1) follow the radiation safety and handling instructions that are required by the licensing agency to be furnished by the manufacturer on the label attached to the source or permanent container thereof or in the leaflet or brochure that accompanies the source;

(2) maintain such instructions in a legible and conveniently available form; and

(3) conduct a quarterly physical inventory to account for all sources received and possessed under the license. Records of the inventories shall be maintained for inspection by the agency and shall include the quantities and kinds of radioactive material, location of the sources and the date of the inventory.

(f) Any licensee who is licensed pursuant to Rules .0318, .0319, .0320, or .0324 of this Section for medical use of unsealed radioactive material also is authorized to use radioactive material under the general license in Rule .0314 of this Chapter for the specified in vitro uses without filing agency forms as required by Rule .0314(b) of the Chapter, provided that the licensee is subject to the other provisions of that Rule.

(g) For each individual receiving radiopharmaceutical therapy and hospitalized because the individual cannot be released in accordance with Rule .0358 of this Section, a licensee shall:

(1) provide a private room with a private sanitary facility;

(2) post on the individual's door a "Radioactive Materials" sign and note on the door or the individual's chart, where and how long visitors may stay in the individual's room;

(3) either monitor material or items removed from the individual's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste; and

(4) notify the Radiation Safety Officer and authorized user as soon as feasible if the individual has a medical emergency and immediately after the determination that the patient died.

History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. October 1, 2013; November 1, 2007; August 1, 2002; April 1, 1999; May 1, 1993;
(a) In addition to the requirements set forth in Rule .0318, .0319, or .0320 of this Section, a specific license for human use of sealed sources shall be issued only if the applicant, or if the application is made by an institution, the individual user:

1. Has training and experience as required by 10 CFR 35.490 or 10 CFR 35.690; and
2. Is a physician.

(b) The licensee shall comply with the provisions of Section .0700 of this Chapter and the requirements of Subpart H of 10 CFR Part 35.

(c) For medical use, a licensee may only use:

1. Sealed sources or devices manufactured, labeled, packaged and distributed in accordance with a license issued under 10 CFR Part 30 and 10 CFR 32.74 or equivalent requirements of an Agreement State;
2. Sealed sources or devices noncommercially transferred from a licensee licensed pursuant to Section .0300 of this Chapter, 10 CFR Part 35, or an Agreement State medical use licensee;
3. Teletherapy sources manufactured and distributed in accordance with 10 CFR Part 30 or the equivalent requirements of an Agreement State; or
4. Brachytherapy sources, photon emitting remote afterloader units, teletherapy units or gamma stereotactic radiosurgery units for therapeutic medical uses;
   a. As approved in the Sealed Source and Device Registry; or
   b. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 10 CFR 35.49(a) are met.

(d) In addition to the requirements in Rule .1003 of this Chapter, the licensee shall provide radiation safety instruction prior to assignment and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released in accordance with Rule .0358 of this Section. To satisfy this requirement the instruction must be commensurate with the duties of the personnel and include:

1. Size and appearance of the brachytherapy sources;
2. Safe handling and shielding instructions;
3. Patient or human research subject control;
4. Visitor control, including both:
   a. Routine visitation to hospitalized individuals in accordance with the provisions of Rule .1611(a)(1) of this Chapter;
   b. Visitation authorized by Rule .1611(e) of this Chapter; and
5. Notification of the Radiation Safety Officer, or his designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(e) The licensee shall retain records of the radiation safety instruction required in Paragraph (d) of this Rule for three years. The record must include:

1. A list of topics covered;
2. The date of the instruction;
3. The name(s) of the attendee(s); and
4. The name(s) of the individual(s) who provided the instruction.

History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. October 1, 2013; November 1, 2007;

10A NCAC 15 .0323 SPECIFIC LICENSES: SEALED SOURCES IN INDUSTRIAL RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

(a) Persons conducting industrial radiography using radioactive materials shall comply with the requirements of 10 CFR 34, which are hereby incorporated by reference including subsequent amendments and editions, except for: 10 CFR 34.5, 34.8, 34.121, and 34.123. Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part034/.

(b) Applications required by 10 CFR 34 shall be made on forms provided by the agency. Applications and supporting material shall be submitted to the agency by e-mail at Licensing.RAM@dhhs.nc.gov, or at the address shown in Rule .0111 of this Chapter in lieu of the NRC:

1. Persons applying for new radioactive materials licenses, or for the renewal of existing radioactive materials licenses, shall submit an Application for Radioactive Materials License. The following information shall appear on the application:
legal business name and mailing address;

physical address(es) where radioactive material shall be used or possessed. The application shall indicate if radioactive materials shall be used at temporary jobsites;

the name, telephone number, and e-mail address of the Radiation Safety Officer;

the name, telephone number, and e-mail address of the individual to be contacted about the application. If this individual is same as the Radiation Safety Officer, the application may so state;

the application shall indicate if the application is for a new license, or for the renewal of an existing license, by marking the corresponding check box;

if the application is for the renewal of an existing license, the license number shall be provided on the application;

applicants shall indicate the type and category of license as shown on the form by marking the corresponding check box; and

the printed name, title, and signature of the certifying official. The certifying official shall be an individual employed by the business or licensee, who is authorized by the licensee to sign license applications on behalf of the business or licensee.

Persons applying for an amendment to an existing license shall submit an Application for Amendment of Radioactive Materials and Accelerator Licenses. The following information shall appear on the application:

the license number;

amendment number of the current license;

expiration date of the license;

licensee name as it currently appears on the license;

the name, telephone number, and e-mail address of the Radiation Safety Officer;

the name, telephone number, and e-mail address of the individual to be contacted about the application. If this individual is same as the Radiation Safety Officer, item 5b on the application may be left blank;

applicants shall provide a description of the action requested by marking the corresponding checkbox in item 6a. If the check box next to "Other" is marked in item 6a, provide a brief description of the action requested in the space provided in item 6b;

explanation of the action requested; and

the printed name, title, and signature of the certifying official. The certifying official shall be an individual employed by the business or licensee who is authorized by the licensee to sign license applications on behalf of the business or licensee.

Applications specified in this Rule are available at: www.ncradiation.net/rms/rmsforms2.htm(Rev01).htm

c) Reports of leaking sealed sources required by 10 CFR 34.27 shall be made to the agency at the address shown in Rule .0111 of this Chapter in lieu of the NRC.

d) Notifications required by 10 CFR 34.101, including notifications of source disconnects, shall be made to the agency at the address shown in Rule .0111 of this Chapter in lieu of the NRC. In addition to the information required by 10 CFR 34.101(b), notifications of devices with failed or worn through S-tubes shall contain the serial number and storage location of the device, whether the device has been disposed of or returned to the manufacturer, and whether personnel contamination occurred.

e) Requests for exemption under 10 CFR 34.111 shall be made to the agency as specified in Paragraph (b) of this Rule.

(a) In addition to the requirements set forth in Rule .0317 of this Section, a specific license of broad scope for radioactive material will be issued if:

(1) the applicant has engaged in a wide variety of activities involving the use of many different types of radioactive material in a variety of physical and chemical forms; and

History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. April 1, 1999; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0323 Eff. February 1, 2015;

10A NCAC 15 .0324 SPECIFIC LICENSES: BROAD SCOPE
the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(A) the establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

(B) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety measures; and

(C) the establishment of appropriate administrative procedures to assure:

(i) control of procurement and use of radioactive material;

(ii) completion of safety evaluations of proposed uses of radioactive material which takes into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(iii) review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with Part (a)(2)(C) of this Rule prior to use of the radioactive material.

(3) Unless specifically authorized pursuant to other rules of this Section, persons licensed under this Rule shall not:

(A) conduct tracer studies in the environment involving direct release of radioactive material;

(B) receive, acquire, own, possess, use, or transfer devices containing 100,000 curies or more of byproduct material in sealed sources used for irradiation of materials;

(C) conduct activities for which a specific license issued by the agency under the rules of this Section is required; or

(D) add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

(4) Each specific license of broad scope issued under this Rule shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee’s radiation safety committee.

(b) In addition to the requirements set forth in Rule .0319 of this Section, a specific license of broad scope for radioactive material, human use, will be issued only if:

(1) the applicant has appointed a radiation safety committee as required in Part (a)(2)(A) of this Rule, except that this committee shall evaluate all proposals for research, diagnostic and therapeutic use of radioactive material within the medical facility;

(2) membership of the committee consists of physicians specializing in nuclear medicine, diagnostic radiology, clinical pathology, and a pharmacist specializing in radiopharmacy, someone competent in radiation safety and a representative of the hospital management; and

(3) the applicant for a medical radioactive materials license of broad scope has an ongoing teaching program with interns and residents associated with a four-year medical school.
An application for a specific license authorizing the manufacture and initial distribution of devices containing byproduct material to persons exempt from licensing under Rule .0305(c) of this Section shall comply with the provisions of Rule .0317(a), (b)(1), (c), and (d) of this Section as applicable to the licensed activities.

History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0327 Eff. February 1, 2015;

10A NCAC 15 .0328 SPECIFIC LICENSES: MANUFACTURE DEVICES TO PERSONS LICENSED
An application for a specific license authorizing the manufacture and initial transfer of devices containing byproduct material to persons generally licensed under Rule .0309 of this Section shall comply with the provisions of Rule .0317(a), (b)(2), (c), and (d) of this Section as applicable to the licensed activities.

History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0329 Eff. February 1, 2015;

10A NCAC 15 .0329 SPECIFIC LICENSES: LUMINOUS SAFETY DEVICES IN AIRCRAFT
An application for a specific license authorizing the manufacture, assembly, repair, and initial transfer devices containing byproduct material to persons generally licensed under Rule .0311 of this Section shall comply with the provisions of Rule .0317(a), (b)(2), (c), and (d) of this Section as applicable to the licensed activities.

History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0329 Eff. February 1, 2015;

10A NCAC 15 .0330 SPECIFIC LICENSES: MANUFACTURE OF CALIBRATION SOURCES
An application for a specific license authorizing the manufacture and initial transfer of calibration or reference sources for distribution to persons generally licensed under Rule .0312 of this Section shall comply with the provisions of:

(1) Rule .0317(a), (c), and (d) of this Section;
(2) Rule .0317(b)(2) of this Section for calibration or reference sources containing byproduct material; and
(3) Rule .0317(b)(12) of this Section for calibration or reference sources containing plutonium.

History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0330 Eff. February 1, 2015;

10A NCAC 15 .0331 SPECIFIC LICENSES-MANUFACTURE OF IN VITRO TEST KITS
An application for a specific license authorizing the manufacture and initial transfer of devices containing byproduct material to persons generally licensed under Rule .0314 of this Section shall comply with the provisions of Rule .0317(a), (b)(2), (c), and (d) of this Section as applicable to the licensed activities.

History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. October 1, 2013; January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0331 Eff. February 1, 2015;

10A NCAC 15 .0332 SPECIFIC LICENSES: MANUFACTURE OF ICE DETECTION DEVICES
An application for a specific license authorizing the manufacture and initial transfer of generally licensed ice detection devices for transfer to a person generally licensed under Rule .0315 of this Section shall comply with the provisions of Rule .0317(a), (b)(2), (c), and (d) of this Section as applicable to the licensed activities.

History Note: Authority G.S. 104E-7; 104E-10(b); Eff. February 1, 1980; Transferred and Recodified from 15A NCAC 11 .0332 Eff. February 1, 2015; Amended Eff. March 1, 2017.

10A NCAC 15 .0333 SPECIFIC LICENSES: MANUFACTURE OF RADIOPHARMACEUTICALS
(a) An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to Rules .0318, .0319, or .0320 of this Section for medical use shall be approved if the applicant meets the following conditions:
   (1) the applicant satisfies the requirements of Rule .0317 of this Section; and
   (2) the applicant meets the applicable requirements in Section 32.72 of 10 CFR Part 32, and Section 30.32(j) of 10 CFR Part 30.
(b) Authorization under this Rule to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.
(c) Each licensee authorized under this Rule to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:
   (1) satisfy the labeling requirements in Rule .1626 of this Chapter for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium; and
   (2) possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in this Rule.
(d) A licensee that is a pharmacy authorized under Rule .0333 of this Section to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs be:
   (1) an authorized nuclear pharmacist that meets the requirements in Rule .0318 of this Section; or
   (2) an individual under the supervision of an authorized nuclear pharmacist as specified in Rule .0318 of this Section.
(e) A pharmacy authorized under this Rule to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist shall meet the requirements of Rule .0318 of this Section.

History Note: Authority G.S. 104E-7; 104E-10(b); Eff. February 1, 1980; Amended Eff. October 1, 2013; November 1, 2007; Transferred and Recodified from 15A NCAC 11 .0333 Eff. February 1, 2015.

10A NCAC 15 .0334 SPECIFIC LICENSES: GENERATORS AND REAGENT KITS
An application for a specific license to manufacture and distribute generators and reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to Rule .0321 of this Section for the generators, reagent kits and associated medical uses shall be approved if the applicant meets the following conditions:
   (1) the applicant satisfies the general requirements of Rule .0317 of this Section; and
   (2) the applicant satisfies the applicable requirements in Section 32.73 of 10 CFR Part 32 or their agreement state equivalent.

History Note: Authority G.S. 104E-7; 104E-10(b); Eff. February 1, 1980; Amended Eff. October 1, 2013; Transferred and Recodified from 15A NCAC 11 .0334 Eff. February 1, 2015.

10A NCAC 15 .0335 SPECIFIC LICENSES: PRODUCTS CONTAINING DEPLETED URANIUM
An application for a specific license authorizing the manufacture and initial transfer of products containing depleted uranium to persons generally licensed under Rule .0307(b) of this Section, shall comply with the provisions of Rule .0317(a), (b)(9), (c), and (d) of this Section as applicable to the licensed activities.

History Note: Authority G.S. 104E-7; 104E-10(b); Eff. February 1, 1980; Amended Eff. January 1, 1994; Transferred and Recodified from 15A NCAC 11 .0335 Eff. February 1, 2015; Amended Eff. March 1, 2017.

10A NCAC 15 .0336 COPIES OF APPLICABLE FEDERAL REGULATIONS

History Note: Authority G.S. 104E-7; 104E-10(b); Eff. February 1, 1980; Repealed Eff. May 1, 1993; Transferred and Recodified from 15A NCAC 11 .0336 Eff. February 1, 2015.

10A NCAC 15 .0337 ISSUANCE OF SPECIFIC LICENSES AND SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATES

(a) An application for a specific license shall be approved, and a specific license issued, or amended by the agency if the agency determines that the applicant satisfies the provisions of 10 CFR 30.33(a)(1) through (4), 30.39, 40.32(a) through (f), and 70.23(a)(1) through (6) as applicable to the licensed activities, and any additional requirements in:

1. 10 CFR 32.11, 32.14, 32.18, 32.21, 32.22, 32.26, and 32.30 as applicable to the manufacture of exempt concentrations of byproduct material, and items containing exempt concentrations of byproduct material listed in 10 CFR Part 32, Subpart A;
2. 10 CFR 32.51, 32.53, 32.57, 32.61, and 32.71 as applicable to the manufacturing and distribution of generally licensed items and devices listed in 10 CFR Part 32, Subpart B;
3. 10 CFR 32.72 and 32.74 as applicable to the manufacturing and distribution of radioactive drugs, sources, or devices listed in 10 CFR Part 32, Subpart C;
4. 10 CFR 33.13 through 33.15, and 33.17 as applicable to activities of broad scope;
5. 10 CFR 34.13 for industrial radiography;
6. 10 CFR 35.18 for the medical use of radioactive materials;
7. 10 CFR 36.13 for the use of sealed sources to irradiate materials;
8. 10 CFR 39.13, 39.15, and 39.17 for the use of radioactive materials in well logging;
9. 10 CFR 40.34 for the use of source material in the manufacture and initial transfer of devices containing depleted uranium to a person generally licensed under Rule .0307(b) of this Section;
10. 10 CFR 40.52 for the use of source material in the manufacture of exempt devices listed in Rule .0305 of this Section;
11. 10 CFR 40.54 for the initial transfer of source material to a person generally licensed under Rule .0307(a) of this Section;
12. 10 CFR 61.23(a) through (h), and (k), and Section .1200 of this Chapter for the receipt, possession, transfer, or disposal of radioactive waste received from another person; and
13. 10 CFR 70.31(a) and (b) for the use of special nuclear material.

(b) An application for a new or amended Sealed Source and Device Registration certificate shall be approved by the agency, and a new or amended Sealed Source and Device Registration certificate issued in accordance with 10 CFR 32.210(d) and (e).

(c) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

History Note: Authority G.S. 104E-7; 104E-10(b); Eff. February 1, 1980; Amended Eff. June 1, 1993; Transferred and Recodified from 15A NCAC 11 .0337 Eff. February 1, 2015; Amended Eff. March 1, 2017.
10A NCAC 15 .0338  SPECIFIC TERMS AND CONDITIONS OF LICENSES

(a) All licenses issued by the agency for activities authorized under the rules of this Section are subject to the terms and conditions listed in 10 CFR 30.34(a) through (d), and 30.34(e)(2) through (j)(4). In addition to these terms and conditions, licenses of broad scope are subject to the terms and conditions listed in 10 CFR 33.17.

(b) All licenses issued by the agency authorizing the possession and use of source material are subject to the terms and conditions listed in 10 CFR 40.35, 40.41, 40.46, 40.53, 40.55, and 40.56.

(c) All licenses issued by the agency authorizing the receipt, possession, or disposal of radioactive waste received from another person are subject to the terms and conditions listed in 10 CFR 61.24, 61.25, and the Rules in Section .1200 of this Chapter.

(d) All licenses issued by the agency authorizing the possession and use of special nuclear material are subject to the terms and conditions of 10 CFR 70.32.

(e) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-id?SID=2beeece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

History Note:  Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. October 1, 2013; May 1, 1993; May 1, 1992; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0338 Eff. February 1, 2015;

10A NCAC 15 .0339  EXPIRATION AND TERMINATION OF LICENSES AND DECOMMISSIONING

(a) Each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal, as required in Rule .0340 of this Section, not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days prior to the expiration date stated in the existing license, the existing license expires at the end of the day on which the agency makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(b) Each specific license revoked by the agency, as provided for in Rule .0344 of this Section, expires at the end of the day on the date of the agency's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by agency order.

(c) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of residual radioactive material present as contamination until the agency notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

(1) limit actions involving radioactive material to those related to decommissioning; and
(2) continue to control entry to restricted areas until they are suitable for release for unrestricted use and the agency notifies the licensee in writing that the license is terminated.

(d) Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the agency in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Commission requirements, or submit within 12 months of notification a decommissioning plan, if required by Subparagraph (g)(1) of this Rule, and begin decommissioning upon approval of that plan if:

(1) The license has expired pursuant to Paragraphs (a) or (b) of this Rule;
(2) The licensee has decided to permanently cease principal activities at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Commission requirements;
(3) No principal activities under the license have been conducted for a period of 24 months; or
(4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Commission requirements.

(e) Coincident with the notification requirements set forth in Paragraph (d) of this Rule, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to Rule .0353 of this Section in conjunction with a license issuance or renewal, or as required by this Rule. The amount of the financial assurance must
be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established in Paragraph (g) of this Rule.

(1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this Rule becomes effective.

(2) Following agency approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the agency.

(f) The agency may grant a request to extend the time periods required in Paragraph (d) of this Rule if the agency determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request shall be submitted to the agency no later than 30 days before notification pursuant to Paragraph (d) of this Rule. The schedule for decommissioning set forth in Paragraph (d) of this Rule may not commence until the agency has made a determination on the licensee's request.

(g) A decommissioning plan shall be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the agency and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of following cases:

(1) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(2) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(3) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(4) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation. For the purpose of Subparagraphs (g)(2)-(4) of this Rule, significantly higher or significantly greater is defined as an increase likely to result in either an increase in radiation exposure to workers or the public in excess of one percent of their respective annual radiation exposure limit.

(h) The agency may approve an alternate schedule for submittal of a decommissioning plan required pursuant to Paragraph (d) of this Rule if the agency determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(i) Procedures such as those listed in Paragraph (g) of this Rule with potential health and safety impacts may not be carried out prior to agency approval of the decommissioning plan.

(j) The proposed decommissioning plan for the site or separate building or outdoor area shall include:

(1) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(2) A description of planned decommissioning activities;

(3) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(4) A description of the planned final radiation survey;

(5) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning; and

(6) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in Paragraph (m) of this Rule.

(k) The proposed decommissioning plan shall be approved by the agency if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be protected.

(l) Except as provided in Paragraph (m) of this Rule, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning. Except as provided in Paragraph (m) of this Rule, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(m) The agency may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the agency determines that the alternative is warranted by consideration of the following:
Whether it is technically feasible to complete decommissioning within the allotted 24 month period;
Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24 month period;
Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;
Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and
Other site-specific factors which the agency may consider appropriate on a case-by-case basis, such as:
- regulatory requirements of other government agencies;
- lawsuits;
- ground-water treatment activities;
- monitored natural ground-water restoration;
- actions that could result in more environmental harm than deferred cleanup; and
- other factors beyond the control of the licensee.

As the final step in decommissioning, the licensee shall:
(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed "Certificate of Disposition"; and
(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner. The licensee shall, as appropriate:
- Report levels of gamma radiation in units of microrem (millisieverts) per hour at one meter from surfaces;
- Report levels of radioactivity, including alpha and beta, in units of microcuries per 100 square centimeters (or disintegrations per minute), removable and fixed, for surfaces; microcuries per milliliter for water; and picocuries per gram for solids such as soils or concrete; and
- Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

Specific licenses shall be terminated by written notice to the licensee when the agency determines that:
(1) radioactive material has been properly disposed;
(2) reasonable effort has been made to eliminate residual radioactive contamination, if present; and
(3) a radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the requirements for decommissioning described in Rule .1653 of this Chapter, or other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the requirements for decommissioning described in Rule .1653 of this Chapter.

History Note:  Authority G.S. 104E-7; 104E-10(b); 104E-18;
Eff. February 1, 1980;
Amended Eff. April 1, 1999; August 1, 1998; May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0339 Eff. February 1, 2015.

10A NCAC 15 .0340  RENEWAL OF LICENSES
Applications for renewal of specific licenses shall be filed in accordance with Rule .0317 of this Section.

History Note:  Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. August 1, 1998;
Transferred and Recodified from 15A NCAC 11 .0340 Eff. February 1, 2015.

10A NCAC 15 .0341  AMENDMENT OF LICENSES AT REQUEST OF LICENSEE
Applications for amendment of a license shall be filed in accordance with Rule .0317 of this Section and shall specify the respects in which the licensee desires his license to be amended and the grounds for such amendment. The applicant shall submit such other supporting information as required by the agency.

History Note:  Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
10A NCAC 15 .0342 AGENCY ACTION ON APPLICATIONS TO RENEW OR AMEND
In considering an application by a licensee to renew or amend his license, the agency shall apply the criteria set forth in the applicable rules of this Section.

History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0342 Eff. February 1, 2015.

10A NCAC 15 .0343 TRANSFER OF MATERIAL
(a) Any person licensed under the rules of this Section transferring byproduct material shall comply with the provisions of 10 CFR 30.41.
(b) Any person licensed under the rules of this Section transferring source material shall comply with the provisions of 10 CFR 40.51.
(c) Any person licensed under the rules of this Section transferring special nuclear material shall comply with the provisions of 10 CFR 70.42.
(d) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/textidx?SID=2beece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. May 1, 1993; June 1, 1989;
Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0343 Eff. February 1, 2015;

10A NCAC 15 .0344 MODIFICATION: REVOCATION: AND TERMINATION OF LICENSES AND SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATES
(a) All licenses authorizing the receipt, possession, use, and transfer of byproduct material, and all sealed source and device registration certificates issued by the agency under the rules of this Section, are subject to modification by the agency in accordance with 10 CFR 30.61.
(b) All licenses issued by the agency for the receipt, possession, use, and transfer of source material under the rules of this Section, are subject to modification by the agency in accordance with 10 CFR 40.71.
(c) All licenses issued by the agency for the receipt, possession, transfer, or disposal of radioactive waste from another person are subject to modification by the agency in accordance with the provisions of 10 CFR 61.24.
(d) All licenses issued by the agency for the receipt, possession, use, and transfer of special nuclear material are subject to modification by the agency in accordance with 10 CFR 70.81.
(e) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/textidx?SID=2beece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

History Note: Authority G.S. 104E-7; 104E-10(b); 104E-13;
Eff. February 1, 1980;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0344 Eff. February 1, 2015;

10A NCAC 15 .0345 RECIPROCAL RECOGNITION OF LICENSES
(a) Subject to these Rules, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the
licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in any calendar year provided that the following requirements are satisfied:

1. The licensing document does not limit the activity authorized by such document to specified installations or locations;

2. The out-of-state licensee notifies the agency in writing at least three days prior to engaging in such activity; such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document; if, for a specific case, the three day period would impose an undue hardship on the out-of-state licensee, including but not limited to adverse impact on the business of the licensee or his customer, he may upon application to the agency, obtain permission to proceed sooner; the agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in this Rule if the agency determines that such written notifications are not necessary to ensure compliance with the rules in this Chapter or to protect the public;

3. The out-of-state licensee complies with all applicable rules of the agency and with all the terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the agency;

4. The out-of-state licensee supplies such other information as the agency may request; and

5. The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this Rule except by transfer to a person:
   (A) specifically licensed by the agency or by the U.S. Nuclear Regulatory Commission to receive the material, or
   (B) exempt from the requirements for a license for the material under Rule .0303 of this Section.

(b) Additional reciprocity is provided in Rule .0310 of this Section.

(c) The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining that the action is necessary in order to prevent undue hazard to public health and safety or property.

History Note: Authority G.S. 104E-7; 104E-10(b); Eff. February 1, 1980; Amended Eff. June 1, 1993; Transferred and Recodified from 15A NCAC 11 .0345 Eff. February 1, 2015.

10A NCAC 15 .0346 PREPARATION OF RADIOACTIVE MATERIAL FOR TRANSPORT
(a) No licensee shall deliver any radioactive material to a carrier for transport, unless:

1. The licensee complies with the applicable requirements of the regulations, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such regulations relate to the packing of radioactive material, and to the monitoring, marking and labeling of those packages;

2. The licensee has established procedures for opening and closing packages in which radioactive material is transported to provide safety and to assure that, prior to the delivery to a carrier for transport, each package is properly closed for transport; and

3. Prior to delivery of a package to a carrier for transport, the licensee shall assure that any special instructions needed to safely open the package are sent to, or have been available to the consignee.

(b) For the purpose of this Rule, a licensee who transports his own licensed material as a private carrier is considered to have delivered the material to a carrier for transport.

(c) In addition to the requirements of Paragraphs (a) and (b) of this Rule, prior to the transport of any nuclear waste, as defined in Part (d)(2)(A) of Rule .0316 of this Section, outside the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport to the governor's designee of each state through which the waste will be transported.

(d) Each advance notification required by Paragraph (c) of this Rule shall contain the following information:

1. the name, address, and telephone number of the shipper, carrier and receiver of the shipment;

2. a description of the nuclear waste contained in the shipment as required by the regulations of the U.S. Department of Transportation in 49 CFR 172.202 and 172.203(d);

3. the point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;
(4) the seven-day period during which arrival of the shipment at state boundaries is estimated to occur;
(5) the destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and
(6) a point of contact with a telephone number for current shipment information.

(e) The notification required by Paragraph (c) of this Rule shall be made in writing to the office of each appropriate governor or governor's designee. A notification delivered by mail must be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger must reach the office of the governor or governor's designee at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for one year.

(f) The licensee shall notify each appropriate governor or governor's designee of any changes to schedule information provided pursuant to Paragraph (c) of this Rule. Such notification shall be by telephone to a responsible individual in the office of the governor or governor's designee of the appropriate state or states. The licensee shall maintain for one year a record of the name of the individual contacted.

(g) Each licensee who cancels a nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor or governor's designee of the appropriate state or states. A copy of the notice shall be retained by the licensee for one year.

(h) A list of governors or governors' designees for other states is available from the agency by contacting the North Carolina Division of Radiation Protection, P.O. Box 27687, Raleigh, North Carolina 27611-7687, Phone No. 919/571-4141 or facsimile number 919/571-4148. For the notification required in Paragraphs (c) through (g) of this Rule in North Carolina:

(1) governor's designee is the North Carolina Highway Patrol, Operations Office;
(2) mailing address: P. O. Box 27687, Raleigh, North Carolina 27611-7687;
(3) telephone 919/733-4030 from 8 a.m. to 5 p.m. workdays, and 919/733-3861 all other times.

History Note: Authority G.S. 104E-7; 104E-10(b); 104E-15(a);
Eff. February 1, 1980;
Amended Eff. May 1, 1993; November 1, 1989; October 1, 1982;
Transferred and Recodified from 15A NCAC 11 .0346 Eff. February 1, 2015.

10A NCAC 15 .0347 SECURITY REQUIREMENTS

History Note: Authority G.S. 104E-18;
Eff. February 1, 1980;
Repealed Eff. May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0347 Eff. February 1, 2015.

10A NCAC 15 .0348 SPECIFIC LICENSES: CERTAIN INCINERATOR FACILITIES

(a) In addition to the requirements set forth in Rule .0317 of this Section, an application for a license authorizing construction and operation of an incinerator as part of a radioactive waste processing facility as defined in Rule .0104 of this Chapter shall include an environmental assessment that addresses the following topics:

(1) description of the applicant:
   (A) the company or corporate structure with the names, addresses and titles of officers;
   (B) present products and activities;
   (C) prior experience in the use, processing and disposal of radioactive material;
   (D) financial and technical ability to construct, operate and decommission the proposed radioactive waste processing facility;

(2) description of the site:
   (A) physical location and general description to include nearest buildings, residences, schools, hospitals, etc.;
   (B) populations and land use in the general area to include nearest buildings, residences, schools, hospitals, etc.;
   (C) geological and hydrological characterization of the site to include soil type, topography, past and projected seismic activity, groundwater, aquifers and surface waters;
   (D) meteorology to include climate, distribution of wind speed and direction, atmospheric stability and dispersion characteristics, and data on precipitation, floods, hurricanes and tornados;
(E) background radiation and radioactivity;
(F) transportation routes;

(3) incinerator design:
(A) general description;
(B) manufacturer, basis for selecting the proposed incinerator design and identification of operating incinerators of the same or similar design;
(C) maximum capacity, minimum chamber temperatures, minimum chamber residence times, residual ash collection and effluent controls (e.g., scrubber filters and stack);
(D) decontamination, maintenance and anticipated operating life;
(E) waste handling, storage and injection systems;
(F) instrumentation and controls;
(G) minimum performance specifications for the incinerator and effluent control systems, and preoperational testing/certification program;

(4) facility design:
(A) compartmentalization/zoning, waste storage and handling areas, waste flow, ventilation and contamination control/containment;
(B) sanitary sewer, drains, holdup systems, showers and other liquid handling systems;

(5) management and staffing:
(A) structure of facility organization showing line configuration of the radiation safety officer;
(B) qualifications of management, supervisory and safety personnel;
(C) staff training program;

(6) description of waste:
(A) general chemical, physical and radiological properties;
(B) maximum quantity of each radionuclide to be incinerated per year;
(C) maximum quantity of each radionuclide to be stored on-site at any one time;
(D) maximum quantity of each toxic or hazardous constituent of the waste to be incinerated per year;
(E) maximum quantity of each toxic or hazardous constituent of the waste to be stored on-site at any one time;
(F) acceptance and rejection criteria for waste to be received for incineration;

(7) treatment of waste to be shipped off-site:
(A) classification;
(B) immobilization;
(C) packaging;
(D) storage;
(E) shipment;
(F) disposal;
(G) processing and disposal of ash;

(8) prelicensing and operational public information program:
(A) state and local government;
(B) media and public;

(9) plan for maintaining radiation exposures and releases of radioactivity as low as reasonably achievable (ALARA):
(A) procedures, systems and criteria to maintain whole body, thyroid, and other organ radiation doses of the off-site public as low as reasonably achievable below the limits stated in Section .1600 of this Chapter;
(B) procedures, systems and criteria to maintain whole body, thyroid, and other organ radiation doses of on-site personnel as low as reasonably achievable below the limits established in Section .1600 of this Chapter;

(10) off-site impact assessment for routine operation:
(A) maximum quantity and concentration of each radionuclide and toxic or hazardous constituent of the waste released annually to the air, to the water and to the soil;
(B) maximum radiation doses to off-site populations to include dose to the nearest resident, a description of computational models, sample computations and a summary of any previous experience;
(C) maximum off-site radionuclide concentrations in air, soil, water and food;
(11) monitoring programs and systems:
   (A) analytical and portable monitoring equipment for radiological and chemical measurements;
   (B) inspection, monitoring and analysis of waste containers and waste prior to incineration;
   (C) alarms, area monitors, stack/effluent monitors and facility shutdown mechanisms to include action levels, reset and restart procedures and criteria;
   (D) personnel monitoring and bioassay;
   (E) preoperational environmental monitoring;
   (F) operational environmental monitoring, to include, if available, a copy of the last environmental monitoring report filed with the U.S. Nuclear Regulatory Commission or agreement state program;

(12) other rules, standards and permits:
   (A) federal, state and local regulations and standards which will apply to the proposed facility or would apply to the facility in the absence of the radioactive content of the waste;
   (B) other permits which are required to include the current status of applications for and issuance of such permits;

(13) accident analysis:
   (A) identification of accident modes;
   (B) major credible accidents and projected potential off-site impacts;
   (C) mitigation of accidents and protection of the public;

(14) emergency response plan:
   (A) on-site response;
   (B) local and county;
   (C) state and regional;
   (D) training and public information;
   (E) if available, copies of most current emergency response plans submitted to the U.S. Nuclear Regulatory Commission or an agreement state;

(15) decontamination and decommissioning:
   (A) schedule;
   (B) procedure;
   (C) radioactive waste disposal plan.

(b) The applicant shall submit to the agency ten copies of the license application, environmental assessment, and other information required in Paragraph (a) of this Rule and Rule .0317 of this Section.

History Note:  Authority G.S. 104E-7(2); 104E-7(a)(8); 104E-10(b);
Eff. October 1, 1984;
Amended Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0348 Eff. February 1, 2015.

10A NCAC 15 .0349 EXEMPTIONS: WASTE MANAGEMENT BY GENERATORS

History Note:  Authority G.S. 104E-7(a)(10);
Eff. June 1, 1989;
Amended Eff. January 1, 1994;
Filed as a Temporary Amendment Eff. November 22, 1995, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. May 1, 1996;
Transferred and Recodified from 15A NCAC 11 .0349 Eff. February 1, 2015;

10A NCAC 15 .0350 RECORDS AND REPORTS OF MISADMINISTRATION

History Note:  Authority G.S. 104E-7(a)(2);
Eff. June 1, 1989;
Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. May 1, 1995; May 1, 1992;
10A NCAC 15 .0351  SPECIFIC LICENSES: MOBILE NUCLEAR MEDICINE SERVICES

(a) Provided that mobile nuclear medicine services shall be limited to clients who do not have a specific radioactive material license for the same services, unless the client’s specific license specifically authorizes the use of such mobile services, the agency will license a mobile nuclear medicine service for the following services:

1. uptake, dilution and excretion;
2. imaging and localization;
3. sealed sources for diagnosis; and
4. certain in vitro clinical or laboratory testing.

(b) The mobile nuclear medicine service licensee shall:

1. obtain a letter signed by the management of each client for which services are rendered that authorizes the licensee to use radioactive material at the client's address of use;
2. retain the letter for two years after the last provision of service;
3. not order radioactive material to be delivered directly from the manufacturer or distributor to the client's address of use;
4. transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceuticals kits;
5. bring into each address of use of all radioactive material to be used and before leaving, remove all unused radioactive material and all associated waste;
6. secure or keep under constant surveillance and immediate control all radioactive material when in transit or at an address of use;
7. carry survey instruments, dose calibrators and all other transported equipment for proper function before medical use at each address of use;
8. carry a radiation detection survey meter in each vehicle that is being used to transport radioactive material and, before leaving a client address of use, survey all radiopharmaceutical areas of use with a radiation detection survey meter to ensure that all radiopharmaceuticals and all associated waste have been removed; and
9. retain a record of each survey required in Subparagraph (b)(8) of this Rule for two years, where such records shall include:
   (A) the date of the survey,
   (B) a plan of each area that was surveyed,
   (C) the measured dose rate at several points in each area of use expressed in millirem per hour,
   (D) the instrument used to make the survey; and
   (E) the initials of the individual who performed the survey.

History Note: Filed as a Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Authority G.S. 104E-7(a)(2); 104E-10(b); Eff. June 1, 1989; Amended Eff. May 1, 1995; Transferred and Recodified from 15A NCAC 11 .0351 Eff. February 1, 2015.

10A NCAC 15 .0352  EMERGENCY PLANS

(a) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in the table in Subparagraph (e)(1) of this Rule must contain either:

1. an evaluation showing that the maximum dose to a person off-site due to a release of radioactive materials would not exceed one rem effective dose equivalent or five rems to the thyroid; or
2. an emergency plan for responding to a release of radioactive material.

(b) The following factors shall be used to support an evaluation submitted under Subparagraph (a)(1) of this Rule:

1. the radioactive material is physically separated so that only a portion could be involved in an accident;
2. all or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;
3. the release fraction in the respirable size range would be lower than the release fraction shown in Subparagraph (e)(1) of this Rule due to the chemical or physical form of the material;
the solubility of the radioactive material would reduce the dose received; 
the facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Subparagraph (e)(1) of this Rule; and 
the operating restrictions or procedures would prevent a release fraction as large as that shown in Subparagraph (e)(1) of this Rule; or 
the factors appropriate for the specific facility.

(c) An emergency plan for responding to a release of radioactive material submitted under Subparagraph (a)(2) of this Rule must include the following information:

(1) a description of the licensee's facility and potentially impacted area; 
(2) the identification of each type of radioactive materials accident for which protective actions may be needed; 
(3) the classification system for classifying accidents as alerts or site area emergencies; 
(4) the identification of the means of detecting each type of accident in a timely manner quickly enough to mitigate off-site consequences; 
(5) a description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on-site, and a description of the program for maintaining the equipment; 
(6) a description of the methods and equipment to assess releases of radioactive materials; 
(7) a description of the responsibilities of licensee personnel, should an accident occur, including identification of personnel responsible for notifying off-site response organizations and the agency, and responsibilities for developing, maintaining, and updating the plan; 
(8) a description of notification and coordination, to include a commitment to and a brief description of the means to notify off-site response organizations and request off-site assistance, including medical assistance for the treatment of contaminated injured on-site workers when needed, provided that:

(A) a control point is established; 
(B) the notification and coordination is planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination; 
(C) the licensee commits to notify the agency after notification of the appropriate off-site response organizations, within one hour after the licensee declares an emergency; and 
(D) the reporting requirements in this Subparagraph do not substitute for or relieve the licensee from responsibility for complying with the requirements in the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499 or other State or federal reporting requirements; 
(9) description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to off-site response organizations and to the agency; 
(10) description of the frequency, performance objectives and plans for the training that the licensee will provide to workers on how to respond to an emergency, including any instructions and orientation tours the licensee offers to fire, police, medical and other emergency personnel, where such training shall:

(A) familiarize personnel with site-specific emergency procedures; and 
(B) prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios; 
(11) description of the means of restoring the facility to a safe condition after an accident; 
(12) description of provisions for conducting quarterly communications checks with off-site response organizations and biennial on-site exercises to test response to simulated emergencies where such provisions meet the following requirements:

(A) quarterly communications checks with off-site response organizations include the check and update of all necessary telephone numbers; 
(B) while participation of off-site response organizations in biennial exercises is not required, the licensee shall invite off-site response organizations to participate in the biennial exercises; 
(C) accident scenarios for biennial exercises are not known to most exercise participants; 
(D) critique of each exercise using individuals who do not have direct implementation responsibility for the plan. Critiques of exercises evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response; and 
(E) deficiencies found by the critiques in Part (c)(12)(D) of this Rule are corrected; and
(13) certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499, if applicable to the applicant’s activities at the proposed place of use of the radioactive material.

(d) The licensee shall submit the emergency plan to allow the off-site response organizations expected to respond in case of an accident 60 days to comment on the licensee’s emergency plan before submitting the plan to the agency. The licensee shall provide any comments received within the 60 day comment period to the agency with the emergency plan.

(e) Quantities of radioactive material requiring an emergency plan for responding to a release as used in this Rule and instructions for use are:

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<thead>
<tr>
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<td>Any other beta-gamma emitter</td>
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<td>Any other alpha emitter</td>
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<tr>
<td>Packaged waste, alpha</td>
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For combinations of radioactive materials, an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in the table in Paragraph (e) of this Rule exceeds one.

Waste packaged in Type B containers, as defined in 10 CFR Part 71.4, does not require an emergency plan.

History Note: Authority G.S. 104E-7; 104E-18; 10 CFR 30.72; Eff. May 1, 1992; Amended Eff. October 1, 2013; May 1, 1993; October 1, 1992; Transferred and Recodified from 15A NCAC 11 .0352 Eff. February 1, 2015.

10A NCAC 15 .0353 FINANCIAL ASSURANCE AND RECORD-KEEPING FOR DECOMMISSIONING

(a) Applications for a new license filed with the agency under Rule .0317 of this Section, and applications for the renewal of a license filed with the agency under Rule .0340 of this Section, shall include an evaluation of the need for financial assurance based upon the quantity of radioactive material requested in the application.

(b) Applications for amendment of a license filed with the agency under Rule .0341 of this Section, changing the quantity of radioactive material authorized for possession by a licensee, shall include an evaluation of the need for financial assurance based upon the quantity of radioactive material that shall be authorized by the amended license.

(c) Evaluation of the need for financial assurance shall be performed by the applicant based upon the type of application listed in Paragraph (a) or (b) of this Rule, using one or more the methods shown in Paragraph (d) of this Rule.

(d) Applicants shall require financial assurance to possess the following types and quantities of radioactive material:

(1) byproduct material in the quantities shown in 10 CFR 30.35(a) or (b); 
(2) source material in the quantities shown in 10 CFR 40.36(a) or (b); and 
(3) special nuclear material in the quantities shown in 10 CFR 70.25(a)(2) or (b).

(e) Applicants requiring financial assurance shall:

(1) comply with the provisions of 10 CFR 30.35(c) for the possession of byproduct material; 
(2) comply with the provisions of 10 CFR 40.36(c) for the possession of source material; and 
(3) comply with the provisions of 10 CFR 70.25(c) for the possession of special nuclear material.

(f) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/textidx?SID=2beeece594411a03e50b2468ae31f89b&pid=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

History Note: Authority G.S. 104E-7; 104E-18; Eff. May 1, 1992; Amended Eff. May 1, 2006; April 1, 1999; August 1, 1998; January 1, 1994; Transferred and Recodified from 15A NCAC 11 .0353 Eff. February 1, 2015; Amended Eff. March 1, 2017.

10A NCAC 15 .0354 METHODS OF FINANCIAL ASSURANCE FOR DECOMMISSIONING

(a) Licensees or applicants for a radioactive materials license authorizing the use of:

(1) byproduct material shall provide for financial assurance in compliance with 10 CFR 30.35(f);
(2) source material shall provide for financial assurance in compliance with 10 CFR 40.36(e); and
(3) special nuclear material shall provide for financial assurance in compliance with 10 CFR 70.25(f).

(b) Licensees or applicants for a radioactive materials license authorizing the use of any combination of radioactive material listed in Paragraph (a) of this Rule shall provide for financial assurance in accordance with the evaluation performed for Rule .0353(c) of this Section.

(c) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/textidx?SID=2beeece594411a03e50b2468ae31f89b&pid=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

History Note: Authority G.S. 104E-7; 104E-18; Eff. May 1, 1992; Transferred and Recodified from 15A NCAC 11 .0354 Eff. February 1, 2015; Amended Eff. March 1, 2017.
10A NCAC 15 .0355  FINANCIAL TESTS: SELF- AND PARENT CO. GUARANTEES: DECOMMISSIONING FUNDING

(a) Licensees or applicants for a radioactive materials license requiring financial assurance under Rule .0353 of this Section may self-guarantee funds, or provide a guarantee of funds by their parent company for decommissioning funding in accordance with the provisions of Rule .0354 of this Section, except that:

1. Parent companies guaranteeing funds for decommissioning shall have a tangible net worth of at least ten million dollars ($10,000,000) to meet the asset requirement set forth in Section II, Paragraphs A.1(iii) or A.2(iii), of Appendix A to 10 CFR Part 30;

2. Licensees self-guaranteeing funds for decommissioning who issue bonds, and whose bonds meet the bond rating requirements of Section II, Paragraph A.(3) of Appendix C to 10 CFR Part 30 shall have a tangible net worth of at least ten million dollars ($10,000,000), and at least six times the amount of decommissioning funds being assured by the self-guarantee to meet the asset requirements set forth in Section II, Paragraph A.(2) and A.(3) of Appendix C to 10 CFR Part 30;

3. Licensees self-guaranteeing funds for decommissioning who do not issue bonds, or whose bonds do not meet the bond rating requirements of Section II, Paragraph A.(3) of Appendix C to 10 CFR Part 30, shall have a tangible net worth of at least ten million dollars ($10,000,000), and at least six times the amount of decommissioning funds being assured by the self-guarantee to meet the asset requirements set forth in Section II, Paragraph A.(1) and A.(2) of Appendix D to 10 CFR Part 30;

4. Licensees self-guaranteeing funds for decommissioning who are nonprofit publicly funded colleges, universities, or hospitals shall meet the funding requirements set forth in 10 CFR 30.35(f)(4). For the purpose of this Rule, publicly funded trade schools, technical institutes, technical colleges, technical universities, or other publicly funded educational institutions are to be interpreted as "nonprofit publicly funded colleges;"

5. Licensees self-guaranteeing funds for decommissioning who are nonprofit privately funded, or nonprofit semi-privately funded colleges, or universities who do not issue bonds, or whose bonds do not meet the bond rating requirements of Section II, Paragraph A.(1) of Appendix E to Part 30 shall have an unrestricted endowment consisting of assets worth of at least ten million dollars ($10,000,000), and at least six times the amount of decommissioning funds being assured by the self-guarantee to meet the asset requirements set forth in Section II, Paragraph A.(2) of Appendix E to 10 CFR Part 30; or

6. Licensees self-guaranteeing funds for decommissioning who are nonprofit privately funded, or nonprofit semi-privately funded hospitals who do not issue bonds, or whose bonds do not meet the bond rating requirements of Section II, Paragraph B.(1) of Appendix E to 10 CFR Part 30 shall have a tangible net worth of at least ten million dollars ($10,000,000), and at least six times the amount of decommissioning funds being assured by the self-guarantee to meet the asset requirements set forth in Section II, Paragraph B.(2) of Appendix E to 10 CFR Part 30.

(b) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/textidx?SID=2beeece594411a03e50b2468ae3f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

History Note: Authority G.S. 104E-7; 104E-18;
Eff. May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0355 Eff. February 1, 2015;

10A NCAC 15 .0356  PROCEDURES FOR ADMINISTRATIONS REQUIRING A WRITTEN DIRECTIVE

(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide that:

1. The patient or human research subject's identity is verified before each administration; and

2. Each administration is in accordance with the written directive.

(b) The procedures required by Paragraph (a) of this Rule must address the following items that are applicable to the licensee's use of radioactive material:

1. Verify the identity of the patient or human research subject;

2. Verify that the administration is in accordance with the treatment plan, if applicable, and the written directive;
(3) Check both manual and computer-generated dose calculations; and
(4) Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units.

(c) A licensee shall retain a copy of the procedures required under Paragraph (a) until the agency terminates the pertinent license.

(d) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive shall be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

(e) A revision to an existing written directive may be made:
   (1) if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose, or
   (2) if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

(f) The licensee shall retain a record of the written directive and any revisions to the written directive for three years.

History Note:  Authority G.S. 104E-7; 104E-10(b);
Temporary Adoption Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. May 1, 1995;
Amended Eff. November 1, 2007;

10A NCAC 15 .0357 REPORTING REQUIREMENTS

(a) All reports required by this Rule shall be made to the agency in accordance with Rule .0111 of this Chapter.
(b) Reports of incidents involving exposure, or incidents threatening to cause exposure to radiation in excess of the annual occupational limits of Rule .1604 of this Chapter, shall be made to the agency in accordance with the provisions of 10 CFR 20.2202.
(c) Reports of an event that prevents taking protective actions to avoid exposure to radiation or to radioactive material that could cause exposures in excess of the regulatory limits of this Chapter shall be made to the agency in accordance with the provisions of:
   (1) 10 CFR 30.50 for licensees authorized for the possession and use of byproduct material;
   (2) 10 CFR 40.60 for licensees authorized for the possession and use of source material; and
   (3) 10 CFR 70.50 of this Chapter for licensees authorized for the possession and use of special nuclear material.
(d) Reports of exposure to radiation exceeding the exposure limits in Section .1600 of this Chapter, or to concentrations of radioactive material in any restricted or unrestricted area in excess of licensed or regulatory limits of 10 CFR 20.2203(a)(3) shall be made to the agency in accordance with 10 CFR 20.2203.
(e) Reports of incidents or events occurring at irradiation facilities licensed under the provisions of 10 CFR 36.1(b) shall be made to the agency in accordance with 10 CFR 36.83.
(f) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/textidx?SID=2beeece594411a03e50b2468ae31f89b&pfid=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

History Note:  Authority G.S. 104E-7(a)(2); 104E-10(b);
Temporary Adoption Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0357 Eff. February 1, 2015;
10A NCAC 15 .0358 RELEASE OF PATIENTS CONTAINING RADIOPHARMACEUTICALS OR PERMANENT IMPLANTS

(a) A licensee may authorize the release from its control any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 500 millirem (5 mSv).

(b) The licensee shall provide the released individual, or the individual's parent or guardian, with oral and written instructions, on actions recommended to maintain doses to other individuals as low as reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 100 millirem (1 mSv). If the dose to a breast-feeding infant or child could exceed 100 millirem (1 mSv) if there is no interruption of breast-feeding, the instructions shall include:

(1) Guidance on the interruption or discontinuation of breast-feeding; and
(2) Information on the consequences of failure to follow the guidance.

(c) The licensee shall maintain a record of the basis for authorizing the release of an individual for three years after the date of release, if the total effective dose equivalent is calculated by:

(1) Using the retained activity rather than the activity administered;
(2) Using an occupancy factor less than 0.25 at one meter;
(3) Using the biological or effective half-life; or
(4) Considering the shielding by tissue.

(d) The licensee shall maintain a record for three years after the date of the release that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 100 millirem (1 mSv).

History Note: Authority G.S. 104E-7(a)(8); 104E-12;
Eff. August 1, 1998;
Amended Eff. October 1, 2013;

10A NCAC 15 .0359 MEASUREMENTS/DOSAGES OF UNSEALED RADIOACTIVE MATERIAL FOR MEDICAL USE

(a) Licensees shall comply with the provisions of 10 CFR 35.63, except that dosage determination shall be made by direct measurement for all unsealed photon-emitting radioactive drugs prior to administration to any person. Licensees shall ensure that instruments used to measure dosages under this Rule are calibrated in accordance with the provisions of 10 CFR 35.60.

(b) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/textidx?SID=2beeece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

History Note: Authority G.S. 104E-7; 104E-10(b); 104E-12;
Eff. April 1, 1999;
Amended Eff. November 1, 2007;
Transferred and Recodified from 15A NCAC 11 .0359 Eff. February 1, 2015;

10A NCAC 15 .0360 SURVEYS OF RADIOPHARMACEUTICAL AREAS FOR RADIATION EXPOSURE RATE

(a) A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

(b) A licensee shall conduct the survey required by Paragraph (a) of this Rule so as to be able to detect dose rates as low as 0.1 millirem (1 microsievert) per hour.

(c) A licensee shall establish radiation dose rate trigger levels for the surveys required by Paragraph (a) of this Rule. A licensee shall require the individual performing the survey to promptly notify the Radiation Safety Officer if a dose rate exceeds a trigger level.

(d) A licensee shall retain a record of the survey required by this Rule for three years. The record shall include:

(1) the date of the survey;
(2) a plan of each area surveyed;
(3) the trigger level established for each area;
(4) the detected dose rate at several points in each area surveyed expressed in millirem (or microsievert) per hour;
(5) the instrument used to make the survey; and
(6) the initials of the individual who performed the survey.
(e) Any licensee authorized by the rules of this Chapter to manufacture, produce, acquire, receive, possess, use or transfer radioactive material for medical use shall have in its possession a calibrated portable radiation survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour (1 microsievert per hour) to 100 millirem per hour (.01 millisievert per hour), and a portable radiation survey instrument capable of measuring dose rates over the range of one millirem per hour (.01 millisievert per hour) to 1,000 millirem per hour (10 millisievert per hour). A licensee shall calibrate the survey instruments used to show compliance with this Section before first use, annually, and following repair. The licensee shall:
(1) calibrate all scales with readings up to 1,000 millirem (10 millisievert) per hour with a radiation source;
(2) calibrate two separated readings on each scale that must be calibrated; and
(3) conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration.
(f) When calibrating a survey instrument, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent.
(g) A licensee shall check each survey instrument for proper operation with the dedicated check source each day of use. A licensee is not required to keep records of these checks.
(h) A licensee shall retain a record of each survey instrument calibration for three years. The record must include:
(1) a description of the calibration procedure; and
(2) the date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the identity of the individual who performed the calibration.

History Note: Authority G.S. 104E-7; 104E-10(b); 104E-12; Eff. April 1, 1999; Amended Eff. November 1, 2007; Transferred and Recodified from 15A NCAC 11 .0360 Eff. February 1, 2015.

10A NCAC 15 .0361 MEDICAL USE OF UNSEALED RADIOACTIVE MATERIAL
(a) A licensee may use any unsealed radioactive material prepared for use for uptake, dilution, or excretion studies, imaging and localization studies, and use requiring a written directive as set forth in Rule .0104 of this Chapter that is:
(1) Obtained from a manufacturer or preparer licensed under 10 CFR 32.72 or equivalent Agreement State requirements;
(2) Obtained from a positron emission tomography (PET) radioactive drug producer licensed under 10 CFR 30.32(j), 15A NCAC 11 .0333, or equivalent Agreement State requirements;
(3) Excluding production of PET radionuclides, prepared by:
   (A) An authorized nuclear pharmacist;
   (B) A physician is an authorized user identified on a North Carolina Radioactive Materials License, an Agreement State Radioactive Materials License, or a license issued by the U.S. Nuclear Regulatory Commission or who meets the requirements in 15A NCAC 11 .0318(c); or
   (C) An individual under the supervision, as specified in Rule .0318 of this Section, of the authorized nuclear pharmacist in Part (a)(3)(A) of this Rule or the physician who is an authorized user in Part (a)(3)(B) of this Rule;
(4) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA; or
(5) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA.
(b) A licensee shall not administer to humans a radiopharmaceutical that contains;
(1) more than 0.15 microcurie (0.15 kilobecquerel) of molybdenum-99 per millicurie (megabecquerel) of technetium-99m; or
(2) more than 0.02 microcurie (0.02 kilobecquerel) of strontium-82 per millicurie (megabecquerel) of rubidium-82 chloride, or 0.2 microcurie (0.2 kilobecquerel) of strontium-85 per millicurie (megabecquerel) of rubidium-82 chloride.

(c) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99 radiopharmaceutical shall measure the molybdenum-99 concentration in the first eluate after receipt of a generator to demonstrate compliance with Paragraph (b) of this Rule.

(d) A licensee that uses strontium-82/rubidium-82 generators for preparing a rubidium-82 radiopharmaceutical shall measure the concentrations of strontium-82 and strontium-85 before the first patient use of the day to demonstrate compliance with Paragraph (b) of this Rule.

(e) A licensee that must measure molybdenum-99 or strontium-82 and strontium-85 concentration shall retain a record of each measurement for three years. The record shall include:

1. for each measured elution of technetium-99m: the ratio of the measures expressed as microcuries of molybdenum-99 per millicurie of technetium-99m (or kilobecquerels of molybdenum-99 per megabecquerel of technetium-99m);
2. for each measured elution of rubidium-82: the ratio of the measures expressed as microcuries of strontium-82 and strontium-85 per millicurie of rubidium-82 (or kilobecquerel strontium-82 and strontium-85 per megabecquerel rubidium-82); and
3. the time and date of the measurement; and
4. the initials of the individual who made the measurement.

History Note: Authority G.S. 104E-7(a)(2); 104E-10(b); 104E-12;
Eff. April 1, 1999;
Amended Eff. October 1, 2013; November 1, 2007;

10A NCAC 15 .0362 DECAY-IN-STORAGE

(a) A licensee may hold radioactive material with a physical half-life of less than 275 days for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of Rule .1628 of this Chapter if the licensee:

1. holds radioactive material for decay a minimum of 10 half-lives;
2. monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter capable of detecting a dose rate of 0.1 millirem (1 microsievert) per hour and with no interposed shielding; and
3. removes or obliterates all radiation labels.

(b) A licensee shall retain a record of each disposal permitted under Paragraph (a) of this Rule for three years. The record shall include:

1. the date of the disposal;
2. the date the radioactive material was placed in storage;
3. the radionuclides disposed;
4. the survey instrument used;
5. the background dose rate used; and
6. the dose rate measured at the surface of each waste container.

History Note: Authority G.S. 104E-7(a)(2); 104E-10(b); 104E-12;
Eff. April 1, 1999;
Amended Eff. October 1, 2013;

10A NCAC 15 .0363 PROVISIONS FOR THE PROTECTION OF HUMAN RESEARCH SUBJECTS

(a) A licensee may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on its license.

(b) If the research is conducted, funded, supported, or regulated by a Federal agency that has implemented the Federal Policy for the Protection of Human Research Subjects (Federal Policy), the licensee shall, before conducting research:

1. Obtain review and approval of the research from an "Institutional Review Board" as defined and prescribed in the Federal Policy; and
(2) Obtain “informed consent” as defined and described in the Federal Policy, from the human research subject.

(c) If the research will not be conducted, funded, supported, or regulated by a Federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its medical use license. The amendment request must include a written commitment that the licensee will, before conducting research:

(1) Obtain review and approval of the research from an “Institutional Review Board” as defined and described in the Federal Policy; and

(2) Obtain “informed consent,” as described in the Federal Policy, from the human research subject.

(d) Nothing in this Rule relieves licensees from complying with the other requirements in this Chapter or with any other applicable Rules and Laws in the State of North Carolina.

History Note: Authority G.S. 104E-7; 104E-10(b); 104E-12; Eff. November 1, 2007; Transferred and Recodified from 15A NCAC 11 .0363 Eff. February 1, 2015.

10A NCAC 15 .0364 MEDICAL EVENTS

(a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in:

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sievert (Sv)) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin; and

(A) The total dose delivered differs from the prescribed dose by 20 percent or more;

(B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(C) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) A dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:

(A) An administration of a wrong radioactive drug containing radioactive material;

(B) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(C) An administration of a dose or dosage to a wrong individual or human research subject;

(D) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(E) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in an unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify by telephone the agency no later than the next calendar day after discovery of the medical event.

(d) The licensee shall submit a written report to the agency at the address listed in Rule .0111 of this Chapter within 15 days of the discovery of the medical event. The written report must include:

(1) The licensee’s name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

(5) The effect, if any, on the individual(s) who received the administration;

(6) What actions, if any, have been taken or are planned to prevent recurrence; and

(7) Certification that the licensee notified the individual (or the individual’s responsible relative or guardian) and if not, why not.

The report may not contain the individual’s name or any other information that could lead to identification of the individual.
(e) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery unless the referring physician personally informs the licensee either that he or she will inform the individual or that based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this Paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual’s responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) Aside from the notification requirement, nothing in this Section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual’s responsible relatives or guardians.

(g) A licensee shall:

1. Annotate a copy of the report provided to the agency with the:
   - Name of the individual who is the subject of the event; and
   - Social security number or other identification number, if one has been assigned, of the individual who is the subject of the medical event; and

2. Provide a copy of the annotated report to the referring physician if other than the licensee, no later than 15 days after the discovery of the event.

### History Note:

Authority G.S. 104E-7(a)(2); 104E-10(b); 104E-12; Eff. November 1, 2007; Transferred and Recodified from 15A NCAC 11 .0364 Eff. February 1, 2015.

10A NCAC 15 .0365 REPORT AND NOTIFICATION OF A DOSE TO AN EMBRYO/FETUS OR A NURSING CHILD

(a) A licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by that authorized user.

(b) A licensee shall report any dose to a nursing child that is a result of administration of radioactive material to a breast-feeding individual, that:

1. Is greater than 5 rem (50 mSv) total effective dose equivalent; or

2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(c) The licensee shall notify by telephone the agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in Paragraphs (a) or (b) of this Rule.

(d) The licensee shall submit a written report to the agency at the address listed in Rule .0111 of this Chapter within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in Paragraphs (a) or (b) in this Rule.

1. The written report must include:
   - The licensee's name;
   - The name of the prescribing physician;
   - A brief description of the event;
   - Why the event occurred;
   - The effect, if any, on the embryo/fetus or the nursing child;
   - What actions, if any, have been taken or are planned to prevent recurrence; and
   - Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

2. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(e) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under Paragraphs (a) or (b) of this Rule, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The
licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this Paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) A licensee shall:

(1) Annotate a copy of the report provided to the agency with the:
(A) Name of the pregnant individual or the nursing child who is the subject of the event; and
(B) Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

History Note: Authority G.S. 104E-7; 104E-10(b); 104E-12; Eff. November 1, 2007; Transferred and Recodified from 15A NCAC 11 .0365 Eff. February 1, 2015.

SECTION .0400 - STANDARDS FOR PROTECTION AGAINST RADIATION

Codifier's Note: 10 NCAC 03G .2500 was transferred to 15A NCAC 11 .0400 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .0401 PURPOSE AND SCOPE
10A NCAC 15 .0402 RADIATION DOSE TO INDIVIDUALS IN RESTRICTED AREAS
10A NCAC 15 .0403 DETERMINATION OF PRIOR DOSE
10A NCAC 15 .0404 CONCENTRATIONS IN A RESTRICTED AREA
10A NCAC 15 .0405 EXPOSURE OF MINORS
10A NCAC 15 .0406 PERMISSIBLE LEVELS IN UNRESTRICTED AREAS
10A NCAC 15 .0407 CONCENTRATION IN EFFLUENTS TO UNRESTRICTED AREAS
10A NCAC 15 .0408 BIOASSAY SERVICES
10A NCAC 15 .0409 SURVEYS
10A NCAC 15 .0410 PERSONNEL MONITORING
10A NCAC 15 .0411 CAUTION SIGNS; LABELS; AND SIGNALS
10A NCAC 15 .0412 EXCEPTIONS FROM POSTING AND LABELING
10A NCAC 15 .0413 INSTRUCTION OF PERSONNEL
10A NCAC 15 .0414 STORAGE OF SOURCES OF RADIATION
10A NCAC 15 .0415 PICKING UP; RECEIVING; AND OPENING PACKAGES
10A NCAC 15 .0416 WASTE DISPOSAL
10A NCAC 15 .0417 RECORDS
10A NCAC 15 .0418 REPORTS OF THEFT OR LOSS
10A NCAC 15 .0419 NOTIFICATION OF INCIDENTS
10A NCAC 15 .0420 OVEREXPOSURES AND EXCESSIVE LEVELS AND CONCENTRATIONS
10A NCAC 15 .0421 VACATING PREMISES
10A NCAC 15 .0422 NOTIFICATION AND REPORTS TO INDIVIDUALS
10A NCAC 15 .0423 REFERENCE CONCENTRATIONS IN AIR AND WATER
10A NCAC 15 .0424 REFERENCE FOR LABELING AND DISPOSAL REQUIREMENTS

History Note: Authority G.S. 104E-7; 104E-7(2),(5); 104E-12(a); 104E-12(a)(1),(2); 104E-12(b); Eff. February 1, 1980; Amended Eff. May 1, 1992; June 1, 1989; October 1, 1984; September 1, 1981; October 1, 1980; Repealed Eff. August 1, 1998; Transferred and Recodified from 15A NCAC 11 .0401-.0424 Eff. February 1, 2015.
SECTION .0500 - SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHY OPERATIONS

Codifier's Note: 10 NCAC 03G.2600 was transferred to 15A NCAC 11 .0500 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .0501 PURPOSE AND SCOPE
(a) The rules in this Section establish radiation safety requirements for persons utilizing sources of radiation for industrial radiography. The requirements of this Section are in addition to and not in substitution for the other requirements of this Chapter.
(b) The rules in this Section apply to all licensees or registrants who use sources of radiation for industrial radiography; provided, however that nothing in this Section shall apply to the use of sources of radiation in the healing arts.

10A NCAC 15 .0502 DEFINITIONS
In addition to terms found in Rule .0104 of this Chapter and 10 CFR 34.3, the following definitions shall apply to this Section. 10 CFR 34.3 is incorporated by reference to include subsequent amendments and editions, and can be accessed at: http://www.nrc.gov/reading-rm/doc-collections/cfr/part034/part034-0003.html at no cost:

(1) "Collimator" means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to limit the size, shape, and direction of the primary radiation when the sealed source is cranked into position to make a radiographic exposure.

(2) "Control device," commonly called a crank-out, means the control cable, the protective sheath, and control drive mechanism used to move the sealed source from the shielded position in the radiographic device or camera to an unshielded position outside the device for the purpose of making a radiographic exposure.

(3) "Field examination" means a practical examination.

(4) "Independent certifying organization" means an independent organization that meets all of the requirements of Rule .0525 of this Section.

(5) "Periodic training" means instruction provided at least every 12 months by the licensee or registrant for operators and individuals subject to the requirements of Rule .1003 of this Chapter on radiation safety aspects of radiography. The topics shall include the results of internal inspections, new procedures or equipment, accidents or errors that have been observed, and opportunities for employees to ask safety questions.

(6) "Projection sheath" means a guide tube.

(7) "Radiation safety officer" means an individual named by the licensee or registrant who has knowledge of and responsibility for the overall radiation safety program on behalf of the licensee or registrant and who meets the requirements of Rule .0510(h) of this Section.

History Note: Authority G.S. 104E-7; 10 CFR 34.3;
Eff. February 1, 1980;
Amended Eff. January 1, 1994; June 1, 1989;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule
becomes effective, whichever is sooner;
Amended Eff. April 1, 1999; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0502 Eff. February 1, 2015;
Amended Eff. October 1, 2015;

10A NCAC 15 .0503    EQUIPMENT RADIATION LEVEL LIMITS
The maximum exposure rate limits for source changers and storage containers are 200 millirem (2 millisieverts) per hour
at any exterior surface, and 10 millirem (0.1 millisieverts) per hour at one meter from any exterior surface. The radiation
levels specified are with the sealed source in the shielded position.

History Note: Filed as a Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the
permanent rule becomes effective, whichever is sooner;
Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. April 1, 1999; May 1, 1995; May 1, 1992;

10A NCAC 15 .0504    RADIOGRAPHIC EXPOSURE DEVICES AND STORAGE CONTAINERS
(a) Each radiographic exposure device shall have a lock or outer locked container designed to prevent unauthorized or
accidental removal of the sealed source from its shielded position. The exposure device or its container shall be kept
locked when not under the direct surveillance of a radiographer or a radiographer's assistant or as otherwise may be
authorized in Rule .0515 of this Section. If the exposure device or container is secured with a keyed lock, the key shall
be removed at all times when the device or container is not being used. In addition, during radiographic operations, the
sealed source assembly shall be manually secured in the shielded position each time the sealed source is returned to that
position in those devices manufactured prior to the effective date of this Rule.
(b) Each sealed source storage container and source changer shall have a lock or outer locked container designed to
prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and
source changers shall be kept locked when containing sealed sources except when under the direct surveillance of a
radiographer or a radiographer's assistant.
(c) Prior to moving a radiographic exposure device, source changer or storage container from one temporary jobsite to
another, the licensee shall:
(1) perform a survey to ensure that the sealed source is in the shielded position;
(2) disassemble the radiographic exposure device, source changer or storage container from associated
equipment;
(3) apply safety plugs or covers;
(4) lock the radiographic exposure device, source changer or storage container; and
(5) physically secure the radiographic exposure device, source changer or storage container to prevent
accidental loss, tampering or removal of sealed sources.

History Note: Filed as a Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the
permanent rule becomes effective, whichever is sooner;
Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0504 Eff. February 1, 2015.

10A NCAC 15 .0505    STORAGE, LABELS AND TRANSPORTATION PRECAUTIONS
(a) Security precautions during storage or transportation:
(1) Locked radiographic exposure devices and storage containers shall be physically secured to prevent
tampering or removal by unauthorized personnel. The licensee shall store sealed sources in a manner
which will minimize danger from explosion or fire.
The licensee shall lock and physically secure the transport package containing sealed sources in the transporting vehicle to prevent accidental loss, tampering or unauthorized removal of the sealed sources from the vehicle.

(b) Labels:

(1) The licensee shall not use a source changer or storage container to store sealed sources unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label. The label shall contain the radiation symbol specified in Rule .1623 of this Chapter and the wording:

CAUTION (OR DANGER)
RADIOACTIVE MATERIAL-- DO NOT HANDLE
NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)

(2) The licensee shall not transport sealed sources unless the material is packaged, labeled, marked, and accompanied with the appropriate shipping papers in accordance with regulations set out in 10 CFR Part 71, including documentation of the Quality Assurance program requirements outlined in 10 CFR 71.105.

History Note: Filed as a Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Authority G.S. 104E-7; Eff. February 1, 1980; Amended Eff. May 1, 1995; Transferred and Recodified from 15A NCAC 11 .0505 Eff. February 1, 2015.

10A NCAC 15 .0506 SURVEY INSTRUMENTS

(a) The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each temporary jobsite and at any location where sealed sources or radiation machines are used or stored to make physical radiation surveys as required by this Rule and Rules .1613 and .1627 of this Chapter.

(b) Each radiation survey instrument required by Paragraph (a) of this Rule shall be calibrated:

(1) at intervals not to exceed six months and after each instrument servicing except for battery change;

(2) at the following points for each instrument, as applicable:

(A) linear scale instruments shall be calibrated at two points located approximately 1/3 and 2/3 of full-scale on each scale;

(B) logarithmic scale instruments shall be calibrated at the midrange of each decade and at two points in the same decade for at least one decade; and

(C) digital instruments shall be calibrated in accordance with procedures that include the following calibration points:

(i) 2 mR/hr or 0.02 mSv/hr;
(ii) 5 mR/hr or 0.05 mSv/hr;
(iii) 50 mR/hr or 0.5 mSv/hr;
(iv) 500 mR/hr or 5 mSv/hr; and
(v) 1 R/hr or 0.01 Sv/hr;

(3) so that an accuracy within plus or minus 20 percent of the calibration standard can be demonstrated on each scale.

(c) Instrumentation required by this Rule shall have a range such that two milliroentgens (0.02 millisieverts) per hour through one roentgen (0.01 sievert) per hour can be measured.

(d) Survey instruments shall be checked for operability prior to use. This may be accomplished by evaluating the instrument response to the previously measured fields at the projection sheath port or the control cable sheath port on a radiographic exposure device.

(e) The licensee or registrant shall maintain records of the results of the instrument calibrations in accordance with Rule .0523 of this Section.

History Note: Authority G.S. 104E-7; 104E-12(a)(1); Eff. February 1, 1980; Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Amended Eff. April 1, 1999; May 1, 1995; January 1, 1994;
10A NCAC 15 .0507 LEAK TESTING AND REPLACEMENT OF SEALED SOURCES
(a) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source shall be performed only by persons specifically authorized by the agency to do so pursuant to the rules in this Section.
(b) The opening, repair, or modification of any sealed source shall be performed only by persons specifically named in a license condition to perform that function.
(c) Each sealed source shall be tested for leakage at intervals not to exceed six months. In the absence of a certificate from a transferee that a test has been made within the six months prior to the transfer, the sealed source shall not be put into use until tested.
(d) The wipe of a sealed source shall be performed using a leak test kit or similar materials and methods. The wipe sample shall be taken from the nearest accessible point to the sealed source. The wipe sample shall be analyzed for radioactive contamination. The analysis shall be capable of detecting 0.005uCi (185 Bq) of radioactive material on the test sample and shall be performed by persons licensed or registered by the agency to perform such a service.
(e) Any test conducted pursuant to Paragraphs (c) and (d) of this Rule which reveals the presence of 0.005 microcurie (185 Bq) or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of, in accordance with these Rules. A report describing the equipment involved, the test results, and the corrective action taken shall be submitted in writing to the agency at the address in Rule .0111 of this Chapter within five days after the test.
(f) The licensee shall maintain records of the leak test results in accordance with Rule .0523 of this Section.

History Note: Filed as a Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. April 1, 1999; May 1, 1995; June 1, 1993;

10A NCAC 15 .0508 QUARTERLY INVENTORY
(a) Each licensee shall conduct a quarterly physical inventory to account for all sealed sources and devices containing depleted uranium received and possessed under the license.
(b) The licensee shall maintain records of the quarterly inventory in accordance with Rule .0523 of this Section.

History Note: Filed as a Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Authority G.S. 104E-7; 104E-12(a)(1);
Eff. February 1, 1980;
Amended Eff. April 1, 1999; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0508 Eff. February 1, 2015.

10A NCAC 15 .0509 UTILIZATION LOGS
Each licensee or registrant shall maintain current utilization logs for inspection by the agency at the address specified in the license, showing for each sealed source and radiation machine the information required by Rule .0523(a)(6) of this Section.

History Note: Authority G.S. 104E-7; 104E-12(a)(1);
Eff. February 1, 1980;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. April 1, 1999; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0509 Eff. February 1, 2015;
10A NCAC 15 .0510 LIMITATIONS

(a) The licensee or registrant shall not permit any person to act as a radiographer until the person:

(1) has been instructed in the subjects outlined in Rule .0519 of this Section and has demonstrated understanding thereof by successful completion of a written test. The person shall also have a minimum of two months of on-the-job training, and be certified through a radiography certification program by a certifying entity in accordance with the requirements of Rule .0525 of this Section;

(2) has received copies of and instruction in the rules contained in this Section and in the applicable rules of Sections .0200, .0300, .0900 and .1600 of this Chapter, in applicable U.S. Department of Transportation regulations referenced in Rule .0117 of this Chapter, and the licensee's or registrant's operating and emergency procedures, and has demonstrated understanding thereof by successful completion of a written test;

(3) has received training in the use of the licensee or registrant's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments;

(4) has demonstrated competence to use the radiographic exposure devices, sealed sources, related handling tools, radiation machines and survey instruments which will be employed in his assignment by successful completion of a practical examination covering this material; and

(5) has demonstrated understanding of the instructions in Paragraph (a) of this Rule by successful completion of a written test on the subjects covered.

(b) The licensee or registrant shall not permit any person to act as a radiographer's assistant until the person:

(1) has received copies of and instructions in the licensee's or registrant's operating and emergency procedures, and has demonstrated understanding thereof by successful completion of a written or oral test and practical examination on the subjects covered;

(2) has demonstrated competence to use under the personal supervision of the radiographer, the radiographic exposure devices, sealed sources, related handling tools, radiation machines and radiation survey instruments which will be employed in his assignment; and

(3) has demonstrated understanding of the instructions in Paragraph (b) of this Rule by successfully completing a written or oral test and a field examination on the subjects covered.

(c) Records of the training including copies of written tests and dates of oral tests and field examinations shall be maintained in accordance with Rule .0523 of this Section.

(d) Each licensee or registrant shall conduct an internal audit program to ensure that the agency's radioactive material license, registration conditions and the licensee's or registrant's operating and emergency procedures are followed by each radiographer and radiographer's assistant. These internal audits shall be performed and records maintained by the licensee or registrant as specified in Items (3) and (4) of Rule .0323 of this Chapter.

(e) The licensee or registrant shall provide periodic training for radiographers and radiographer's assistants at least once during every 12 months.

(f) Whenever radiography is performed outside of a permanent radiographic installation, the radiographer shall be accompanied by another radiographer or an individual with, at least, the qualifications of a radiographer's assistant. This person's responsibilities shall include but not be limited to observing the operations and being capable and prepared to provide immediate assistance to prevent unauthorized entry.

(g) A licensee or registrant may conduct lay-barge, off-shore platform, or underwater radiography only if procedures have been developed and submitted to the agency that ensure radiation exposure to the workers and the public are ALARA during the radiographic operation.

(h) The radiation safety officer shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's or registrant's program.

(1) The radiation safety officer's qualifications shall include:

(A) completion of the training and testing requirements of Paragraph (a) of this Rule; and

(B) Two thousand hours documented experience in industrial radiographic operations, with at least 40 hours of classroom training with respect to the establishment and maintenance of radiation protection programs; or

(C) an equivalent combination of education and experience.

(2) The specific duties and authorities of the radiation safety officer shall include, but are not limited to the following:

(A) to establish and oversee operating, emergency and ALARA procedures, and to review them at least annually to assure that the procedures are current and conform with these Rules and to the license conditions;
(B) to oversee and approve all phases of the training of radiographic personnel so that appropriate and effective radiation protection practices are taught;

(C) to ensure that required radiation surveys and leak tests are performed and documented in accordance with this Rule, including any corrective measures when levels of radiation exceed established limits;

(D) to ensure that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by Rule .1646 of this Chapter;

(E) to assure that operations are conducted safely and to assume control and have the authority to institute corrective actions including stopping of operations when necessary in emergency situations or unsafe conditions.

History Note: Authority G.S. 104E-7; 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540; 10 C.F.R. 34.43; 10 C.F.R. Appendix A;
Eff. February 1, 1980;
Amended Eff. June 1, 1993; June 1, 1989;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. January 1, 2005; April 1, 1999; May 1, 1995; June 1, 1993; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0510 Eff. February 1, 2015;

10A NCAC 15 .0511 INSPECTION AND MAINTENANCE
(a) Prior to use each day, the licensee or registrant shall visually check for obvious defects in radiographic exposure devices, storage containers, source changers, radiation machines and associated equipment. The purpose of the visual check is to assure that the radiographic exposure devices, storage containers, source changers, radiation machines and associated equipment are in good working condition and that the required labeling is present. If defects are found, the affected radiographic exposure devices, storage containers, source changers, radiation machines and associated equipment shall be removed from service until repaired and a record shall be made in accordance with Rule .0523 of this Section.

(b) Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration shall be tested for DU contamination at intervals not to exceed 12 months. This test shall be performed by the licensee using procedures approved by the agency pursuant to Rule .0323 of this Chapter or by the licensee returning the exposure device to the manufacturer for such testing. If the test reveals the presence of DU contamination, the exposure device shall be removed from use and arrangements for proper disposal shall be made.

(c) Each licensee or registrant shall have written procedures for:

(1) inspection and maintenance or radiographic exposure devices, transport and storage containers, source changers, survey instruments, radiation machines and associated equipment at intervals not to exceed three months or prior to the first use thereafter to assure proper functioning of components important to safety. Records of these inspections and maintenance shall be made in accordance with Rule .0523 of this Section. If defects are found, the affected radiographic exposure and associated equipment shall be removed from service until repaired and a record made in accordance with Rule .0523 of this Section.

(2) inspection and maintenance necessary to maintain Type B packaging used to transport radioactive materials. The inspection and maintenance program shall include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

(d) Records of equipment problems and of any maintenance performed under Paragraphs (a) and (b) of this Rule shall be made in accordance with Rule .0523 of this Section.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. April 1, 1999; May 1, 1995; October 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0511 Eff. February 1, 2015;
10A NCAC 15 .0512 PERSONNEL MONITORING

(a) The licensee or registrant shall not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each such individual wears on the trunk of the body a direct reading pocket dosimeter, an operating alarm ratemeter, and a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. At permanent radiography facilities where other alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required. Direct reading pocket dosimeters shall have a range from zero to 200 milliroentgens (2 millisieverts) and shall be recharged at the start of each shift. Each personnel dosimeter shall be assigned to and worn by only one individual. Film badges shall be exchanged at least monthly, and other personnel dosimeters that are processed and evaluated by an accredited NVLAP processor shall be exchanged at least once each three months. Each film badge or other personnel dosimeter shall be submitted for processing within 30 days of replacement.

(b) Electronic personal dosimeters may be used in place of direct reading ion-chamber pocket dosimeters.

(c) Direct reading dosimeters such as electronic personal dosimeters or pocket dosimeters shall be read and exposures recorded at the beginning and end of each shift.

(d) Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters shall be checked at periods not to exceed 12 months for correct response to radiation. Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation exposure.

(e) If an individual's pocket dosimeter is found to be off-scale or if the individual's electronic personal dosimeter reads greater than 200 millirem (2 millisieverts), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter shall be immediately sent for processing. In addition, the individual shall not work with sealed sources until a determination of his radiation exposure has been made by the radiation safety officer or his designee.

(f) If a personnel dosimeter is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter is provided and exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter.

(g) Each alarm ratemeter shall:
   (1) be checked to ensure that the alarm functions properly prior to use at the start of each shift;
   (2) be set to give an alarm signal at a preset rate not to exceed 500 mR/hr or 5 mSv/hr;
   (3) require special means to change the preset alarm function;
   (4) alarm within plus or minus 20 percent of the true radiation rate;
   (5) be calibrated at periods not to exceed one year for correct response to radiation.

(h) Records of daily dosimeter readings, determination of exposure as a result of a lost or damaged personnel dosimeter, 12 month response checks on dosimeters and results from the accredited NVLAP personnel dosimeter processor shall be maintained in accordance with Rule .0523 of this Section.

(i) Notwithstanding the requirements of Paragraph (a) of this Rule, the agency may approve a higher pocket dosimeter range upon written request by the licensee or registrant if the agency determines that the requested range shall afford the protection required by the rules in this Chapter.

History Note: Authority G.S. 104E-7; 104E-12(a)(2);
Eff. February 1, 1980;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. January 1, 2005; April 1, 1999; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0512 Eff. February 1, 2015;

10A NCAC 15 .0513 OPERATING AND EMERGENCY PROCEDURES

The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

(1) the handling and use of licensed sealed sources of radiation and radiographic exposure devices to be employed such that no individual is likely to be exposed to radiation doses in excess of the limits established in Rule .1604 of this Chapter;

(2) methods and occasions for conducting radiation surveys;

(3) methods for controlling access to radiographic areas;

(4) methods and occasions for locking and securing radiographic exposure devices, transport and storage containers and sealed sources of radiation;
personnel monitoring and the use of personnel monitoring equipment;
transportation of sealed sources to field locations, including packing of radiographic exposure devices, and storage containers in the vehicles, placarding of vehicles, and control of sealed sources during transportation;
minimizing exposure of individuals in the event of an accident;
the procedure for notifying proper personnel in the event of an accident;
maintenance of records;
the inspection and maintenance and operability checks of radiographic exposure devices, radiation machines, survey instruments, transport containers, and storage containers;
steps that shall be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off scale or an alarm ratemeter alarms unexpectedly; and
sealed source recovery procedure if the licensee will perform sealed source recovery.

History Note:
Authority G.S. 104E-7;
Eff. February 1, 1980;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. April 1, 1999; May 1, 1995; January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0513 Eff. February 1, 2015;

10A NCAC 15 .0514 SECURITY
During each radiographic operation the radiographer or radiographer's assistant shall maintain a continuous direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in Rule .0104 of this Chapter, except where the high radiation area:
(1) is equipped with a control device or an alarm system as described in Rule .1615 of this Chapter, or
(2) is locked to protect against unauthorized or accidental entry.

History Note:
Authority G.S. 104E-7;
Eff. February 1, 1980;
Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. May 1, 1995; January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0514 Eff. February 1, 2015;

10A NCAC 15 .0515 RADIATION SURVEYS AND SURVEY RECORDS
(a) No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation as described in Rule .0506 of this Section is available and used at each site where radiography is performed, including sealed source exchange and at the storage area whenever a radiographic exposure device, a storage container or sealed source is being placed in storage.
(b) A survey with a radiation detection instrument shall be made after each radiographic exposure to determine that the sealed source has returned to its shielded position in the radiographic exposure device or the radiation machine is off. For sealed sources, the licensee shall conduct a survey of the guide tube as the radiographer or radiographer's assistant approaches the camera. The survey must determine that the sealed source has returned to its shielded position prior to exchanging films, repositioning the exposure head or dismantling the radiographic exposure device and associated equipment.
(c) When the use of a radiographic exposure device or storage container is to be terminated at the end of a work period, a survey with a radiation detection instrument shall be made of the locked radiography device or storage container to determine that the sealed source is in its shielded position.
(d) A survey of the radiographic exposure device and source changer shall be performed with a radiation detection instrument any time the sealed source is exchanged and whenever a radiographic exposure device is placed in a storage area.
(e) An area survey of the perimeter of the restricted area with a radiation detection instrument shall be made with the sealed source exposed or the radiation machine on before or during the initial radiographic exposure on each shift and when the sealed source or the radiation machine target configuration for an exposure is different from that of the
preceding exposure such that the radiation exposure rate at the perimeter of the restricted area is likely to increase by a measurable amount using a radiation detection instrument. These surveys are not required for radiography performed in a permanent radiographic installation.

(f) Records of surveys required by this Rule shall be maintained in accordance with the requirements of Rule .0523 of this Section.

History Note: Authority G.S. 104E-7; 104E-12(a)(1);
Eff. February 1, 1980;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. April 1, 1999; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0515 Eff. February 1, 2015;

10A NCAC 15 .0516 POSTING

Notwithstanding any provisions in Rule .1625 of this Chapter, areas in which radiography is being performed shall be conspicuously posted as required by Rule .1624 of this Chapter. The exception listed in Rule .1625 of this Chapter does not apply to industrial radiography.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. April 1, 1999; January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0516 Eff. February 1, 2015;

10A NCAC 15 .0517 SUPERVISION OF RADIOGRAPHERS' ASSISTANTS

(a) Whenever a radiographer's assistant uses radiographic exposure devices or radiation machines, uses sealed sources or related source handling tools, or conducts radiation surveys required by Rule .0515(b) and (c) of this Section to determine that the exposure has been terminated and, if applicable, the sealed source has returned to the shielded position after an exposure, the assistant shall be under the personal supervision of a radiographer.

(b) The personal supervision shall include:

(1) the radiographer's physical presence at the site where the sealed sources or radiation machines are being used;
(2) the availability of the radiographer to give immediate assistance, if required; and
(3) the radiographer's direct observation of the assistant's performance of the operations referred to in this Section.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. April 1, 1999; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0517 Eff. February 1, 2015;

10A NCAC 15 .0518 RADIATION MACHINES

History Note: Authority G.S. 104E-7; 104E-12(a)(1);
Eff. February 1, 1980;
Amended Eff. June 1, 1993;
Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0518 Eff. February 1, 2015;
The following subjects shall be covered in the instructions of radiographers:

1. Fundamentals of radiation safety:
   (a) characteristics of gamma and x-radiation;
   (b) units of radiation dose (mrem, sievert) and quantity of radioactivity (curie, becquerel);
   (c) hazards of exposure of radiation;
   (d) levels of radiation from sources of radiation;
   (e) methods of controlling radiation dose:
      (i) working time,
      (ii) working distances,
      (iii) shielding;

2. Radiation detection instrumentation to be used:
   (a) use of radiation survey instruments:
      (i) operation,
      (ii) calibration,
      (iii) limitations,
   (b) survey techniques;
   (c) use of personnel monitoring equipment:
      (i) film badges,
      (ii) pocket dosimeters,
      (iii) pocket chambers,

3. Radiographic equipment to be used:
   (a) remote handling equipment;
   (b) radiographic exposure devices, radiation machines and sealed sources;
   (c) storage containers;
   (d) operation and control of radiography equipment;
   (e) storage, control and disposal of sealed sources;

4. The requirements of pertinent federal and state regulations;

5. The licensee's or registrant's written operating and emergency procedures;

6. Inspection and maintenance performed by radiographers;

7. Case histories of radiography accidents;

8. The conditions of the license or registration issued by the agency.

History Note:  Authority G.S. 104E-7;
Eff. February 1, 1980;
Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0519 Eff. February 1, 2015;

PERMANENT RADIOGRAPHIC INSTALLATIONS
(a) Permanent radiographic installations having high radiation area entrance controls of the types described in Subparagraphs (a)(1), (2) and (3) of Rule .1615 of this Chapter shall also meet the following special requirements:

1. Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation to which this Section applies shall have both visible and audible warning signals to warn of the presence of radiation.

2. The visible signal shall be actuated by radiation whenever the sealed source is exposed.

3. The audible signal shall be actuated when an attempt is made to enter the installation while the sealed source is exposed.

(b) The alarm system shall be tested for proper operation with a radiation source at the beginning of each day of equipment use. The daily test shall include a check of the visible and audible signals by exposing the sealed source or operating the radiation machine prior to use of the room. Entrance control devices that reduce the radiation level upon entry as required in Paragraph (a) of this Rule shall be tested monthly. If a control device or alarm is operating improperly, it shall immediately be labeled as defective and repaired within seven calendar days. The facility may
continue to be used during this seven day period, provided the licensee or registrant implements continuous surveillance to protect against unauthorized entry and uses an alarming ratemeter.

(c) Records of test of alarm functions shall be maintained in accordance with Rule .0523 of this Section.

History Note: Authority G.S. 104E-7; 104E-12(a)(1);
Eff. October 1, 1980;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. April 1, 1999; May 1, 1995; January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0520 Eff. February 1, 2015;

10A NCAC 15 .0521 PERFORMANCE REQUIREMENTS FOR RADIOGRAPHY EQUIPMENT

(a) Equipment used in industrial radiographic operations shall meet the performance requirements of 10 CFR 34.20.
(b) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

History Note: Authority G.S. 104E-7;
Temporary Adoption Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. May 1, 1995;
Amended Eff. April 1, 1999;
Transferred and Recodified from 15A NCAC 11 .0521 Eff. February 1, 2015;

10A NCAC 15 .0522 REPORTING REQUIREMENTS

(a) In addition to the reporting requirements specified in other rules of this Chapter, each licensee or registrant shall provide a written report to the agency at the address specified in Rule .0111 of this Chapter within 30 days of the occurrence of any of the following incidents involving radiographic equipment:
   (1) unintentional disconnection of the source assembly from the control cable;
   (2) inability to retract the source assembly to its fully shielded position and secure it in this position; or
   (3) failure of any component critical to safe operation of the device to properly perform its intended function.

(b) The licensee or registrant shall include the following information in each report required by Paragraph (a) of this Rule, and in each report of overexposure submitted pursuant to Section .1600 which involves failure of safety components of radiography equipment:
   (1) a description of the equipment problem;
   (2) cause of each incident, if known;
   (3) manufacturer and model number of equipment involved in the incident;
   (4) place, time and date of the incident;
   (5) actions taken to establish normal operations;
   (6) corrective actions taken or planned to prevent recurrence; and
   (7) qualifications of personnel involved in the incident.

(c) Any licensee or registrant conducting radiographic operations or storing radioactive material at any location not listed on the license for a period in excess of 180 days in a calendar year, shall notify the agency prior to exceeding the 180 days.

History Note: Authority G.S. 104E-7;
Temporary Adoption Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. May 1, 1995;
Amended Eff. April 1, 1999;
Transferred and Recodified from 15A NCAC 11 .0522 Eff. February 1, 2015;
(a) Each licensee or registrant shall maintain, for a period of three years after the record is made, the following records for inspection by the agency:

1. copies of the following documents:
   (A) radioactive materials license or registration issued by the agency;
   (B) the complete application submitted for the license or registration that includes all amendments; and
   (C) current operating and emergency procedures;

2. records showing the receipt and transfer of all sealed sources and devices using depleted uranium (DU) for shielding that include:
   (A) date;
   (B) individual making the record;
   (C) radionuclide;
   (D) activity in curies or becquerel or mass for depleted uranium; and
   (E) make, model and serial number of each sealed source and device;

3. records of the calibrations of radiation detection instrumentation;

4. records of leak tests for sealed sources and devices containing depleted uranium in units of microcuries or becquerel;

5. records of quarterly inventories that include:
   (A) radionuclide;
   (B) activity in curies or becquerel;
   (C) specific information on each sealed source and the radiographic exposure device, storage container or source changer which contains the sealed source to include:
      (i) model numbers;
      (ii) serial numbers; and
      (iii) manufacturers names;
   (D) location of sealed sources;
   (E) name of the individual conducting the inventory; and
   (F) the date of the inventory;

6. records of utilization logs showing the following information:
   (A) a description of each radiographic exposure device, radiation machine or transport or storage container in which the sealed source is located that includes:
      (i) make;
      (ii) model number; and
      (iii) serial number;
   (B) the identity and signature of the radiographer to whom assigned;
   (C) the plant or site where used; and
   (D) dates of use that includes the dates removed and returned to storage;

7. records of inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers and radiation machines. The record shall include:
   (A) date of the check;
   (B) name of the individual performing the check;
   (C) equipment involved;
   (D) any problems found in daily checks and quarterly inspections; and
   (E) any repairs or maintenance made and name of individual or company performing the repair;

8. records of alarm system tests for permanent radiographic installations;

9. records of the training and certification of each radiographer and radiographer's assistant as follows:
   (A) radiographer certification documents and verification of certification status;
   (B) for initial training, copies of written tests; dates and results of oral tests and field examinations; and names of individuals conducting and receiving the oral test or field examination;
   (C) for periodic training and semi-annual inspections of job performance, list of topics discussed; date(s) of the review; and names of the instructors and the attendees; and
   (D) for inspections of job performance, the records shall also include a list showing the items checked and any noncompliance observed by the Radiation Safety Officer.
records for pocket dosimeters to include daily exposure readings and yearly operability checks;

(11) records of reports received from the accredited National Voluntary Laboratory Accreditation Program (NVLAP) personnel dosimetry processor. These records, as well as any records of exposure estimates required as a result of off-scale direct reading dosimeters, or lost or damaged personnel dosimeters, shall be maintained until the agency terminates the license or registration or until authorized by the agency:

(12) records of exposure device surveys performed at the end of the work day and prior to placing the device in storage;

(13) records of area surveys required by Rule .0515 of this Section;

(14) copy of current operating and emergency procedures until the agency terminates the license or registration and copies of superseded material shall be retained for three years after the change is made; and

(15) evidence of the latest calibrations of alarm ratemeters and operability checks of pocket dosimeters or electronic personal dosimeters.

(b) Each licensee or registrant conducting operations at temporary jobsites shall maintain copies of the following documents and records at the temporary jobsite until the radiographic operation is completed:

(1) operating and emergency procedures required by Rule .0513 of this Section;

(2) radioactive materials license or registration;

(3) evidence of training of the radiographers and radiographer's assistants. The individuals shall either be listed on the radioactive materials license or registration and offer identification or shall have certification of his training and offer identification;

(4) evidence of the latest calibration of the radiation detection instrumentation in use at the site as required by Rule .0506 of this Section;

(5) evidence of the latest leak test of the sealed source required by Rule .0507 of this Section;

(6) records of the latest surveys required by Rule .0515 of this Section;

(7) records of the latest direct reading dosimeters such as pocket dosimeter or electronic personal dosimeter readings;

(8) shipping papers for the transportation of radioactive materials required by 10 CFR Part 71.5; and

(9) records of area surveys required by Rule .0515 of this Section;

(10) a copy of Section .0500 of this Chapter;

(11) utilization records for each radiographic exposure device dispatched from that location as required by Subparagraph (a) of Rule .0523 of this Section;

(12) records of equipment problems identified in daily checks of equipment; and

(13) when operating under reciprocity, a copy of the Nuclear Regulatory Commission or agreement state license authorizing the use of radioactive material.

(c) Each record required by this Rule shall be legible throughout the specified retention period. The record may be an original, a reproduced copy or microform provided that the copy or microform is authenticated by the licensee and the microform is capable of reproducing a clear copy throughout the required record retention period. The record may also be stored in electronic media with the capability for producing legible, accurate and complete records during the required record retention period. Records, such as letters, drawings and specifications shall include all pertinent information, such as stamps, initials and signatures. The licensee or registrant shall maintain safeguards against tampering with and loss of records.

History Note: Authority G.S. 104E-7;
Temporary Adoption Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. May 1, 1995;
Amended Eff. January 1, 2005; April 1, 1999;
Transferred and Recodified from 15A NCAC 11 .0523 Eff. February 1, 2015;

10A NCAC 15 .0524 SPECIFIC LICENSE FOR INDUSTRIAL RADIOGRAPHY
An application for a specific license for the use of licensed material in industrial radiography shall be approved if the applicant meets the following requirements:

(1) the applicant satisfies the general requirements specified in Rules .0317 and .0323 of this Chapter for radioactive material, as appropriate, and any special requirements contained in this Section;
(2) the applicant submits a program for training radiographers and radiographers' assistants, that meets the requirements of Rule .0323 of this Chapter and Rule .0510 of this Section.

(3) the applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid;

(4) the applicant submits written operating and emergency procedures as described in Rule .0323 of this Chapter and Rule .0513 of this Section;

(5) the applicant submits a description of a program for inspections of the job performance of each radiographer and radiographers' assistant at intervals not to exceed six months as described in Rule .0323 of this Chapter;

(6) the applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility;

(7) the applicant identifies and lists the qualifications of the individual(s) designated as the radiation safety officer and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with the requirements of this Chapter;

(8) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium shielding, the applicant shall describe the procedures for performing and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application shall include a description of the procedures to be followed. The description shall include the:
   (a) instruments to be used;
   (b) methods of performing the analysis; and
   (c) pertinent experience of the person who will analyze the wipe samples;

(9) If the applicant intends to perform "in-house" calibrations of survey instruments, the applicant shall describe methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations shall be performed according to the procedures described and at the intervals prescribed in Rule .0506 of this Section;

(10) The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations; and

(11) The applicant identifies the locations where all records required by this Section and other Sections of this Chapter will be maintained.

History Note: Authority G.S. 104E-7; 104E-10(b); Eff. April 1, 1999; Transferred and Recodified from 15A NCAC 11 .0524 Eff. February 1, 2015.

10A NCAC 15 .0525 RADIOGRAPHER CERTIFICATION

(a) An independent certifying organization shall:

   (1) be an organization such as the American Society of Nondestructive Testing (ASNT) or other society or association, whose members participate in, or have an interest in, the field of industrial radiography;
   (2) make its membership available to the general public nationwide that is not restricted because of race, color, religion, sex, age, national origin or disability;
   (3) have a certification open to nonmembers, as well as members;
   (4) be an incorporated, nationally recognized organization, such as ASNT, that is involved in setting national standards of practice within its field of expertise;
   (5) have staff, a viable system for financing its operations, and policy and decision-making review board;
   (6) have a set of written organizational by-laws and policies that provide assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;
   (7) have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;
   (8) have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;
   (9) have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program;
have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;

(11) have procedures for proctoring examinations, including qualifications for proctors;

(12) ensure that the procedures in Subparagraph (a)(11) of this Paragraph require that the individuals proctoring each examination are not employed by the same company or corporations (or a wholly-owned subsidiary of such company or corporation) as any of the examinees;

(13) exchange information about certified individuals with the agency and other independent certifying organizations or the U.S. Nuclear Regulatory Commission and other agreement states, and allow periodic review of its certification program and related records; and

(14) provide a description to the agency of its procedures for choosing examination sites and for providing an environment suitable for examination.

(b) All certification programs shall:

(1) require applicants for certification to receive training in the topics set forth in Rule .0519 of this Section and satisfactorily complete a written examination covering the topics in Rule .0519 of this Section;

(2) require applicants for certification to provide documentation that demonstrates that the applicant has:
   (A) received training in the topics set forth in Rule .0519 of this Section; or
   (B) satisfactorily completed a minimum period of on-the-job training; and
   (C) received verification by an agreement state or a Nuclear Regulatory Commission licensee that the applicant has demonstrated the capability of independently working as a radiographer;

(3) include procedures to ensure that all examination questions are protected for disclosure;

(4) include procedures for denying an application, and for revoking, suspending, and reinstating a certification;

(5) provide a certification period of not less than three years and not more than five years;

(6) include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training; and

(7) provide a timely response to inquiries by telephone or letter, from members of the public, about an individual’s certification status.

(c) All examinations shall be:

(1) designed to test an individual's knowledge and understanding of the topics set forth in Rule .0519 of this Section;

(2) written in a multiple-choice format; and

(3) have test items drawn from a question list based on the material contained in Rule .0519 of this Section.

History Note: Authority G.S. 104E-7; 104E-10(b); 10 C.F.R. 34.43; 10 C.F.R. 34, Appendix A; Eff. April 1, 1999;
Transferred and Recodified from 15A NCAC 11 .0525 Eff. February 1, 2015;

SECTION .0600 - X-RAYS IN THE HEALING ARTS

Codifier's Note: 10 NCAC 03G .2700 was transferred to 15A NCAC 11 .0600 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .0601 PURPOSE AND SCOPE

This Section establishes requirements for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of this Section are in addition to, and not in substitution for, the provisions of Sections .0100, .0200, .0900, .1000, and .1600 of this Chapter.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. January 1, 1994;
DEFINITIONS

(a) As used in this Section, the following definitions shall apply:

(1) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

(2) "Added filter" means the filter added to the inherent filtration.

(3) "Aluminum equivalent" means the thickness of aluminum, type 1100 alloy, affording the same attenuation, under specified conditions, as the material in question. The nominal composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum and 0.12 percent copper.

(4) "Attenuation block" means a block or stack, having dimensions 20 cm by 20 cm by 3.8 cm, of type 1100 aluminum alloy or other materials having equivalent attenuation.

(5) "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain, at a preselected location(s), a required quantity of radiation. Phototimer is described separately.

(6) "Beam axis" means a line from the source of x-rays through the centers of the x-ray fields.

(7) "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.

(8) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

(9) "Changeable filters" means any added filter which can be removed from the useful x-ray beam through any electronic, mechanical or physical process.

(10) "Contact therapy system" means that the x-ray tube target is put within five centimeters of the surface being treated.

(11) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for manually setting the technique factors.

(12) "Cooling curve" means the graphical relationship between heat units stored and cooling time.

(13) "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

(14) "Diagnostic source assembly" means the tube housing assembly with a device attached.

(15) "Diagnostic-type protective tube housing" means a tube housing so constructed that the leakage radiation measured at a distance of one meter from the source does not exceed 100 mR in one hour when the tube is operated at its leakage technique factors.

(16) "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

(17) "Direct scattered radiation" means that radiation which has been deviated in direction by materials irradiated by the useful beam. (See also scattered radiation).

(18) "Entrance exposure rate" means the roentgens per unit time at the point where the center of the useful beam enters the patient.

(19) "Exposure" means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons, negatrons and positrons, liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The special unit of exposure is the roentgen.

(20) "Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

(21) "Filter" means material placed in the useful beam to preferentially attenuate selected radiations.

(22) "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks and structural material providing linkage between the image receptor and the diagnostic source assembly.

(23) "General purpose radiographic x-ray system" means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

(24) "Gonad shield" means a protective barrier used to reduce exposure to the testes or ovaries.

(25) "Half-value layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.
"Healing arts mass screening" means the examination of human beings using x-rays for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts who is legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment. It does not include the use of x-ray tests as a requirement for hospital admission or as a condition of employment.

"Image intensifier" means a device, including housing, which converts an x-ray pattern into a corresponding light image of higher energy density.

"Image receptor" means any device, such as fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

"Inherent filtration" means the filtration permanently in the useful beam; it includes the window of the x-ray tube and any permanent tube or source enclosure.

"Installation" means the act of physical movement of a radiographic system from one location to another in conjunction with a change of ownership.

"Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

"Leakage radiation" means radiation emanating from a diagnostic or therapeutic source assembly except for:
(A) the useful beam and
(B) radiation produced when the exposure switch or timer is not activated.

"Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly (i.e., tube housing and beam limiting device) which are used in measuring leakage radiation. They are defined as follows:
(A) for diagnostic source assemblies intended for capacitor energy storage equipment, the maximum rated peak tube potential and the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (mC) or the minimum obtainable from the unit, whichever is larger;
(B) for diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum rated peak tube potential and the maximum rated number of x-ray pulses in an hour for operation at the maximum rated peak tube potential; and
(C) for all other diagnostic or therapeutic source assemblies, the maximum rated peak tube potential and the maximum rated continuous tube current for the maximum rated peak tube potential.

"Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

"Maximum line current" means the rms (root-mean-square) current in the supply line of an x-ray machine operating at its maximum rating.

"Mobile equipment" (see x-ray equipment).

"Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

"Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (see also "Automatic exposure control").

"Position indicating device (PID)" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-skin distance. It may or may not incorporate or serve as a beam-limiting device.

"Primary protective barrier" means the material, excluding filters, placed in the useful beam, for radiation protection purposes, to reduce the radiation exposure.

"Protective apron" means an apron made of radiation attenuating materials used to reduce radiation exposure.

"Protective barrier" means a barrier of radiation attenuating material(s) used to reduce radiation exposure. Types of protective barriers are defined in other items of this Rule.
"Protective glove" means a glove made of radiation attenuating materials used to reduce radiation exposure.

"Qualified expert" means an individual who is registered pursuant to Rule .0205 of this Chapter.

"Radiograph" means an image receptor on which the image has been created directly or indirectly by an x-ray pattern and results in a permanent record.

"Radiographic imaging system" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

"Rating" means the operating limits as specified by the component manufacturer.

"Recording" means producing a permanent form of an image resulting from x-ray photons such as film and video tape.

"Registrant", as used in this Section, means any person who owns or possesses and administratively controls an x-ray system which is used to deliberately expose humans or animals to the useful beam of the system and is required by the provisions contained in Sections .0100 and .0200 of this Chapter to register with the agency.

"Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state mid-scale reading.

"Scattered radiation" means radiation that, during passage through matter, has been deviated in direction. (See also "direct scattered radiation").

"Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

"SID" means source-image receptor distance.

"Source" means the focal spot of the x-ray tube.

"Source-image receptor distance (SID)" means the distance from the source to the center of the input surface of the image receptor.

"Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

"Stationary equipment" (see x-ray equipment).

"Stray radiation" means the sum of leakage and scattered radiation.

"Technique factors" means the conditions of operation. They are specified as follows:
(A) for capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
(B) for field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses; and
(C) for all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

"Therapeutic-type protective tube housing" means the tube housing with tube installed, and it includes high voltage and filament transformers and other appropriate elements when they are contained within that housing.

"Transportation equipment" means x-ray equipment which is installed in a vehicle or trailer.

"Tube" means an x-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and filament transformers and other appropriate elements when they are contained within the tube housing.

"Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

"Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

"Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at the given SID.

"Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons produce a visible image.

"X-ray control" means a device which controls input power to the x-ray high-voltage generator or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers and similar devices which control the technique factors of an x-ray exposure.

"X-ray equipment" means an x-ray system, subsystem or component thereof.
"Mobile equipment" means x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

"Portable equipment" means x-ray equipment designed to be hand-carried.

"Stationary equipment" means x-ray equipment which is installed in a fixed location.

"X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices and other appropriate elements.

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

"X-ray subsystem" means any combination of two or more components of an x-ray system for which there are requirements specified in this Section.

"X-ray tube" means an electron tube which is designed for the conversion of electrical energy into x-ray energy.

(b) Other definitions applicable to this Section may be found in Sections .0100 and .0200 of this Chapter.

History Note: Authority G.S. 104E-7; Eff. February 1, 1980; Amended Eff. June 1, 1993; May 1, 1992; October 1, 1980; Transferred and Recodified from 15A NCAC 11 .0602 Eff. February 1, 2015.

10A NCAC 15 .0603 GENERAL REQUIREMENTS

(a) Administrative controls

(1) The registrant shall be responsible for directing the operation of the x-ray machines which he has registered with the agency. He or his agent shall assure that the following provisions are met in the operation of the x-ray machine(s):

(A) An x-ray machine which does not meet the provisions of these Rules shall not be operated for diagnostic or therapeutic purposes, if so ordered by the agency in accordance with Rules .0109 and .0110 of this Chapter.

(B) Individuals who will be operating the x-ray equipment shall be instructed in the safe operating procedures and use of the equipment and demonstrate an understanding thereof to the registrant.

(C) In the vicinity of each diagnostic x-ray system's control panel, a chart shall be provided, which specifies for all usual examinations and associated projections which are performed by that system, a listing of information including patient's anatomical size versus technique factors to be utilized at a given source to image receptor distance. The chart shall also provide:

(i) type and size of the film or film-screen combination to be used,
(ii) type and ratio of grid to be used, if any, and focal spot to film distance,
(iii) type and placement of gonad shielding to be used.

(D) Written safety procedures and rules shall be established and made available to each individual operating x-ray equipment under his control. The operator shall be familiar with these rules.

(E) Only the professional staff and ancillary personnel required for the medical procedure or for training shall be in the room during the radiographic exposure. Other than the patient being examined:

(i) All individuals shall be positioned such that no part of the body including the extremities which is not protected by 0.5 mm lead equivalent will be exposed to the useful beam.

(ii) Professional staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead equivalent.
(iii) Patients who cannot be removed from the room shall be protected from the direct
scatter radiation by whole body protective barriers of 0.25 mm lead equivalent or
shall be so positioned that the nearest portion of the body is at least six feet from
both the tube head and the nearest edge of the image receptor.

(iv) When a portion of the body of a non- occupationally exposed professional staff or
ancillary personnel is potentially subjected to stray radiation which would result in
that individual receiving one-fourth of the maximum permissible dose as defined in
Rule .1604 of this Chapter, additional protective measures shall be employed.

(v) Upon written application to the agency, the agency may waive the requirements in
Subparts (a)(1)(E)(ii) and (a)(1)(E)(iii) of this Rule if the registrant demonstrates that
such waiver is necessary for best management of patients and will not result in
violation of the public and occupational dose limits established in the rules in this
Chapter.

(F) Gonad shielding of not less than 0.5 mm lead equivalent shall be used for potentially
procreative patients during radiographic procedures in which the gonads are in the direct, or
useful beam, except for cases in which this would interfere with the diagnostic procedures.

(G) Individuals shall not be exposed to the useful beam except for healing arts purposes. Such
exposures shall have been authorized by a licensed practitioner of the healing arts. This
provision specifically prohibits deliberate exposure of an individual for training,
demonstration or other nonhealing arts purposes.

(H) When a patient or film must be provided with auxiliary support during a radiographic
exposure:
(i) Mechanical holding devices shall be used whenever medical circumstances permit.
Written safety procedures, as required in Part (a)(1)(D) of this Rule shall indicate the
requirements for selecting a holder;
(ii) If a human holder is required, written safety procedures as required in Part (a)(1)(D)
of this Rule, shall indicate the instructions provided to the holder;
(iii) The human holder shall be protected as required in Part (a)(1)(E) of this Rule;
(iv) No individual shall be used routinely to hold patients or film.

(I) Procedures and auxiliary equipment designed to minimize patient and personnel exposure
commensurate with the needed diagnostic information shall be utilized. This includes, but is
not limited to, the following requirements:
(i) The speed of film or screen and film combinations shall be the fastest speed
consistent with the diagnostic objective of the examinations.
(ii) The radiation exposure to the patient shall be the minimum exposure required to
produce images of good diagnostic quality.
(iii) Portable or mobile equipment shall be used only for examinations where it is
impractical for medical reasons to transfer the patient to a stationary radiographic
installation.

(J) All persons who are associated with the operation of an x-ray system are subject to the
occupational exposure limits as defined in Rules .1604 and .1638 of this Chapter, and
personnel monitoring procedures in Rule .1614 of this Chapter. In addition, when protective
clothing or equipment is worn on portions of the body and a monitoring device(s) is required,
least one such monitoring device shall be utilized as follows:
(i) When an apron is worn the monitoring device shall be worn at the collar outside the
apron.
(ii) The dose to the whole body shall be recorded in the reports required in Rule .1640 of
this Chapter. If more than one device is used, each dose shall be identified with the
area where the device was worn on the body.

(2) The registrant shall maintain at least the following information for each x-ray machine:
(A) current registration information and other correspondence with the agency regarding that
machine;
(B) records of surveys and calibrations;
(C) records of maintenance or modifications which affect the useful beam after the effective date
of these Rules, along with the names of persons who performed the service.
(b) Plans Review. Prior to construction or structural modification, the floor plans and equipment arrangement of all installations utilizing x-rays for diagnostic or therapeutic purposes shall be reviewed by a qualified expert. The registrant shall submit recommendations of the expert to the agency.

(c) Radiation Survey

(1) For installations of x-ray equipment after the effective date of this Rule, an area radiation survey shall be performed within 30 days following initial operation of each radiation machine to show compliance with Rule .0604(b) of this Section. This survey shall include:

(A) a drawing of the room in which a stationary x-ray system is located and radiation levels in adjacent areas; and

(B) the name of the person approved by the agency performing the survey and the date the survey was performed.

(2) Any modification to the x-ray room or adjacent areas which could increase the radiation dosage to any individual shall require a new survey.

(3) Records of this survey shall be maintained in accordance with Subparagraph (a)(2) of this Rule.

History Note: Authority G.S. 104E-7; 104E-12(a);

Eff. February 1, 1980;
Amended Eff. January 1, 1994; October 1, 1980;

10A NCAC 15 .0604    GENERAL REQUIREMENTS FOR ALL DIAGNOSTIC SYSTEMS

(a) In addition to other requirements of this Section, all diagnostic x-ray systems shall meet the following requirements:

(1) The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operation instructions are observed."

(2) Equivalent wording may be used on battery-powered generators; visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(3) The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 100 millirem in one hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(4) The radiation emitted by a component other than the diagnostic source assembly shall not exceed two millirem in one hour at five centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(5) Beam Quality

(A) Half-Value Layer

(i) The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the appropriate value shown in the following table. "Specified Dental System" is any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980. "Other X-Ray Systems" shall be all other x-ray systems subject to this Section.

<table>
<thead>
<tr>
<th>X-Ray Tube Voltage (kilovolt peak)</th>
<th>Minimum HVL (millimeters of Aluminum)</th>
<th>Minimum HVL (millimeters of Aluminum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designed operating range</td>
<td>Measured Operating Potential Specified Dental Systems Other X-ray Systems</td>
<td></td>
</tr>
<tr>
<td>Below 50--------------------</td>
<td>30  1.5  1.5  0.3</td>
<td>40  1.5  1.5  0.4</td>
</tr>
</tbody>
</table>
If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in the table, linear interpolation or extrapolation may be made. Positive means shall be provided to insure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure.

(ii) The requirements of Subpart (a)(5)(A)(i) of this Rule shall be considered to be met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in the following table:

<table>
<thead>
<tr>
<th>Operating Voltage (kVp)</th>
<th>Minimum total filtration (millimeters aluminum equivalent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Below 50</td>
<td>0.5 millimeters</td>
</tr>
<tr>
<td>50-70</td>
<td>1.5 millimeters</td>
</tr>
<tr>
<td>Above 70</td>
<td>2.5 millimeters</td>
</tr>
</tbody>
</table>

(iii) Notwithstanding the requirements of Subpart (a)(5)(A)(ii) of this Rule, all intraoral dental systems manufactured after December 1, 1980, shall have a minimum of 1.5 mm aluminum equivalent filtration permanently installed in the useful beam.

(iv) Beryllium window tubes shall have a minimum of 0.5 mm aluminum equivalent filtration permanently mounted in the useful beam.

(v) For capacitor energy storage equipment, compliance shall be determined with the maximum quantity of charge per exposure.

(vi) The required minimum aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the focal spot of the tube and the patient, such as a tabletop when the tube is mounted under the table and inherent filtration of the tube.

(B) For new x-ray systems installed after the effective date of these Rules and which have variable kVp and selectable filtration for the useful beam, a device shall link the kVp selector with the filter(s), so that the minimum filtration is always present for the kVp selected.

(6) Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected and their location shall be clearly indicated on the master control panel prior to initiation of the exposure.

(7) The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a design function of the x-ray system.

(8) The location of the focal spot may be indicated on a readily visible area of the x-ray source housing in the plane parallel to the image receptor when the image receptor is perpendicular to the beam axis.

(9) Technique Indicators
The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated.

Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

On equipment having fixed technique factors, the recommendation in Part (a)(9)(A) of this Rule may be met by permanent markings.

(b) Structural Shielding

(1) For stationary diagnostic systems, except for intraoral dental systems which shall meet the requirements of Rule .0607(j) of this Section, structural shielding shall be provided to assure compliance with Rules .1604 and .1611 of this Chapter. The following shall be provided:

(A) All wall, floor and ceiling areas exposed to the useful beam shall have primary barriers. Primary barriers in walls shall extend to a minimum height of 84 inches above the floor;

(B) Secondary barriers in the wall, floor and ceiling areas not having a primary barrier or where the primary barrier requirements are lower than the secondary barrier requirements; and

(C) A window of lead-equivalent glass equal to that required by the adjacent barrier or a mirror system shall be provided large enough and so placed that the operator can see the patient without having to leave the protected area during exposures.

(2) When a mobile system is used routinely in one location, the structural shielding in that location shall meet the requirements for stationary diagnostic systems in Subparagraph (b)(1) of this Rule.

History Note:

Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. January 1, 1994; October 1, 1980;

10A NCAC 15 .0605 FLUOROSCOPIC X-RAY SYSTEMS

All fluoroscopic x-ray systems shall meet the following requirements:

(1) Limitation of useful beam

(a) The fluoroscopic tube shall not produce x-rays unless the primary protective barrier is in position to intercept the entire useful beam at all times.

(b) The entire cross section of the useful beam shall be intercepted by the primary protective barrier of the fluoroscopic image assembly at any SID.

(c) Limitation to the Imaging Surface

(i) The x-ray field produced by fluoroscopic equipment without image intensification shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size during both fluoroscopic procedures and spot-filming procedures.

(ii) Image-intensified fluoroscopy and spot-filming shall comply with the following:

(A) During fluoroscopic or spot-filming procedures, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed the visible area of the image receptor by more than three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID.

(B) Compliance shall be determined with the beam axis perpendicular to the image receptor. For rectangular x-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(iii) In addition to other requirements of this Rule, equipment manufactured after the effective date of these Rules shall comply with the following:

(A) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. This adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film.
(B) It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID, shall be equal to or less than five centimeters by five centimeters.

(C) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent of the SID.

(2) X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(3) Entrance exposure rates shall be limited as required in the following:

(a) Fluoroscopic equipment shall not be operated at any combination of tube potential and current which will result in an exposure rate in excess of ten roentgens per minute at the point where the center of the useful beam enters the patient, except:
   (i) during recording of fluoroscopic images; or
   (ii) when provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of five roentgens per minute at the point where the center of the beam enters the patient unless the high level control is activated. Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(b) In addition to the other requirements of this Rule equipment manufactured after August, 1974, which does not incorporate an automatic exposure control (e.g., automatic brightness control or ionization chamber control) shall not be operated at any combination of tube potential and current which will result in an exposure rate in excess of five roentgens per minute at the point where the center of the useful beam enters the patient except during the recording of fluoroscopic images or when provided with an optional high level control.

(c) Compliance with the provisions of Item (3) of this Rule shall be determined as follows:
   (i) Movable grids and compression devices shall be removed from the useful beam during the measurement.
   (ii) If the source is below the table, the exposure rate shall be measured one centimeter above the tabletop or cradle.
   (iii) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
   (iv) In a C-arm type fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

(d) Periodic measurement of entrance exposure rate limits shall comply with the following:
   (i) Such measurements shall be made every two years or after any maintenance of the system which might affect the exposure rate.
   (ii) Results of these measurements shall be available or posted where any fluoroscopist may have ready access to them and shall be in the record required in Rule .0603(a)(2)(B) of this Section. Results of the measurements shall include the exposure rate, as well as the physical factors used to determine all data; the name of the person approved by the agency performing the measurements and the date the measurements were performed.
   (iii) Entrance exposure rate shall be determined with the attenuation block in Rule .0602(a) in the primary beam.

(4) Radiation transmitted through the primary protective barrier of the fluoroscopic imaging assembly shall comply with the following requirements:
   (a) The exposure rate resulting from transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed two milliroentgens per hour at ten centimeters from any accessible
surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(b) Measurements to determine compliance with Sub-item (4)(a) of this Rule shall be in accordance with the following:

(i) The exposure rate resulting from transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters;

(ii) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly, positioned 30 centimeters above the tabletop.

(iii) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters;

(iv) Movable grids and compression devices shall be removed from the useful beam during the measurement;

(v) The attenuation block shall be positioned in the useful beam ten centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

(5) During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated.

(6) The source-skin distance shall not be less than:

(a) 38 centimeters on stationary fluoroscopes,
(b) 30 centimeters on all mobile fluoroscopes, or
(c) 20 centimeters for image intensified fluoroscopes during surgical application.

(7) Fluoroscopic timers shall meet the following requirements:

(a) Means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

(b) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

(8) Mobile fluoroscopes, in addition to the other requirements of this Rule, shall provide image intensification.

(9) Scattered radiation shall be controlled in accordance with the following requirements:

(a) A shielding device of at least 0.25 mm lead equivalent for covering the Bucky slot during fluoroscopy shall be provided.

(b) A shield of at least 0.25 mm lead equivalent, such as overlapping protective drapes or hinged or sliding panels, shall be provided to intercept scattered radiation which would otherwise reach the fluoroscopist and others near the machine.

(c) Upon application to the agency with adequate justification, exceptions from Sub-items (9)(a) or (9)(b) of this Rule may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers or where the protective barriers would interfere with the procedures.

History Note: Authority G.S. 104E-7; Eff. February 1, 1980; Amended Eff. May 1, 1993; May 1, 1992; October 1, 1980; Transferred and Recodified from 15A NCAC 11 .0605 Eff. February 1, 2015.

10A NCAC 15 .0606 SYSrEMS OTHER THAN FLUOROSCOPIC AND DENTAL INTRAORAL

(a) Unless specifically provided otherwise by the rules in this Chapter, the requirements in this Rule shall apply to all x-ray systems, except for fluoroscopic and dental intraoral x-ray systems. The useful beam of x-ray systems subject to provisions of this Rule shall be limited to the area of clinical interest or the image receptor, whichever is smaller.

(1) General purpose stationary and mobile x-ray systems shall meet the following special requirements:
(A) There shall be provided a means for stepless adjustment of the size of the x-ray field. The minimum field size at a SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters.

(B) Means shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(C) Notwithstanding Parts (a)(1)(A) and (B) of this Rule, equipment manufactured before August 1, 1974 may employ fixed cones and diaphragms or variable collimators without beam defining lights.

(2) In addition to the requirements of Subparagraph (a)(1) of this Rule, all stationary x-ray systems, except equipment originally manufactured before the effective date of this Rule, shall meet the following requirements:

(A) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within two percent of the SID, and to indicate the SID to within two percent;

(B) The beam limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

(C) Indication of field size dimensions and SID's shall be specified in inches or centimeters and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent of the SID when the beam axis is perpendicular to the plane of the image receptor.

(3) Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor and to align the center of the x-ray field with the center of the image receptor to within two percent of the SID.

(4) Special purpose x-ray systems shall meet the following requirements:

(A) These systems shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(B) Such systems shall also be provided with means to align the center of the x-ray field with the center of the image receptor to within two percent of the SID.

(C) The requirements in Parts (a)(4)(A) and (B) of this Rule may be met with a system that meets the requirements for a general purpose x-ray system as specified in Subparagraph (a)(1) of this Rule or, when alignment means are also provided, as follows:

(i) an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed, where each device has clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(ii) a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed, where the device has permanent, clearly legible, markings indicating image receptor size and SID for which the unit is designed, where the device has permanent, clearly legible, markings indicating image receptor size and SID for which each aperture is designated and indicating which aperture is in position for use.

(b) Radiation exposure control devices shall meet the following requirements:

(1) Means shall be provided to terminate the exposure after a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. In addition:

(A) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero except during serial radiography, and

(B) It shall not be possible to make an exposure when the timer is set to a zero or “off” position if either position is provided.
Control over x-ray exposures shall be in accordance with the following requirements:

(A) A control shall be incorporated into each x-ray system such that the operator can terminate an exposure at any time except for serial radiography where means may be provided to permit completion of any single exposure of the series in process.

(B) Each x-ray control shall be located in such a way as to meet the following criteria.
   (i) For stationary x-ray systems, the control shall be permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and
   (ii) The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, except for equipment originally manufactured before the effective date of this Rule, a signal audible to the operator shall indicate that the exposure has terminated.

(3) When an automatic exposure control (e.g., phototimer) is provided the following requirements shall be met, except equipment originally manufactured before the effective date of this Rule:
   (A) Indication shall be made on the control panel when this mode of operation is selected;
   (B) When the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;
   (C) The minimum exposure time for all equipment other than that specified in Part (b)(3)(B) of this Rule shall be equal to or less than 1/60 second or a time interval required to deliver five mAs, whichever is greater;
   (D) Either the product of peak x-ray tube potential, current and exposure time shall be limited to not more than 60 kWs per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x-ray tube potential is less than 50 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and
   (E) A visible signal shall indicate when an exposure has been terminated at the limits described in Part (b)(3)(D) of this Rule and manual resetting shall be required before further automatically timed exposures can be made.

(4) When four timer tests are performed at identical timer setting equal to 5.0 seconds or less, the average time period (T) shall be greater than five times the difference between the maximum period (Tmax) and the minimum period (Tmin) in accordance with the formula:

\[ T > 5(T_{\text{max}} - T_{\text{min}}) \]

(c) Source-skin or source-image receptor distance shall meet the following requirement:
All radiographic systems shall be provided with a durable, securely fastened means to limit the source-skin distance to at least 30 centimeters. This is considered to be met when the collimator or cone provides the required limits.

(d) The exposure produced shall be reproducible to within the following criteria:
When all technique factors are held constant, the coefficient of variation shall not exceed 0.10. This shall be deemed to be met if, when four exposures at identical technique factors are made, the value of the average exposure (E) is greater than five times the difference between the maximum exposure (Emax) and the minimum exposure (Emin) in accordance with the formula:

\[ E > 5(\text{E}_{\text{max}} - \text{E}_{\text{min}}) \]

(e) Standby radiation from capacitor energy storage equipment, when the exposure switch or timer is not activated, shall not exceed a rate of two milliroentgens per hour at five centimeters from any accessible surface of the diagnostic source assembly with the beam-limiting device fully open.

(f) Linearity

(1) When the equipment allows a choice of x-ray tube current settings, the average ratios of exposure to the indicated milliampere-seconds product, i.e., mR/mAs, obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum, i.e., \[ \frac{1}{\text{mean of } x_1 + x_2} < \text{mean of } (x_1 + x_2), \] where the mean of x1 and x2 are the average mR/mAs values obtained at each of two consecutive tube current settings.
Compliance shall be determined at the most commonly used mA stations by measuring mR/mAs at those stations and at one adjacent station to each.

(g) Timer accuracy
   (1) For indicated values of 0.10 seconds and above, the measured value shall be within plus or minus 15 percent of the indicated values for equipment manufactured before August 1, 1974.
   (2) For equipment manufactured after August 1, 1974, the deviation of measured values from indicated values shall not exceed the limits specified for that system by its manufacturer.

History Note: Authority G.S. 104E-7; Eff. February 1, 1980; Amended Eff. May 1, 1993; November 1, 1989; October 1, 1980; Transferred and Recodified from 15A NCAC 11.0606 Eff. February 1, 2015.

10A NCAC 15.0607 INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS
(a) In addition to the provisions of Rules .0603 and .0605 of this Section, the requirements of this Rule apply to x-ray equipment and associated facilities used for dental radiography. Criteria for extraoral dental radiographic systems are covered in Rule .0606 of this Section.
(b) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-skin distance to not less than:
   (1) 18 centimeters, if operated above 50 kilovolts peak; or
   (2) ten centimeters, if operated at or below 50 kilovolts peak.
(c) The size of the direct radiation beam shall be limited in accordance with the following rules:
   (1) Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:
      (A) If the source-skin distance (SSD) is 18 centimeters or more, the x-ray field at the SSD shall be containable in a circle having a diameter of no more than seven centimeters; and
      (B) If the SSD is less than 18 centimeters, the x-ray field at the SSD shall be containable in a circle having a diameter of no more than six centimeters.
   (2) Effective February 1, 1981, equipment manufactured prior to August 1974 shall be equipped with a lead line open position indicating device with at least 0.79 mm lead.
(d) The timing device shall comply with the following requirements:
   (1) Termination of the exposure after a preset interval;
   (2) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero;
   (3) It shall not be possible to make an exposure when the timer is set to a zero or "off" position if either position is provided; and
   (4) When four timer tests are performed at identical timer settings equal to five seconds or less, the average time period (T) shall be greater than five times the difference between the maximum period (Tmax) and the minimum period (Tmin) in accordance with the formula:

   \[ T > 5(T_{max} - T_{min}) \]

   (5) Effective February 1, 1983, intraoral dental radiographic systems shall be equipped with an electronic timer.
   (6) Timer accuracy
      (A) For indicated values of 0.10 seconds and above, the measured value shall be within plus or minus 15 percent of the indicated values for equipment manufactured before August 1, 1974.
      (B) For equipment manufactured after August 1, 1974, the deviation of measured values from indicated values shall not exceed the limits specified for that system by its manufacturer.
(e) The exposure switch shall comply with the following requirements:
   (1) A control shall be incorporated into each x-ray system such that an exposure can be terminated at any time, except for exposures of one-half second or less.
   (2) Each x-ray control shall be located in such a way as to meet the following criteria:
      (A) For stationary x-ray systems installed after the effective date of this Rule, the exposure switch shall be permanently mounted in a protected area (e.g., corridor outside the room) so that the operator is required to remain in that protected area during the entire exposure.
(B) For stationary x-ray systems without a protected area and installed before the effective date of this Rule, the exposure switch shall be such that the operator shall stand at least six feet away from the tube and out of the direct beam.

(C) For mobile and portable x-ray systems the switch shall meet the requirements of Part (e)(2)(B) of this Rule.

(3) For equipment manufactured after August 1, 1974, the x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(f) The exposure produced shall be reproducible to within the following criteria:

When all technique factors are held constant, the coefficient of variation shall not exceed 0.10. This shall be deemed to be met if, when four exposures at identical technique factors are made, the value of the average exposure (E) is greater than five times the difference between the maximum exposure (Emax) and the minimum exposure (Emin) in accordance with the formula:

\[ E > 5(Emax - Emin) \]

(g) Patient and film holding devices shall be used when the techniques permit.

(h) Neither the tube housing nor the position indicating device shall be hand-held during an exposure.

(i) Dental fluoroscopy without image intensification shall not be used.

(j) Structural shielding

(1) All wall, floor and ceiling areas shall have protective barriers sufficient to meet the requirements of Rules .1604 and .1611 of this Chapter.

(2) When intraoral x-ray systems are installed in adjacent rooms or areas, protective barriers as specified in Subparagraph (j)(1) of this Rule shall be provided between the rooms or areas.

History Note: Authority G.S. 104E-7; Eff. February 1, 1980; Amended Eff. January 1, 1994; October 1, 1980; Transferred and Recodified from 15A NCAC 11 .0607 Eff. February 1, 2015.

10A NCAC 15 .0608 THERAPEUTIC X-RAY INSTALLATIONS: LESS THAN ONE MEV

(a) Unless specifically provided otherwise by the rules in this Chapter, the requirements in this Rule shall apply only to therapeutic x-ray installations which are not capable of operating at or above one MeV. Therapeutic x-ray equipment subject to the provisions of this Rule shall comply with the following requirements:

(1) When the tube is operated at its leakage technique factors, the leakage radiation in any direction shall not exceed the value specified at the distance specified for the classification of that x-ray system.

(A) For contact therapy systems, the leakage radiation shall not exceed 100 mR/hr at five centimeters from the tube housing.

(B) Systems operating from zero to 150 kVp which are manufactured or installed prior to the effective date of this Rule shall have a leakage radiation which does not exceed one R in one hour at one meter from the source.

(C) Systems operating from zero to 150 kVp which are manufactured on or after the effective date of this Rule shall have a leakage radiation which does not exceed 100 mR in one hour at one meter from the source.

(D) Systems operating from 151 to 999 kVp shall have leakage radiation which does not exceed one R in one hour at one meter from the source, except systems which operate in excess of 500 kVp may have a leakage radiation in one hour at one meter from the source equivalent to 0.1 percent of the exposure in the useful beam in one hour at a distance of one meter from the source.

(2) Permanent beam limiting devices used for collimating the useful beam shall provide the same or higher degree of protection as that required by the tube housing assembly.

(3) Adjustable or removable beam limiting devices shall transmit not more than five percent of the useful beam as determined at the maximum tube potential and maximum treatment filter.

(4) The filter system shall be so designed that:

(A) Filters cannot be accidentally displaced from the useful beam at any tube orientation;
(B) Each filter is marked as to its material of construction and its thickness or wedge angle for wedges;
(C) It shall be possible for the operator to determine the presence of and identify each filter and the orientation of each wedge filter in the useful beam when the operator is positioned at the control panel either by display at the control panel or by direct observation;
(D) The filters and filter insertion slot opening shall be so designed that the radiation at five centimeters from the filter insertion slot opening does not exceed 30 roentgens per hour under all operating conditions; and
(E) Each machine equipped with a beryllium or other low filtration window shall be clearly labeled as such upon the tube head housing and upon the control panel.

(5) The tube housing assembly shall be immobilized during stationary treatments.
(6) The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within five millimeters and such marking shall be readily accessible.
(7) Equipment of greater than 150 kVp installed after the effective date of this Rule shall be provided with a beam monitor system.
(8) The exposure timer shall meet the following requirements:
   (A) A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and shall terminate irradiation when a preselected time has elapsed.
   (B) The timer shall switch on and off with the radiation and retain its reading after irradiation is interrupted or terminated.

(9) The control panel shall have:
   (A) an indication of whether electrical power is present and activation of the x-ray tube is possible;
   (B) an indication of whether x-rays are being produced;
   (C) the means for indicating kVp and x-ray tube current;
   (D) the means for terminating an exposure at any time;
   (E) a locking device which will prevent unauthorized use of the x-ray system and, for systems not having a lock at the control panel, an alternate method of preventing unauthorized use, shall be provided;
   (F) for equipment manufactured after the effective date of this Rule, a positive display of specific filter(s) in the beam.

(10) When a control panel may energize more than one x-ray tube:
    (A) It shall be possible to activate only one x-ray tube during any one time interval;
    (B) There shall be an indication at the control panel identifying which x-ray tube can be energized; and
    (C) There shall be an indication at the x-ray tube if that tubehead can be energized.

(11) There shall be means of determining the target to patient distance to within one centimeter.
(12) If exposures are controlled by a timer, that timer:
    (A) shall permit the setting of exposure times at least as short as one second, and
    (B) shall not permit an exposure if set at zero or "off".
(13) Unless it is possible to bring the x-ray exposure rate to its prescribed value within five seconds of actuating the x-ray "on" control, the tube housing shall be fitted with a shutter operable only from the control panel, and of lead equivalent not less than that of the tube housing. In addition:
    (A) The status of the shutter "Beam On", "Beam Off" or "Shutter Open", "Shutter Closed" or equivalent description, shall be indicated at the control panel.
    (B) It shall not be possible to initiate an exposure sequence unless the shutter has first been placed in the "Beam Off" or "Shutter Closed" position.
    (C) The shutter shall automatically go to the "Beam Off" or "Shutter Closed" position if the exposure is terminated by:
       (i) the operation of the timer,
       (ii) the dose monitoring system, if provided,
       (iii) the operation of a safety interlock, or
       (iv) a power failure.

(b) In addition to shielding adequate to meet requirements of Section .1600 of this Chapter, the following treatment room design requirements shall be met:
Treatment room entrances shall be provided with warning lights in a readily observable position, which will indicate when the useful beam is "on".

Provision shall be made for two-way communication with the patient from the control room.

A system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may see the patient and the control panel from the same position.

Facilities which contain an x-ray system which may be operated above 150 kVp shall:
(A) have all necessary shielding, except for any beam interceptor, provided by fixed barriers;
(B) have the control panel in a protected area which is outside the treatment room;
(C) have all entrance doors to the treatment room electrically connected such that the x-ray production cannot be initiated unless all doors are closed and shall cease if any door is opened during x-ray production;
(D) if the radiation output of the x-ray tube is affected by any door opening, be so designed that it is possible to initiate x-ray production only by:
   (i) closing all doors and, subsequently,
   (ii) reinitiating the exposure by manual action at the control panel.

(c) Operating procedures, surveys, and calibration shall comply with the following requirements:

(1) All new facilities and existing facilities not previously surveyed shall have a radiation protection survey made by, or under the direction of, a qualified expert. This shall also be done after any change in the facility which might produce a radiation hazard. The expert shall report his findings in writing to the person in charge of the facility, and a copy of this report shall be transmitted by the registrant to the agency at the address in Rule .0111 of this Chapter.

(2) The radiation output of each therapeutic x-ray machine shall be calibrated by, or under the direction of a qualified expert who is physically present at the facility during the calibration procedure. The calibration shall be repeated after any change, in or replacement of, components of the x-ray generating equipment which could cause a change in x-ray output. Calibration of the therapy beam shall be performed with a measurement instrument, the calibration of which is traceable to national standards for exposure or absorbed dose, and which shall have been calibrated within the preceding 12 months. Records of radiation outputs shall be provided to and maintained by the registrant.

(3) Each therapeutic x-ray machine shall be calibrated as described in Subparagraph (c)(2) of this Rule at time intervals not exceeding one year. The calibration shall include at least the following determinations:
   (A) the accurate determination of the air exposure rate or the dose rate at a reference point within a suitable phantom, as appropriate;
   (B) the congruence between the radiation field and light localizer, when such is used;
   (C) the half-value layer for every combination of kVp and filter used for radiation therapy.

(4) Therapeutic x-ray systems capable of operation at greater than 150 kVp, in addition to the annual calibration required in Subparagraphs (c)(2) and (3) of this Rule, shall have spot checks performed.
   (A) The spot check methods and frequency shall be designed and in writing by a qualified expert. Spot checks shall include verification of continued congruency between the radiation field and the localizing device where an optical field illuminator is used.
   (B) Whenever a spot check indicates a significant change in the operating characteristics of a machine, as specified in the qualified expert's spot check design, the machine shall be recalibrated as required.
   (C) A log shall be kept of all spot check measurements.

(5) Therapeutic x-ray machines shall not be left unattended unless the locking device required by Part (a)(10)(E) of this Rule is set to prevent activation of the useful beam.

(6) Except as provided in Rule .0603(a)(1)(H) of this Section, no individual other than the patient shall be in the treatment room during exposures unless he is protected by a barrier sufficient to meet the requirements of Rule .1604 of this Chapter, and no individual other than the patient shall be in the treatment room when the kVp exceeds 150 during exposures.

(7) The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed 50 kVp. In such cases the holder shall wear protective gloves and apron of not less than 0.5 mm lead equivalency at 100 kVp.
10A NCAC 15 .0609 X-RAY AND ELECTRON THERAPY INSTALLATIONS ONE MEV AND ABOVE

(a) The requirements in Paragraphs (b) to (e) of this Rule shall apply only to medical facilities using medical x-ray and electron therapy equipment with energies one MeV and above. In addition, such medical facilities shall also comply with the requirements in Section .0900 of this Chapter.

(b) Equipment requirements are as follows:

   (1) For existing equipment and new equipment manufactured or installed after the effective date of these Rules:

   (A) The leakage radiation, excluding neutrons, at a distance of one meter from the source shall not exceed 0.1 percent of the useful beam dose rate at one meter from the source for any of its operating conditions.

   (B) Within one year after the effective date of these Rules the registrant shall determine or obtain from the manufacturer for each machine the leakage radiation specifications for electrons, x-rays and neutrons existing at the points specified in Part (b)(1)(A) of this Rule for specified operating conditions. Records on radiation leakage shall be maintained at the installation.

   (C) For equipment from which neutron leakage may be a hazard, a qualified expert shall specify such additional requirements as may be necessary to protect health or minimize danger to life or property. The adequacy of these additional requirements shall be confirmed by a survey. Survey records shall be maintained by the registrant.

   (2) Adjustable or interchangeable beam limiting devices shall be provided and shall meet the following requirements:

   (A) For existing equipment and new equipment manufactured or installed after the effective date of these Rules:

      (i) Adjustable or interchangeable beam limiting devices shall attenuate the radiation incident on the beam limiting devices such that the dose equivalent in rems at any distance from the source does not exceed two percent of the maximum dose equivalent in the useful beam measured at an equal distance from the radiation source.

      (ii) If the beam limiting device does not meet the specifications in Subpart (b)(2)(A)(i) of this Rule, the agency may accept auxiliary equipment or methods for accomplishing attenuation.

   (B) Dose equivalent measurements may be averaged over an area up to but not exceeding 100 square centimeters at a distance of one meter from the target.

   (3) In equipment which uses a system of wedge filters, interchangeable field flattening filters or beam scattering devices:

   (A) Irradiation shall not be possible until a selection of filter has been made at the treatment control panel;

   (B) An interlock system shall be provided to prevent irradiation if the filter is not in the correct position;

   (C) An indication of the orientation of the wedge filter with respect to the treatment field shall be provided when wedge filters are used; and

   (D) A display shall be provided at the treatment control panel showing the filter(s) in use, including an indication of "no filters".

   (4) Equipment installed after the effective date of these Rules shall be provided with at least one radiation detector in the radiation head. This detector shall be incorporated into a primary system.

   (A) Each primary system shall have a detector which is a transmission detector and is placed on the patient side of any fixed added filters other than a wedge filter;

   (B) The detector(s) shall be removable only with tools or shall be interlocked to prevent incorrect positioning.

   (C) Each detector shall be capable of independently monitoring and turning "off" the useful beam.

   (D) Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.
(E) Each dose monitoring system shall have a legible display at the treatment control panel which shall:
   (i) maintain a reading until intentionally reset;
   (ii) in the event of power failure, have the capability of retrieving the information displayed at the time of failure.

(5) Selection and display of dose monitor units shall comply with the following requirements:
(A) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.
(B) After useful beam termination, it shall be necessary to reset the preselected dose monitor units before treatment can be reinitiated.
(C) The preselected number of dose monitor units shall be displayed at the treatment control panel until reset for the next irradiation.

(6) Automatic termination of irradiation by the dose monitoring system shall comply with the following requirements:
(A) Each of the monitoring systems shall be capable of independently terminating irradiation. Provisions shall be made to test the correct operation of each system.
(B) Each primary system shall terminate irradiation when the preselected number of dose monitor units have been reached, and each secondary system shall be used as a backup.

(7) It shall be possible to terminate irradiation and equipment movements or to go from an interruption condition to termination conditions at any time from the treatment control panel.

(8) It shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption the equipment shall go to termination condition.

(9) A timer shall be provided and shall meet the following requirements:
(A) The timer shall have a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator.
(B) The timer shall be a cumulative timer which switches "on" and "off" with the radiation and retains its reading after irradiation is interrupted or terminated. It shall be necessary to zero the elapsed time indicator and the preset time selector after irradiation is terminated, before reactivation is possible.
(C) To guard against failure of the dose monitoring systems, the timer shall terminate irradiation when a preselected time has elapsed.

(10) In equipment capable of both x-ray therapy and electron therapy:
(A) Irradiation shall not be possible until a selection of radiation type, x-rays or electrons, has been made at the treatment control panel;
(B) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel;
(C) An interlock system shall be provided to prevent irradiation with x-rays when electron applicators are fitted and irradiation with electrons when x-ray wedge filters are fitted; and
(D) The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

(11) In equipment capable of generating radiation beams of different energies:
(A) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;
(B) An interlock system shall be provided to insure that the equipment emits primarily the energy of radiation which has been selected;
(C) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel; and
(D) The energy selected shall be displayed at the treatment control panel before and during irradiation.

(12) In equipment capable of both stationary-beam therapy and moving-beam therapy:
(A) Irradiation shall not be possible until a selection of stationary-beam therapy or moving-beam therapy has been made at the treatment control panel;
(B) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel;

(C) An interlock system shall be provided to terminate irradiation if the movement stops during moving-beam therapy;

(D) Moving-beam therapy shall be so controlled that the required dose monitor units per degree of rotation is obtained; and

(E) The mode of operation shall be displayed at the treatment control panel.

(13) The registrant shall determine or obtain from the manufacturer the location with reference to an accessible point on the radiation head of:

(A) the x-ray target and the virtual source of x-rays;

(B) the electron window or the scattering foil; and

(C) all possible orientations of the useful beam.

(14) Means shall be provided so that all radiation safety interlocks can be checked. When preselection of any of the operating conditions requires action in the treatment room and at the treatment control panel selection at one location shall not give a display at the other location until the requisite selection operations in both locations have been completed.

(c) Facility shielding shall be adequate to meet the requirements of Section .1600 of this Chapter.

(d) Facility design shall meet the following requirements:

(1) Except for entrance doors, all required barriers shall be fixed barriers.

(2) The control panel shall be located outside the treatment room. The door must be closed during radiation production.

(3) A viewing system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may see the patient and the control panel from the same position. When the viewing system is by electronic means (e.g., television), an alternate viewing system shall be available.

(4) Provision shall be made for two-way aural communication with the patient from the control room, however, where excessive noise levels make aural communication impractical, other methods of communication shall be used.

(5) Treatment rooms to which access is possible through more than one entrance shall be provided with warning lights, in a readily observable position near the outside of all access doors, preferably at eye level, which will indicate when the useful beam is "on".

(6) Have all entrance doors to the treatment room electrically connected such that the x-ray production cannot be initiated unless all doors are closed and shall cease if any door is opened during x-ray production.

(e) The operating procedures which follow are in addition to those in Rule .0908 of this Chapter.

(1) Radiation protection surveys shall comply with the following requirements:

(A) All new facilities and existing facilities not previously surveyed shall have a radiation protection survey made by, or under the direction of, a qualified expert. This shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

(B) The expert shall report his findings in writing to the person in charge of the facility, and a copy of the report shall be transmitted by the registrant to the agency at the address in Rule .0111 of this Chapter.

(2) No person other than the patient shall be in the treatment room during treatment. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

(3) The output of each therapeutic x-ray machine shall be calibrated by, or under the direct supervision of a qualified expert, before it is first used for medical purposes. Calibrations shall be repeated at least once every 12 months and after any change which might significantly increase radiation hazards. Calibration of the therapy beam shall be performed with measurement instruments, the calibration of which is traceable to national standards for exposure or absorbed dose and which shall have been calibrated within the preceding 12 months. Records of calibrations shall be provided to and maintained by the registrant. The calibration shall include at least the following determinations:

(A) the exposure rate or dose rate as appropriate for the field sizes used and for each effective energy and for each treatment distance used for radiation therapy;
the beam quality (e.g., half-value layer when appropriate) for every proposed combination of operating conditions used for radiation therapy;

(C) the congruence between the radiation field and the field indicated by the localized device when used;

(D) verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the side light and backpointer alignment with the isocenter, when applicable, variation in the axis of rotation for the table, gantry and jaw system and beam flatness and symmetry in air or at the specified depths in a water phantom.

(4) Spot checks shall be performed monthly.

(A) The spot check methods shall be in writing and shall be designed by a qualified expert.

(B) Whenever a spot check indicates a significant change (as specified in the qualified expert's spot check design) in the operating characteristics of a machine, the machine shall be recalibrated as required in Subparagraph (e)(3) of this Rule.

(C) A log shall be kept of all spot check measurements.

History Note: Authority G.S. 104E-7; 104E-12(a);
Eff. February 1, 1980;
Amended Eff. January 1, 1994; November 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0609 Eff. February 1, 2015.

10A NCAC 15 .0610 VETERINARY MEDICINE RADIOGRAPHIC INSTALLATIONS
(a) The provisions of this Rule shall apply only to veterinary medicine radiographic installations. Radiographic equipment used in veterinary medicine radiographic installations shall meet the following requirements:

(1) The protective tube housing shall be of the diagnostic type.

(2) Diaphragms or cones shall be provided for collimating the useful beam to the area of the image receptor and shall provide the same degree of protection as is required in the housing.

(3) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50-70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

(4) A device shall be provided to terminate the exposure after a preset time or exposure.

(5) A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least six feet from the animal during all x-ray exposures or behind a protective barrier adequate to assure compliance with Rules .1604 and .1611 of this Chapter.

(b) All wall, ceiling and floor areas shall be equivalent to or provided with primary and secondary protective barriers necessary to comply with Rules .1604 and .1611 of this Chapter.

(c) Operating procedures shall meet the following requirements:

(1) The operator shall stand well away from the useful beam and the animal during radiographic exposures.

(2) No individual other than the operator shall be in the x-ray room while exposures are being made unless such individual's assistance is required.

(3) When an animal must be held in position during radiography, mechanical supporting or restraining devices shall be used; except if the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and shall be so positioned that no part of the individual's body will be struck by the useful beam. The exposure of any professional staff or ancillary personnel used for this purpose shall be monitored and permanently recorded. Exposures shall comply with Rules .1604 and .1609 of this Chapter.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. January 1, 1994; November 1, 1989;

10A NCAC 15 .0611 COMPUTED TOMOGRAPHY (CT) X-RAY SYSTEMS
This Rule provides special requirements for human diagnostic use of computed tomography (CT) x-ray equipment. The uses of Cone Beam CT, Veterinary CT, CT Simulation, and CT attenuation correction shall be exempt from this Rule. The provisions of this Rule are in addition to, and not in substitution for, the Rules in Sections .0100, .0200, .0600, .0900, .1000, and .1600 of this Chapter.

The following definitions shall apply to this Rule:

1. "CT qualified expert (CT QE)" means an individual who is registered or is providing service for a registered facility where they are employed, as required by Section .0200 of this Chapter. The individual shall have the following education and experience:

   A. a master's or doctoral degree in physics, medical physics, biophysics, radiological physics, medical health physics, or equivalent disciplines from a college or university accredited by an agency recognized by the U.S. Department of Education, and three years work experience in a clinical CT environment. The work experience shall be supervised and documented by a medical physicist certified in the specialty area of diagnostic medical physics by the American Board of Radiology, the Canadian College of Physicists in Medicine, or the American Board of Medical Physics; or

   B. certification in the specialty area of diagnostic medical physics by the American Board of Radiology, the Canadian College of Physicists in Medicine, or the American Board of Medical Physics and shall abide by the certifying body’s requirements for continuing education.

2. "general supervision" means the activity is performed under the qualified supervisor's overall direction and control but the qualified supervisor's physical presence shall not be required during the activity.

3. "personal supervision" means overall direction, control, and training of an individual by a qualified supervisor who shall be physically present during the activities performed by the supervised individual.

Equipment and Installation Requirements

1. CT x-ray systems shall meet the requirements of 21 CFR 1020.33 as incorporated by reference in Rule .0117(a)(3) of this Chapter.

2. The operator of a CT scanner shall be able to maintain aural communication with the patient from a shielded position at the control panel.

Personnel Requirements. Individuals who operate CT x-ray systems shall be specifically trained on the operational features of the unit and:

1. hold (CT) registration with the American Registry of Radiologic Technologists (ARRT); or

2. be a Registered Technologist (R.T.) by the ARRT with registration in radiography (R) or a Certified Nuclear Medicine Technologist by the Nuclear Medicine Technology Certification Board; these individuals shall document training and experience that is equivalent to that required to attain (CT) registration with the ARRT; or

3. be in training under the personal supervision of an individual that meets the requirements of Subparagraph (d)(1) or (d)(2) of this Rule.

System Performance Evaluations

1. Performance evaluations of the CT x-ray system shall be performed by, or under the general supervision of, a CT QE who assumes the responsibility for the evaluation.

2. The performance evaluation of a CT x-ray system shall be performed within 30 days of installation and at least every 14 months.

3. Performance evaluation standards and tolerances shall meet manufacturer's specifications or standards and tolerances for the CT x-ray system from the American College of Radiology (ACR) and the American Association of Physicists in Medicine (AAPM) incorporated herein by reference including subsequent amendments and editions. These standards and tolerances may be found at no charge on the ACR website at https://www.acr.org and the AAPM website at www.aapm.org.

4. The performance evaluation shall include the following as applicable to the design of the scanner:

   A. geometric factors and alignment including alignment light accuracy, and table increment accuracy;

   B. image localization from a scanned projection radiograph (localization image);

   C. radiation beam width;

   D. image quality including high-contrast (spatial) resolution, low-contrast resolution, image uniformity, noise, and artifact evaluation;

   E. CT number accuracy;

   F. image quality for acquisition workstation display devices; and
(G) a review of the results of the routine QC, as set forth in Paragraph (f) of this Rule;

(5) The performance evaluation shall also include the evaluation of radiation output and patient dose indices for the following clinical protocols if performed:
(A) pediatric head;
(B) pediatric abdomen;
(C) adult head;
(D) adult abdomen; and
(E) brain perfusion.

(6) Evaluation of radiation output shall be performed with a dosimetry system that is calibrated. The dosimetry system shall have been calibrated within the preceding two years by persons registered to provide such services pursuant to Rule .0205 of this Chapter.

(7) The performance evaluation shall be documented and maintained for inspection by the Agency. The documentation shall include the name of the CT QE performing or supervising the evaluation, as well as any other individuals participating in the evaluation under the general supervision of the CT QE. The documentation shall be retained for 14 months.

(f) Routine Quality Control (QC)

(1) A routine QC program for the CT system shall be developed by or have written approval by a CT QE and include:
(A) instructions for the routine QC;
(B) intervals for QC testing;
(C) acceptable tolerances for the QC tests;
(D) use of a water equivalent phantom to evaluate each day of clinical use: noise, CT number accuracy, and artifacts; and
(E) routine QC tests that may be performed in place of system performance evaluations after equipment repairs or maintenance. This shall include the process for obtaining approval from the CT QE prior to conducting testing.

(2) The duties in the routine QC program, as described in Subparagraph (f)(1) of this Rule, shall be conducted by individuals that meet the requirements of Paragraph (d) of this Rule or individuals approved by the CT QE.

(3) The routine QC shall be documented and maintained for inspection by the Agency. The records shall be retained for 14 months.

(g) Operating Requirements. The following information shall be accessible to the CT operator during use of the machine and while performing routine QC:

(1) instructions on performing routine QC;
(2) a schedule of routine QC;
(3) any allowable variations set by the CT QE for the indicated parameters;
(4) the results of the most recent routine QC completed on the system; and
(5) established scanning protocols.

History Note: Authority G.S. 104E-7; 104E-11; 104E-12; Eff. October 1, 2017.

SECTION .0700 - USE OF SEALED RADIOACTIVE SOURCES IN THE HEALING ARTS

Codifier’s Note: 10 NCAC 03G .2800 was transferred to 15A NCAC 11 .0700 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .0701 SCOPE

The provisions of this Section apply to all licensees who use sealed sources in the healing arts and are in addition to, and not in substitution for, other applicable provisions of the rules of this Chapter.

History Note: Authority G.S. 104E-7; Eff. February 1, 1980; Amended Eff. May 1, 1993; Transferred and Recodified from 15A NCAC 11 .0701 Eff. February 1, 2015.
MANUAL BRACHYTHERAPY

(a) Accountability, storage and transit

(1) Each licensee shall provide accountability of sealed sources and shall keep a record of the issue and return of all sealed sources. A physical inventory shall be made at least quarterly and a written record of the inventory maintained.

(2) When not in use, sealed sources and applicators containing sealed sources shall be kept in a protective enclosure of such material and wall thickness as necessary to assure compliance with the provisions of Rules .1604, .1609 and .1611 of this Chapter.

(b) Testing sealed sources for leakage and contamination

(1) All sealed sources with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and contamination prior to initial use and at intervals not to exceed six months or at other intervals approved by the U.S. Nuclear Regulatory Commission or an Agreement State in the Sealed Source and Device Registry. If there is reason to suspect that a sealed source might have been damaged, or might be leaking, it shall be tested for leakage before further use.

(2) Leak tests shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample, or in the case of radium, the escape of radon at rate of 0.001 microcurie per 24 hours. Any test conducted pursuant to Subparagraph (b)(1) of this Rule which reveals the presence of 0.005 microcurie or more of removable contamination or, in the case of radium, the escape of radon at the rate of 0.001 microcurie or more per 24 hours shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with applicable provisions of Section .1600 of this Chapter. A report describing the sealed sources involved, the test results and the corrective action taken shall be submitted in writing to the agency at the address stated in Rule .0111 of this Chapter within five days after the test.

(3) Leak test results shall be recorded in units of microcuries and maintained for inspection by the agency.

(c) Radiation surveys

(1) Immediately after implanting sources in an individual the licensee shall make a radiation survey of the individual and the area of use to confirm that no source has been misplaced. The licensee shall make a record of each survey.

(2) Immediately after removing the last temporary implant source from an individual, the licensee shall make a radiation survey of the individual with a radiation detection survey instrument to confirm that all sources have been removed. The licensee may not release from confinement for medical care an individual treated by temporary implant until all sources have been removed.

(d) A licensee shall maintain accountability for all brachytherapy sources in storage or in use. After removing sources from an individual, a licensee shall return brachytherapy sources to the storage area. A licensee shall ensure that all sources taken from the storage area have been returned, and shall make a record of the source accountability and retain the record for three years.

(e) For temporary implants, the record shall include:

(1) the number and activity of sources removed from storage;
(2) the date and time the sources were removed from storage;
(3) the name of the individual who removed the sources from storage;
(4) the location of use;
(5) the number and activity of sources returned to storage;
(6) the date and time the sources were returned to storage; and
(7) the name of the individual who returned the sources to storage.

(f) For permanent implants, the record shall include:

(1) the number and activity of sources removed from storage;
(2) the date and time the sources were removed from storage;
(3) the name of the individual who removed the sources from storage;
(4) the number and activity of sources not implanted;
(5) the date the sources were returned to storage; and
(6) the name of the individual who returned the sources to storage.

(g) For each patient or human research subject who is receiving brachytherapy and cannot be released under Rule .0358 of this Section, a licensee shall:

(1) Not quarter the patient or human research subject in the same room as an individual who is not receiving brachytherapy;
(2) Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and
(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(h) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

(1) Dislodged from the patient; or
(2) Lodged within the patient following removal of the source applicators.

(i) A licensee shall notify the Radiation Safety Officer or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

History Note: Authority G.S. 104E-7; 104E-12(a); Amended Eff. February 1, 1980; January 1, 2005; April 1, 1999; January 1, 1994; October 1, 1980; Transferred and Recodified from 15A NCAC 11 .0702 Eff. February 1, 2015.

10A NCAC 15 .0703 TELEThERAPY

History Note: Authority G.S. 104E-7(a)(2); 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540; Eff. February 1, 1980; Amended Eff. April 1, 1999; June 1, 1993; May 1, 1992; October 1, 1984; October 1, 1980; Repealed Eff. November 1, 2007; Transferred and Recodified from 15A NCAC 11 .0703 Eff. February 1, 2015.

SECTION .0800 - REQUIREMENTS FOR NON-HUMAN USE OF RADIATION GENERATING DEVICES

10A NCAC 15 .0801 PURPOSE AND SCOPE

(a) This Section provides special requirements for use of ionizing radiation generating devices (RGDs) operating above five thousand electron volts (5 keV), but below one million electron volts (1 MeV) that are in addition to requirements in the other sections of this Chapter.

(b) This Section does not pertain to radiation safety requirements for x-ray equipment that is covered in other sections of this Chapter (e.g., x-rays in the healing arts in Section .0600 of this Chapter, and particle accelerators in Section .0900 of this Chapter).

History Note: Authority G.S. 104E-7; Eff. February 1, 1980; Transferred and Recodified from 15A NCAC 11 .0801 Eff. February 1, 2015; Amended Eff. October 1, 2015; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .0802 DEFINITIONS

In addition to terms found in Rule .0104 of this Chapter the following definitions shall apply to this Section:

(1) "Accredited bomb squad" means a law enforcement agency utilizing certified bomb technicians.

(2) "Analytical RGD equipment" means equipment that uses electronic means to generate ionizing radiation for the purpose of examining the microstructure of materials, i.e. x-ray diffraction and x-ray spectroscopy.

(3) "Analytical RGD system" means a group of local and remote components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials.

(4) "Bomb detection RGDs" means RGDs used for the sole purpose of remotely detecting explosive devices.

(5) "Certified bomb technician" means a member of an accredited bomb squad who has completed the FBI Hazardous Devices School. Information pertaining to this program can be found on the school website at http://www.fbi.gov/about-us/cis/hazardous-devices.

(6) "Certifiable cabinet x-ray system" means an existing uncertified RGD that has been modified to meet the certification requirements specified in 21 CFR 1020.40 as incorporated by reference in Rule .0117 of this Chapter.
"Certified cabinet x-ray system" means an RGD utilized in an enclosed, interlocked cabinet, such that the radiation machine will not operate unless all openings are securely closed. These systems shall be certified in accordance with 21 CFR 1010.2 as incorporated by reference in Rule .0117 of this Chapter, as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40 as incorporated by reference in Rule .0117 of this Chapter.

"Collimator" means a device or mechanism by which the x-ray beam is restricted in size.

"Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

"Electron Beam Device" means any device using electrons below 1MeV to heat, join, or otherwise irradiate materials.

"Enclosed beam RGD" means an RGD with all possible x-ray beam paths contained in a chamber, coupled chambers, or other beam-path-confinement devices to prevent any part of the body from intercepting the beam during normal operations. Normal access to the primary beam path, such as a sample chamber door, shall be interlocked with the high voltage of the x-ray tube or the shutter for the beam to be considered "enclosed." An open-beam device placed in an interlocked enclosure is considered an "enclosed beam" unless there are provisions for routine bypassing of the interlocks.

"Fail-safe characteristics" means a design feature that causes the radiation beam to terminate, port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device. For example, if an "X-ray On" light indicator or shutter indicator or interlock fails, the radiation beam shall terminate.

"Hand-held x-ray system" means any device or equipment that is portable and used for similar purposes as analytical RGD equipment.

"Hybrid gauge" means an x-ray gauge device utilizing both x-ray and radioactive sources.

"Industrial radiography" means RGDs used to make radiographic images to examine the structure of materials by nondestructive methods. These RGDs shall not be contained in a cabinet and are not permanent installations.

"Ion implantation equipment, low-energy" means any closed device operating below 1MeV used to accelerate elemental ions and implant them in other materials.

"Leakage radiation" means radiation emanating from the source assembly housing except for:

(A) the primary beam;
(B) scatter radiation emanating from other components (e.g., shutter or collimator); and
(C) radiation produced when the beam on switch or timer is not activated.

"Local components" means part of an RGD x-ray system and include areas that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

"Mobile RGD" means RGD equipment mounted on a permanent base with wheels or casters for moving while assembled.

"Normal operating procedures" means step-by-step instructions necessary to accomplish a task. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data recording procedures that are related to radiation safety.

"Open-beam RGD" means a device or system designed in such a way that the primary beam is not completely enclosed during normal operation and used for analysis, gauging, or imaging in which an individual could accidentally place some part of their body in the primary beam or stray radiation path during normal operation.

"Permanent radiographic installation" means an RGD utilized in an enclosed shielded room, cell, or vault that allows entry when the RGD is not energized.

"Portable RGD" means RGD equipment designed to be carried.

"Primary beam" means radiation that passes through an aperture of the source assembly housing by a direct path from the radiation source.

"Radiation generating device (RGD)" means any system, device, subsystem, or machine component that may generate by electronic means x-rays or particle radiation above 5 keV, but below 1 MeV, and not used for healing arts on humans or animals. Examples of RGDs are the following:

(A) analytical RGD equipment;
(B) certified and certifiable cabinet x-ray systems;
(C) gauging devices using x-ray sources;
hybrid gauging devices;

(E) e-beam welders;

(F) baggage scanners;

(G) industrial radiography RGDs; and

(H) permanent radiographic installations.

(26) "Remote components" means parts of an RGD x-ray system that are not struck by x-rays such as power supplies, transformers, amplifiers, readout devices, and control panels.

(27) "Scattered radiation" means radiation, other than leakage radiation, that during passage through matter, has been deviated in direction or has been modified by a decrease in energy.

(28) "Shutter" means an adjustable device, generally made of lead or other high atomic number material, fixed to a source assembly housing to intercept, block, or collimate the primary beam.

(29) "Source" means the point of origin of the radiation, such as the focal spot of an x-ray tube.

(30) "Stationary RGD" means RGD equipment that is installed or placed in a fixed location.

(31) "Stray radiation" means the sum of leakage and scatter radiation emanating from the source assembly or other components except for the primary beam, and radiation produced when the beam on switch or timer is not activated.

(32) "X-ray generator" means the part of an x-ray system that provides the accelerating (high) voltage and current for the x-ray tube.

(33) "X-ray gauge" means an x-ray producing device designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, or interface location of manufactured products.

History Note: Authority G.S. 104E-7; Eff. February 1, 1980; Transferred and Recodified from 15A NCAC 11 .0802 Eff. February 1, 2015; Amended Eff. October 1, 2015; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .0803  EQUIPMENT REQUIREMENTS

(a) Certified cabinet x-ray systems shall meet the requirements of 21 CFR 1020.40 as incorporated by reference in Rule .0117(a)(3) of this Chapter.

(b) All certified and certifiable cabinet x-ray systems shall:

(1) be constructed so that, the radiation emitted from the system shall not exceed an exposure of 0.5 milliroentgen (mR) in one hour at any point five centimeters outside the external surface; and

(2) have a fail-safe interlock that prevents irradiation when the cabinet, chamber, or coupled chambers are open.

(c) Open-beam analytical RGD systems shall be equipped with a safety device that prevents the entry of any portion of an individual's body into the primary x-ray beam path that causes the beam to be shut off upon entry into its path.

(d) Open-beam analytical RGDs shall be provided with a visible and legible indication of:

(1) x-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner; or

(2) shutter status (OPEN-CLOSED) or beam status (ON-OFF) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(e) Warning devices on open-beam analytical RGDs shall be labeled so that their purpose is identified. On open-beam analytical RGDs installed after February 1, 1980, warning devices and lights shall have fail-safe characteristics.

(f) Unused ports on radiation source housings for open-beam RGDs shall be secured in the closed position in a manner that will prevent unintended opening.

(g) Each port on the radiation source housing on open-beam analytical RGDs installed after February 1, 1980 and designed to accommodate interchangeable components shall be equipped with a shutter that cannot be opened unless a collimator or a component coupling is connected to the port.

(h) Portable open-beam analytical RGDs that shall be manufactured to be used hand-held without safety devices are exempt from the requirements of Paragraph (c) of this Rule and shall be constructed according to International Standard IEC 62495 that is incorporated by reference and includes subsequent amendments. This standard can be downloaded for one hundred twenty-one dollars ($121.00) at the following website: http://webstore.ansi.org/FindStandards.aspx?SearchString=IEC+62495+Ed.+1.0+en%3a2011&SearchOption=0&PageNum=0&SearchTermsArray=null%7cIEC+62495+Ed.+1.0+en%3a2011%7cnull.
(i) A registrant may apply to the agency, as defined in Rule .0104 of this Chapter, for an exemption from the requirement of a safety device. This request shall include:
   (1) a description of the safety devices;
   (2) the reason safety devices cannot be used; and
   (3) a description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

(j) Analytical RGDs shall be provided with a visible and legible label(s) bearing the radiation symbol and the words:
   (1) "CAUTION - HIGH INTENSITY X-RAY BEAM," or words having a similar meaning, near the exit port to identify the location of the beam; and
   (2) "CAUTION - RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED", or words having a similar meaning, near any switch that energizes an x-ray tube, if the radiation source is an x-ray tube.

(k) Warning lights labeled with the words "X-RAYS ON," or other words having similar meaning, shall be located:
   (1) near any switch that activates the high voltage to energize an x-ray tube; or
   (2) in a conspicuous location near the radiation source housing and radiation beam(s) and visible from all instrument access areas.

(l) Warning lights shall activate when the x-ray tube is energized.

(m) Each x-ray tube housing shall be:
   (1) constructed that when all shutters are closed the leakage radiation measured at a distance of five centimeters from its surface is not capable of producing an exposure in excess of 2.5 millirem (mrem)/25 microsieverts (µSv) in one hour; and
   (2) if the tube housing is the primary shielding for the x-ray tube, does not produce x-rays when the housing is opened or disassembled.

(n) Each x-ray generator shall be supplied with a protection cabinet which limits leakage radiation measured at a distance of five centimeters from its surface such that it is not capable of producing an exposure in excess of 0.25 mrem/2.5µSv in one hour.

(o) Permanent radiographic installations and industrial radiography RGDs shall comply with the requirements of Rule .0807 of this Section.

History Note: Authority G.S. 104E-7; Eff. February 1, 1980; Transferred and Recodified from 15A NCAC 11 .0803 Eff. February 1, 2015; Amended Eff. October 1, 2015; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .0804 AREA REQUIREMENTS
(a) The local components of RGDs shall be located and arranged to include sufficient shielding or access control to ensure no radiation levels exist in any area surrounding the local components that could result in a dose to an individual present in excess of the dose limits given in Rule .1611(a) of this Chapter.
(b) Survey Requirements
   (1) Radiation surveys, as set forth in Rule .1613(a) and (b) of this Chapter, of all RGDs sufficient to show compliance with Paragraph (a) of this Rule, shall be performed:
      (A) within 30 days after initial operation of the device;
      (B) prior to use following any change in the initial arrangement, including the number or type of local components in the system; and
      (C) prior to use following any maintenance requiring the disassembly or removal of a local component in the system that could affect the radiation exposure to personnel.
   (2) A registrant may apply to the agency for approval of procedures differing from those in Subparagraph (b)(1) of this Rule, provided that the registrant demonstrates satisfactory compliance with Paragraph (a) of this Rule.
   (3) Surveys shall be performed with a radiation survey instrument capable of the following:
      (A) measuring the radiation energies of the system surveyed;
      (B) confirming that the radiation limits of this Section are met; and
      (C) calibrated according to the manufacturer's recommended frequency or at least annually when a frequency is not recommended.
(c) Each area of use or room containing RGDs shall be conspicuously posted with caution signs in accordance with the requirements of Rule .1623 of this Chapter, bearing the radiation caution symbol and the words "CAUTION - X-RAY EQUIPMENT," or words having a similar meaning.

History Note: Authority G.S. 104E-7(a)(2);
               Eff. February 1, 1980;
               Amended Eff. January 1, 1994;
               Transferred and Recodified from 15A NCAC 11 .0804 Eff. February 1, 2015;
               Amended Eff. October 1, 2015;

10A NCAC 15 .0805 OPERATING REQUIREMENTS
(a) RGDs shall be operated by individuals that have completed the training requirements of Rule .0806 of this Section.
(b) Normal operating procedures shall be written and available to all RGD operators and support staff.
(c) No individual shall be permitted to operate RGDs in any manner other than that specified in the operating procedures unless the person has obtained written approval of the individual responsible for radiation or the Radiation Safety Officer (RSO) as defined in Rule .0104 of this Chapter.
(d) No individual shall bypass a safety device unless the person has obtained the approval of the person responsible for radiation safety or the RSO. This process shall be incorporated into the radiation protection program by the RSO, as set forth in Rule .1603(a), and the operating procedures as set forth in Rule .0603(a)(1)(B). The written approval, as granted by the RSO, shall include an expiration date. When a safety device has been bypassed, a legible sign bearing the words "SAFETY DEVICE NOT WORKING" or words having a similar meaning shall be placed on the radiation source housing and the control panel during the bypassing period.
(e) Prior to an individual modifying the:
   (1) x-ray tube system, resulting in the removal of tube housings, covers, or shielding materials;
   (2) shutters;
   (3) collimators; or
   (4) beam stops
the individual shall determine the tube is off and will remain off until safe conditions have been restored.
(f) Safety devices including interlocks, shutters, and warning lights shall be tested once annually for proper operation on all RGDs in operation. Records of the testing shall be retained by the registrant for three years.
(g) No individual shall hold a sample or object while it is being irradiated.

History Note: Authority G.S. 104E-7; 104E-12;
               Eff. February 1, 1980;
               Transferred and Recodified from 15A NCAC 11 .0805 Eff. February 1, 2015;
               Amended Eff. January 1, 2016; October 1, 2015;

10A NCAC 15 .0806 PERSONNEL REQUIREMENTS
(a) Personnel operating or maintaining RGDs shall comply with the following:
   (1) No person shall be permitted to operate or maintain RGDs unless the person has received instruction in the operating and emergency procedures for the RGD and instruction that is in accordance with Rule .1003 of this Chapter.
   (2) Each registrant operating or maintaining RGDs shall maintain, for inspection by the agency, records of training that demonstrate the requirements of this Rule have been satisfied.
(b) The registrant shall provide ring or wrist personnel monitoring equipment to:
   (1) individuals using open-beam RGDs not equipped with a safety device; and
   (2) individuals maintaining RGDs if the maintenance procedures require the presence of a primary x-ray beam when any local component in the RGD is disassembled or removed.

History Note: Authority G.S. 104E-7; 104E-11; 104E-12;
               Eff. February 1, 1980;
               Transferred and Recodified from 15A NCAC 11 .0806 Eff. February 1, 2015;
               Amended Eff. October 1, 2015;
10A NCAC 15 .0807 PERMANENT RADIOGRAPHIC INSTALLATIONS AND INDUSTRIAL RADIOGRAPHY RGDS

(a) Permanent radiographic installations and industrial radiography RGDS are exempt from the requirements of the rules of this Section except Rule .0802 and Rule .0804(a), (b)(1)(A), (b)(1)(C), (b)(2), and (b)(3).
(b) Permanent radiographic installations and industrial radiography RGDS shall comply with the following rules of this Chapter:

(1) .0501;
(2) .0502;
(3) .0506;
(4) .0509-.0520;
(5) .0522;
(6) .0523(a)(1);
(7) .0523(a)(3);
(8) .0523(a)(6) -.0523(a)(15);
(9) .0523(b)(1) -.0523(b)(4);
(10) .0523(b)(6) -.0523(b)(7);
(11) .0523(b)(9) -.0523(b)(12);
(12) .0523(c); and
(13) .0525.

History Note:  Authority G.S. 104E-7;
Eff. October 1, 2015.

10A NCAC 15 .0808 APPLICABLE RULES FOR BOMB DETECTION RGDS

Bomb detection RGDS utilized by accredited bomb squads and certified bomb technicians shall comply with the following rules of this Chapter:

(1) .0501;
(2) .0502;
(3) .0509;
(4) .0511-.0520 except for the requirements for a direct reading pocket dosimeter and operating alarm ratemeter in .0512(a);
(5) .0522;
(6) .0523(a)(1);
(7) .0523(a)(3);
(8) .0523(a)(6) -.0523(a)(15);
(9) .0523(b)(1) -.0523(b)(4);
(10) .0523(b)(6) -.0523(b)(7);
(11) .0523(b)(9) -.0523(b)(12);
(12) .0523(c); and
(13) .0525.

History Note:  Authority G.S. 104E-7;
Eff. October 1, 2015.

SECTION .0900 - REQUIREMENTS FOR PARTICLE ACCELERATORS

Codifier's Note:  10 NCAC 03G .3000 was transferred to 15A NCAC 11 .0900 effective January 4, 1990.  Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .0901 PURPOSE AND SCOPE

(a) This Section establishes procedures for the licensing and the use of particle accelerators.
(b) In addition to the requirements of this Section, all licensees are subject to the requirements of Sections .0100, .0200, .1000, and .1600 of this Chapter. Licensees engaged in industrial radiographic operations are subject to the requirements of Section .0500 of this Chapter, and licensees engaged in the healing arts are subject to Rule .0350 of this Chapter and the applicable requirements of Section .0600 of this Chapter. Licensees engaged in the production of radioactive
material or possessing radioactive material incidental to an accelerator are subject to the requirements of Section .0300 of this Chapter.

(c) In addition to the requirements of this Section, all particle accelerator licensees are subject to the annual fee provisions contained in Section .1100 of this Chapter.

History Note: Authority G.S. 104E-7; 104E-9(a)(8); 104E-19(a);
Eff. February 1, 1980;
Amended Eff. January 1, 1994; June 1, 1989; July 1, 1982;
Transferred and Recodified from 15A NCAC 11 .0901 Eff. February 1, 2015.

10A NCAC 15 .0902 LICENSING REQUIREMENTS

No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a license issued pursuant to these Rules or as otherwise provided for in these Rules. The general procedures for licensing of particle accelerator facilities are included in Section .0903 of this Chapter.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0902 Eff. February 1, 2015.

10A NCAC 15 .0903 REQUIREMENTS FOR ISSUANCE OF A LICENSE FOR ACCELERATORS

Application for use of a particle accelerator will be approved only if the agency determines that:

(1) The applicant and his operators are qualified by reason of training and experience to use the accelerator in such a manner as to minimize danger to public health and safety or property;

(2) The applicant's proposed equipment, facilities, operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

(3) The applicant has appointed a radiation safety officer;

(4) The applicant has established a radiation safety committee to approve that the operation of the particle accelerator is in accordance with applicable radiation protection Sections of this Chapter; and

(5) The applicant for the use of a particle accelerator in the healing arts shall be a physician licensed to practice medicine in the state of North Carolina. The individuals designated on the application as users shall have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;

10A NCAC 15 .0904 LIMITATIONS

(a) No licensee shall permit any person to act as a particle accelerator operator until such person:

(1) has been instructed in radiation safety and shall have demonstrated an understanding thereof;

(2) has received copies of, and instruction in, this Section and the applicable requirements of this Chapter, pertinent licensing conditions and the licensee's operating and emergency procedures; and

(3) has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed in his assignment.

(b) Either the radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if this action is deemed necessary to minimize danger to public health and safety or property.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0904 Eff. February 1, 2015.

10A NCAC 15 .0905 SHIELDING AND SAFETY DESIGN

(a) A qualified expert registered by the agency pursuant to Rule .0205 of this Chapter, shall be consulted in the design of a particle accelerator installation. A qualified expert shall perform a radiation survey when the accelerator is first
capable of producing radiation to verify that radiation levels and shielding effectiveness meet the applicable requirements in this Chapter. A copy of the survey shall be submitted to the agency by the licensee prior to its use for its licensed purpose.

(b) Plans for construction of accelerator installations shall be submitted to the agency.

(c) Each particle accelerator installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with Rules .1604 and .1611 of this Chapter.

**History Note:**

10A NCAC 15 .0906 CONTROLS AND INTERLOCK SYSTEMS

(a) Instrumentation, readouts and controls on the particle accelerator control console shall be clearly identified and easily discernible.

(b) All entrances into a target room or other high radiation area shall conform to the requirements of Rule .1615 of this Chapter.

(c) When an interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the interlock has been tripped and, subsequently at the main control console.

(d) Each safety interlock shall operate independently of all other safety interlocks.

(e) All safety interlocks shall be fail-safe, i.e., designed so that any defect or component failure in the interlock system prevents operation of the accelerator.

(f) A "Scram button" or other emergency power cut-off switch shall be located and easily identifiable in all high radiation areas and at the control console. Such a cut-off switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without first manually resetting the cut-off switch.

**History Note:**

10A NCAC 15 .0907 WARNING DEVICES

(a) All locations designated as high radiation areas, and entrances to such locations shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

(b) Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such high radiation area. This warning device shall be clearly discernible in all high radiation areas and all radiation areas.

(c) Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with Rule .1624 of this Chapter.

**History Note:**

10A NCAC 15 .0908 OPERATING PROCEDURES

(a) Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

(b) Only a switch on the accelerator control console shall be routinely used to turn the accelerator beam "on" and "off". The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

(c) All safety and warning devices, including interlocks shall be checked for proper operability at least every six months unless more frequent checks are required by the agency. Results of such tests shall be maintained for two years at the accelerator facility for inspection by the agency.

(d) Electrical circuit diagrams of the accelerator, and the associated interlock systems, shall be kept current and maintained for inspection by the agency.

(e) If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:
authorized by the radiation safety officer;
recorded in a permanent log and a notice posted at the accelerator control console and at the location of
the bypassed interlock; and
terminated as soon as possible.
(f) A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;

10A NCAC 15 .0909 RADIATION MONITORING REQUIREMENTS
(a) Portable monitoring equipment shall be available at each particle accelerator facility. Such equipment shall be tested
for proper operation monthly and calibrated at intervals not to exceed one year, and after each servicing and repair.
(b) A radiation protection survey shall be performed and documented by a qualified expert registered by the agency
pursuant to Rule .0205 of this Chapter, when changes have been made in shielding, operation, equipment, or occupancy
of adjacent areas. The licensee shall submit the report of the qualified expert to the agency at the address found in Rule
.0111 of this Chapter.
(c) Except for facilities designed for human exposure, radiation levels in all high radiation areas shall be continuously
monitored. The monitoring devices shall be electrically independent of the accelerator control and interlock systems and
capable of providing a remote and local readout with visual or audible alarms at the control panel and other appropriate
locations.
(d) All area monitors shall be tested for proper operation at least every six months unless more frequent checks are
required by the agency.
(e) Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity
present in areas of airborne hazards.
(f) Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination in target and
other pertinent areas.
(g) All area surveys shall be made in accordance with the written procedures established by a qualified expert registered
by the agency pursuant to Rule .0205 of this Chapter, or the radiation safety officer of the particle accelerator facility.
(h) Records of all radiation protection surveys, calibration results, instrumentation tests, and smear results shall be kept
current and on file at each accelerator facility for two years for inspection by the agency.

History Note: Authority G.S. 104E-7; 104E-12(a);
Eff. February 1, 1980;
Amended Eff. October 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0909 Eff. February 1, 2015.

10A NCAC 15 .0910 VENTILATION SYSTEMS
(a) Adequate ventilation shall be provided in areas where airborne radioactivity may be produced to comply with Rule
.1604 of this Chapter.
(b) The licensee shall not vent, release or otherwise discharge airborne radioactive material to an unrestricted area in
excess of the limits specified in Rule .1611 of this Chapter.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. January 1, 1994; May 1, 1992;

SECTION .1000 - NOTICES: INSTRUCTIONS: REPORTS AND INSPECTIONS

Codifier's Note: 10A NCAC 03G .3100 was transferred to 15A NCAC 11 .1000 effective January 4, 1990.
Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .1001 NOTICES, INSTRUCTIONS, AND REPORTS TO EMPLOYEES
(a) Persons registered with the agency pursuant to the rules in Section .0200 of this Chapter and persons licensed under
the rules in Sections .0300, .0900, .1200, and .1300 of this Chapter shall comply with the provisions of 10 CFR 19 as
follows, which are hereby incorporated by reference including subsequent amendments and editions, except that references to and requirements for 10 CFR 2, 50, 52, 54, 60, 63, 72, and 76 shall not apply:

(1) 10 CFR 19.1, "Purpose;"
(2) 10 CFR 19.2, "Scope;"
(3) 10 CFR 19.3, "Definitions," except that the definition of "regulated activities" and "regulated entities" shall not apply. For persons registered with the agency pursuant to the rules in Section .0200 of this Chapter, the following terms used in 10 CFR 19 shall have the following substitutions:
   (A) "license" shall have the same meaning as "registration" as defined in Rule .0104(131) of this Chapter;
   (B) "licensed" means registered pursuant to the rules in Section .0200 of this Chapter;
   (C) "licensee" shall have the same meaning as "registrant" as defined in Rule .0104(130) of this Chapter;
   (D) "materials" shall have the same meaning as "radiation machine" as defined in Rule .0104(122) of this Chapter;
   (E) "NRC-licensed" means registered pursuant to the rules in Section .0200 of this Chapter; and
   (F) "radioactive material" shall have the same meaning as "radiation machine" as defined in Rule .0104(122) of this Chapter;
(4) 10 CFR 19.5, "Communications," except that licensees and registrants shall address communications and reports to the agency as instructed by Rule .0111 of this Chapter in lieu of the NRC;
(5) 10 CFR 19.11, "Posting of notices to workers," except that 19.11(b) and (e) shall not apply;
   (A) NRC Form 3 shall not be used in lieu of the Notice to Employees issued by the agency, except as authorized by the agency in writing;
   (B) licensees and registrants shall not post other notices, postings, notes, or other materials over the Notice to Employees, nor shall equipment be placed in such a manner that the Notice to Employees is obscured or hidden by that equipment; and
   (C) additional copies of the Notice to Employees may be obtained free of charge from the agency by contacting the agency at the addresses shown in Rule .0111(a) of this Chapter in lieu of the NRC, or online at https://radiation.ncdhhs.gov/;
(6) 10 CFR 19.12, "Instructions to workers;"
(7) 10 CFR 19.13, "Notifications and reports to individuals;"
(8) 10 CFR 19.14, "Presence of representatives of licensees and regulated entities, and workers during inspections," except that 19.14(a) shall not apply;
(9) 10 CFR 19.15, "Consultation with workers during inspections;"
(10) 10 CFR 19.16, "Requests by workers for inspections." Requests for inspections shall be mailed or delivered to the agency as instructed by Rule .0111(a) of this Chapter in lieu of the NRC;
(11) 10 CFR 19.17, "Inspections not warranted; informal review." Communications regarding the agency's decisions with respect to a request for inspection submitted to the agency under Subparagraph (a)(10) shall be mailed or delivered to the agency as instructed by Rule .0111(a) of this Chapter in lieu of the NRC;
(12) 10 CFR 19.18, "Sequestration of witnesses and exclusion of counsel in interviews conducted under subpoena;"
(13) 10 CFR 19.20, "Employee protection;"
(14) 10 CFR 19.31, "Application for exemptions," except that the request for exemption shall be made on the licensee's or registrant's business letterhead. Requests for exemptions from the requirements of this Rule shall be made to the agency at the addresses shown in Rule .0111(a) of this Chapter in lieu of the NRC or as otherwise instructed by the agency. To request an exemption, the following information shall be submitted to the agency:
   (A) licensee or registrant name;
   (B) license or registration number;
   (C) name of the individual requesting the exemption;
   (D) contact information for the individual requesting the exemption;
   (E) a description of the exemption being requested; and
   (F) an explanation describing why the exemption is necessary.

(b) Notwithstanding Subparagraph (a)(5) of this Rule, registrants temporarily working in North Carolina and licensees working in North Carolina under reciprocity may post the Notice to Employees, NRC Form 3, or an equivalent form issued under the authority of the regulatory agency issuing the registration or license.
History Note:  Authority G.S. 104E-7; 104E-12; Eff. February 1, 1980; Amended Eff. May 1, 1993; June 1, 1989; Transferred and Recodified from 15A NCAC 11 .1001 Eff. February 1, 2015; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019; Amended Eff. October 1, 2023.

10A NCAC 15 .1002  POSTING OF NOTICES TO WORKERS

10A NCAC 15 .1003  INSTRUCTIONS TO WORKERS

History Note:  Authority G.S. 104E-7; 104E-10; 104E-12; Eff. February 1, 1980; Amended Eff. April 1, 1999; January 1, 1994; May 1, 1992; Transferred and Recodified from 15A NCAC 11 .1002 and .1003, Eff. February 1, 2015; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019; Repealed Eff. October 1, 2023.

10A NCAC 15 .1004  NOTIFICATIONS AND REPORTS TO INDIVIDUALS

History Note:  Authority G.S. 104E-7; 104E-10(b); 104E-12; Eff. February 1, 1980; Amended Eff. October 1, 2013; January 1, 1994; Transferred and Recodified from 15A NCAC 11 .1004 Eff. February 1, 2015; Amended Eff. March 1, 2017; Repealed Eff. October 1, 2023.

10A NCAC 15 .1005  PRESENCE OF REPRESENTATIVES DURING INSPECTIONS

10A NCAC 15 .1006  CONSULTATION WITH WORKERS

History Note:  Authority G.S. 104E-7; 104E-10; 104E-11; Eff. February 1, 1980; Amended Eff. May 1, 1993; Transferred and Recodified from 15A NCAC 11 .1005 and .1006 Eff. February 1, 2015; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019; Repealed Eff. October 1, 2023.

10A NCAC 15 .1007  REQUESTS FOR INSPECTIONS

10A NCAC 15 .1008  INSPECTIONS NOT WARRANTED

History Note:  Authority G.S. 104E-7; 104E-10; Eff. February 1, 1980; Amended Eff. May 1, 1992; November 1, 1989; Transferred and Recodified from 15A NCAC 11 .1007 – .1008 Eff. February 1, 2015; Repealed Eff. October 1, 2023.

SECTION .1100 - FEES

Codifier's Note: 10 NCAC 03G .3200 was transferred to 15A NCAC 11 .1100 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .1101  PURPOSE AND SCOPE
(a) This Section establishes annual fees to cover the anticipated costs of inspection, educational and training activities of the agency.
(b) The fees are imposed on persons registered pursuant to provisions of Section .0200 of this Chapter, on persons licensed pursuant to provisions of Sections .0300 and .0900 of this Chapter, and on certain persons applying for out-of-state reciprocal recognition.

(c) Notwithstanding Paragraph (b) of this Rule, no fee shall be imposed on any person in conjunction with the person's possession and use of any luminous safety device or luminous gunsight pursuant to the general licenses in Rules .0309 and .0311 of this Chapter. For purposes of this Section, "luminous safety device" means an exit marker, hazard warning sign, safety related marker, or other safety equipment containing one or more radioactive material powered light sources for the purpose of improving legibility or visibility.

History Note: Authority G.S. 104E-9(8); 104E-19(a);
Eff. July 1, 1982;
Amended Eff. July 1, 1989; May 1, 1983;
Transferred and Recodified from 15A NCAC 11 .1101 Eff. February 1, 2015;

10A NCAC 15 .1102 PAYMENT DUE
(a) All fees established in this Section shall be due on the first day of July of each year.
(b) Notwithstanding Paragraph (a) of this Rule, when a new license or registration is issued by the agency or after the first day of July of any subsequent year, the initial fee shall be due on the date of issuance of the license or registration.
(c) The initial fee in Paragraph (b) of this Rule shall be computed as follows:
(1) When any new license or registration is issued before the first day of January of any year, the initial fee shall be the full amount specified in Rule .1105 or .1106 of this Section; and
(2) When any new license or registration is issued on or after the first day of January of any year, the initial fee shall be one-half of the amount specified in Rule .1105 or .1106 of this Section.
(d) All fees received by the agency pursuant to provisions of this Section shall be nonrefundable.
(e) Each licensee or registrant shall pay all fees online at https://www.thepayplace.com/northcarolinadhhs/dhs/rnrpsfees/challenge.aspx, or by check or money order made payable to "Radiation Protection Section" and mail such payment to: Radiation Protection Section, Division of Health Service Regulation, Department of Health and Human Services to the address shown on the facility invoice.

History Note: Authority G.S. 104E-9(a)(8); 104E-19(a);
Eff. July 1, 1982;
Amended Eff. May 1, 1993; May 1, 1992; July 1, 1989;
Temporary Amendment Eff. June 30, 2002;
Temporary Amendment Expired on March 28, 2003;
Findings of need for Emergency Rule disapproved by Codifier on June 8, 2007;
Emergency Amendment Eff. June 19, 2007 pursuant to G.S. 150B-21.1A(b);
Amended Eff. August 1, 2007;
Transferred and Recodified from 15A NCAC 11 .1102 Eff. February 1, 2015;

10A NCAC 15 .1103 NOTICES OF PAYMENT DUE
Within five days after the due dates established in Paragraphs (a) and (b) of Rule .1102 of this Section, the agency shall mail to each licensee and registrant, who has not already submitted payment, a notice which indicates the due date, delinquent date and the amount of fees due.

History Note: Authority G.S. 104E-9(8); 104E-19(a);
Eff. July 1, 1982;
Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .1103 Eff. February 1, 2015;

10A NCAC 15 .1104 DELINQUENT AND UNCOLLECTIBLE FEES
(a) Payment of fees established in this Section shall be delinquent, if not received by the agency within 60 days after the due date specified in Paragraphs (a) and (b) of Rule .1102 of this Section.
(b) If a licensee or registrant remits a fee in the form of a check or other instrument which is uncollectible from the paying institution, the agency shall notify the licensee or registrant by certified mail and allow the licensee or registrant 15 days to correct the matter, which includes payment of any fee charged to the agency by a banking institution.

(c) If payment of fees is uncollectible from the paying institution or not submitted to the agency by the delinquent date, the agency may institute legal action to collect.

History Note: Authority G.S. 104E-9(a)(8); 104E-19(a);
Eff. July 1, 1982;
Amended Eff. August 1, 2007; May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .1104 Eff. February 1, 2015;

10A NCAC 15 .1105 X-RAY FEE AMOUNTS

(a) Annual fees for persons registered pursuant to provisions of Section .0200 of this Chapter are as listed in the following table:

<table>
<thead>
<tr>
<th>Type of Registered Facility</th>
<th>Letters Appearing in Registration Number</th>
<th>Facility Plus First X-ray Tube</th>
<th>Each Additional X-ray Tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chiropractors</td>
<td>C</td>
<td>$ 180.00</td>
<td>$ 24.00</td>
</tr>
<tr>
<td>Dentists</td>
<td>D</td>
<td>$ 180.00</td>
<td>$ 24.00</td>
</tr>
<tr>
<td>Educational</td>
<td>E</td>
<td>$ 130.00</td>
<td>$ 22.00</td>
</tr>
<tr>
<td>Government</td>
<td>G</td>
<td>$ 130.00</td>
<td>$ 22.00</td>
</tr>
<tr>
<td>Podiatrists</td>
<td>H</td>
<td>$ 180.00</td>
<td>$ 24.00</td>
</tr>
<tr>
<td>Industrial</td>
<td>I</td>
<td>$ 180.00</td>
<td>$ 24.00</td>
</tr>
<tr>
<td>Industrial Medical</td>
<td>IM</td>
<td>$ 260.00</td>
<td>$ 33.00</td>
</tr>
<tr>
<td>Health Departments</td>
<td>L</td>
<td>$ 260.00</td>
<td>$ 33.00</td>
</tr>
<tr>
<td>Hospitals</td>
<td>M</td>
<td>$ 390.00</td>
<td>$ 44.00</td>
</tr>
<tr>
<td>Physicians</td>
<td>P</td>
<td>$ 180.00</td>
<td>$ 24.00</td>
</tr>
<tr>
<td>Industrial Radiography</td>
<td>R</td>
<td>$ 380.00</td>
<td>$ 44.00</td>
</tr>
<tr>
<td>Services</td>
<td>S</td>
<td>$ 260.00</td>
<td>$ 0.00</td>
</tr>
<tr>
<td>Therapy</td>
<td>T</td>
<td>$ 400.00</td>
<td>$ 50.00</td>
</tr>
<tr>
<td>Veterinarians</td>
<td>V</td>
<td>$ 130.00</td>
<td>$ 22.00</td>
</tr>
<tr>
<td>Other</td>
<td>Z</td>
<td>$ 180.00</td>
<td>$ 24.00</td>
</tr>
</tbody>
</table>

(b) Annual fees for out-of-state persons granted permission to use sources of radiation in this state pursuant to provisions of Rule .0211 of this Chapter are the same as that provided for in the applicable category specified in Paragraph (a) of this Rule.

History Note: Authority G.S. 104E-9(a)(8); 104E-19(a);
Eff. July 1, 1982;
Amended Eff. July 1, 2011; August 1, 2007; August 1, 2002; July 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1105 Eff. February 1, 2015;

10A NCAC 15 .1106 RADIOACTIVE MATERIALS AND ACCELERATOR FEE AMOUNTS

(a) Annual fees for persons licensed pursuant to the provisions of Section .0300 of this Chapter shall be:

<table>
<thead>
<tr>
<th>Type of Radioactive Material License</th>
<th>Annual Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific license of broad scope including:</td>
<td></td>
</tr>
</tbody>
</table>

-academic or research and development (R&D) $ 5,180.00
-manufacture or distribution $ 6,100.00
-medical $ 6,760.00

Specific license including:
-educational institutions, R&D laboratories $ 2,960.00
-industrial radiography $ 5,400.00
-irradiator >10,000Ci $ 19,140.00
-irradiator ≤10,000Ci $ 2,160.00
-manufacture or distribution $ 2,320.00
-medical (human use), diagnostic $ 2,940.00
-medical (human use), therapeutic $ 4,760.00
-services, consultants, gauges (all types), or not specified above $ 1,860.00
-well logging, subsurface tracer studies $ 3,200.00

General license including:
-not subject to annual registration requirements $ 200.00
-subject to annual registration requirements $ 325.00
-possession of self-luminous devices under Rule .0309 of this Chapter no fee
-possession of source material from water remediation activities under Rule .0307 of this Chapter no fee

(b) Annual fees for persons licensed pursuant to the provisions of Section .0900 of this Chapter shall be four thousand seven hundred sixty dollars ($4,760.00).

c) Fees for out-of-state persons granted permission to use sources of radiation in this State pursuant to Rule .0345 of this Chapter are the same as that provided for in the applicable category specified in Paragraphs (a) and (b) of this Rule. The fees shall be due when the application for reciprocal recognition of out-of-state license is made.

d) Each location listed on a license issued by the Agency that is not part of a contiguous property controlled by the licensee shall require an additional fee equal to the amount specified in Paragraphs (a) and (b) of this Rule. Fees for client locations listed on mobile medical licenses shall be one-half of the amount specified in Paragraphs (a) or (b) of this Rule for each client site.

e) Persons licensed to conduct activities subject to multiple categories of fees under Paragraph (a) of this Rule shall be required to pay only the highest fee category.

(f) Persons possessing Sealed Source and Device Registration (SS&D) certificates shall pay an annual fee of one thousand four hundred eighty dollars ($1,480.00) per active SS&D certificate issued by the Agency, in addition to any amounts specified in Paragraph (a) of this Rule.

(g) Notwithstanding Paragraph (a) of this Rule, persons licensed to conduct activities under a specific license with annual receipts of less than two hundred fifty thousand dollars ($250,000) may pay a reduced license fee of one-half of the amount shown in Paragraph (a) of this Rule, provided:

1. payment of fees is made in accordance with Rule .1102 of this Section;
2. an affidavit is submitted to the agency every year that reduced fees are paid, no later than the date that payment of license fees are due, stating that annual receipts for all business activities are less than the amount shown in this Paragraph during the consecutive 12 month period preceding the date license fees are due. This affidavit shall be signed by the individual authorized to sign license amendments and this signature shall be witnessed and notarized;
3. records of annual receipts of all business activities shall be made available to the agency for inspection in accordance with Rule .0107 of this Chapter. These records shall include municipal, county, and State tax records; and
4. a copy of the affidavit and records of annual receipts shall be maintained for five years after the date the affidavit is notarized.

History Note: Authority G.S. 104E-9(a)(8); 104E-19(a);
Eff. August 1, 2007;
Amended Eff. July 1, 2011;
Transferred and Recodified from 15A NCAC 11 .1106 Eff. February 1, 2015;
Amended Eff. May 1, 2019;
10A NCAC 15 .1201 PURPOSE AND SCOPE
10A NCAC 15 .1202 DEFINITIONS

History Note: Authority G.S. 104E-2; 104E-3; 104E-5; 104E-7; 104E-10; 104E-10.1; 104E-10.2; 104E-25; 104E-26; Eff. December 1, 1987; Amended Eff. January 1, 1994; May 1, 1993; May 1, 1992; June 1, 1989; Transferred and Recodified from 15A NCAC 11 .1201 - .1202 Eff. February 1, 2015; Repealed Eff. May 1, 2023.

10A NCAC 15 .1203 LICENSE REQUIRED: LAND DISPOSAL OF LOW-LEVEL RADIOACTIVE WASTE

(a) This Rule establishes the procedures, standards, criteria, and terms and conditions upon which the Department issues licenses authorizing land disposal of low-level radioactive waste received from other persons for disposal.

(1) No person may receive, possess, and dispose of low-level radioactive waste at a land disposal facility located in North Carolina unless authorized by a license issued by the Department pursuant to this Rule.

(2) No low-level radioactive waste shall be received from any source not licensed by the agency except as may be specifically authorized in writing by the agency.

(3) The regulations in 10 CFR 61 which are hereby incorporated by reference, including subsequent amendments and editions, except that 10 CFR 61.5, 61.8, 61.16, 61.23(i) and (j), 61.83, and 61.84 are not incorporated by reference. Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part061/. Communications, records, reports, and notifications required by 10 CFR 61.4 and 61.80 shall be submitted to the agency at the address shown in Rule .0111 of this Chapter in lieu of the NRC.

(4) The requirements found in G.S. 104E-6.1, 104E-10.1(a), (a1), and (b), 104E-10.2, 104E-25(a), (c) through (h), and (j) shall be met.

(5) In addition to the definitions found in 10 CFR 61.2, the definitions in G.S. 104E-5 shall apply.

(6) The agency may access and inspect any licensed low-level radioactive waste disposal facility on a temporary or emergency basis to determine compliance with the rules in this Chapter or to respond to any emergency which involves possible or actual release of radioactive material.

(b) This Rule establishes the procedures, criteria, and terms and conditions upon which the agency issues licenses authorizing access to low-level radioactive waste land disposal facilities licensed under Paragraph (a) of this Rule.

(1) No person shall transport or transfer waste to a low-level radioactive waste land disposal facility licensed under Paragraph (a) of this Rule unless licensed by the agency or otherwise specifically authorized in writing by the agency.

(2) The definitions of terms in G.S. 104E-5 shall apply.

(3) Generators, waste brokers, and waste processors of low-level radioactive waste shall develop procedures and implement practices to prevent, minimize, and reduce the generation of low-level radioactive waste, including segregating radioactive waste by half-life and holding low-level radioactive waste for decay in storage.

(4) Upon receipt of an application for a license authorizing access to low-level radioactive waste land disposal facilities licensed under Paragraph (a) of this Rule, the agency shall review the contents of the application and determine if the applicant’s facilities, staffing, equipment, and procedures are adequate to protect the health and safety of the public and occupationally exposed workers, and if the requirements in Subparagraph (b)(3) of this Rule are met. If the agency determines that the applicant’s facilities, staffing, equipment, and procedures are adequate to protect the health and safety of the public and occupationally exposed workers, and that the applicant's procedures and practices prevent, minimize and reduce the generation of low-level radioactive waste, the agency shall issue a license as described in this Rule.

(5) Licenses issued under this Rule are subject to suspension or revocation for failure to comply with the rules of this Chapter or in accordance with 10 CFR 61.9b(a) and (c).
Facilities licensed by the agency and licensed activities may be inspected by authorized representatives of the Department as permitted by G.S. 104E-11(a). For licenses issued to licensees located outside of the jurisdiction of the Department, the Department may delegate this authority to individuals representing the radiation control programs within those jurisdictions.

Applications required by this Rule shall be made on forms provided by the agency, and the payment of fees required by 10 CFR 61.20(c) shall not apply. Applications and supporting material shall be submitted to the agency by e-mail at Licensing.RAM@dhhs.nc.gov, or at the address shown in Rule .0111 of this Chapter in lieu of the NRC:

(1) Persons applying for new radioactive materials licenses, or for the renewal of existing radioactive materials licenses, shall submit an Application for Radioactive Materials License. The following information shall appear on the application:
   (A) legal business name and mailing address;
   (B) physical address(es) where radioactive material shall be used or possessed. The application shall indicate if radioactive materials shall be used at temporary jobsites;
   (C) the name, telephone number, and e-mail address of the Radiation Safety Officer;
   (D) the name, telephone number, and e-mail address of the individual to be contacted about the application. If this individual is same as the Radiation Safety Officer, the application may so state;
   (E) the application shall indicate if the application is for a new license, or for the renewal of an existing license, by marking the corresponding check box;
   (F) if the application is for the renewal of an existing license, the license number shall be provided on the application;
   (G) applicants shall indicate the type and category of license as shown on the form by marking the corresponding check box; and
   (H) the printed name, title, and signature of the certifying official. The certifying official shall be an individual employed by the business or licensee, who is authorized by the licensee to sign license applications on behalf of the business or licensee.

(2) Persons applying for an amendment to an existing license shall submit an Application for Amendment of Radioactive Materials and Accelerator Licenses. The following information shall appear on the application:
   (A) the license number;
   (B) amendment number of the current license;
   (C) expiration date of the license;
   (D) licensee name as it currently appears on the license;
   (E) the name, telephone number, and e-mail address of the Radiation Safety Officer;
   (F) the name, telephone number, and e-mail address of the individual to be contacted about the application. If this individual is same as the Radiation Safety Officer, item 5b on the application may be left blank;
   (G) applicants shall provide a description of the action requested by marking the corresponding checkbox in item 6a. If the check box next to "Other" is marked in item 6a, provide a brief description of the action requested in the space provided in item 6b;
   (H) explanation of the action requested; and
   (I) the printed name, title, and signature of the certifying official. The certifying official shall be an individual employed by the business or licensee who is authorized by the licensee to sign license applications on behalf of the business or licensee.

(3) Application forms specified in this Rule shall be made available by the agency on the agency's public website.

(d) Nothing in this Rule shall relieve any person of responsibility for complying with other applicable North Carolina laws and rules.

History Note:  Authority G.S. 104E-5; 104E-6.1; 104E-7; 104E-10(b); 104E-10.1; 104E-10.2; 104E-10.3; 104E-11; 104E-18; 104E-25; 104E-26; 104E-27;
Eff. December 1, 1987;
Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .1203 Eff. February 1, 2015;
10A NCAC 15 .1204  CONTENT OF APPLICATION
10A NCAC 15 .1205  GENERAL INFORMATION
10A NCAC 15 .1206  SPECIFIC TECHNICAL INFORMATION
10A NCAC 15 .1207  ENVIRONMENTAL INFORMATION
10A NCAC 15 .1208  TECHNICAL AND ENVIRONMENTAL ANALYSES
10A NCAC 15 .1209  INSTITUTIONAL INFORMATION
10A NCAC 15 .1210  FINANCIAL INFORMATION
10A NCAC 15 .1211  FILING AND DISTRIBUTION OF APPLICATION
10A NCAC 15 .1212  ELIMINATION OF REPEITION
10A NCAC 15 .1213  UPDATING OF APPLICATION
10A NCAC 15 .1214  STANDARDS FOR ISSUANCE OF A LICENSE
10A NCAC 15 .1215  CONDITIONS OF LICENSE
10A NCAC 15 .1216  AMENDMENT OF LICENSE
10A NCAC 15 .1217  APPLICATION FOR RENEWAL OR CLOSURE
10A NCAC 15 .1218  CONTENTS OF APPLICATION FOR CLOSURE
10A NCAC 15 .1219  POSTCLOSURE OBSERVATION AND MAINTENANCE
10A NCAC 15 .1220  TRANSFER OF LICENSE
10A NCAC 15 .1221  TERMINATION OF LICENSE
10A NCAC 15 .1222  PERFORMANCE OBJECTIVES: GENERAL REQUIREMENT
10A NCAC 15 .1223  PROTECTION OF POPULATION FROM RELEASES OF RADIOACTIVITY
10A NCAC 15 .1224  PROTECTION OF INDIVIDUALS FROM INADVERTENT INTRUSION
10A NCAC 15 .1225  PROTECTION OF INDIVIDUALS DURING OPERATIONS
10A NCAC 15 .1226  STABILITY OF THE DISPOSAL SITE AFTER CLOSURE
10A NCAC 15 .1227  TECHNICAL REQUIREMENTS FOR LAND DISPOSAL FACILITIES
10A NCAC 15 .1228  DISPOSAL SITE SUITABILITY REQUIREMENTS
10A NCAC 15 .1229  SITE DESIGN FOR LAND DISPOSAL
10A NCAC 15 .1230  FACILITY OPERATION AND DISPOSAL SITE CLOSURE
10A NCAC 15 .1231  ENVIRONMENTAL MONITORING

History Note: Authority G.S. 104E-5; 104E-6.1; 104E-7; 104E-9(3); 104E-9(a)(3); 104E-10; 104E-10(b); 104E-10.1; 104E-10.2; 104E-12; 104E-13(a); 104E-15; 104E-16; 104E-18; 104E-25; 104E-26; 104G-13; 104G-14; 150B-19(6); 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540;
Eff. December 1, 1987;
Amended Eff. January 1, 1994; June 1, 1993; May 1, 1993; May 1, 1992; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1204 -.1231 Eff. February 1, 2015;

10A NCAC 15 .1232  VARIANCE

History Note: Authority G.S. 104E-7; 104E-9(3); 104E-10(b); 104E-25; 104E-26;
Eff. December 1, 1987;
Repealed Eff. July 1, 1990 in accordance with G.S. 150B-59(c);

10A NCAC 15 .1233  WASTE CLASSIFICATION AND CHARACTERISTICS
10A NCAC 15 .1234  INSTITUTIONAL REQUIREMENTS
10A NCAC 15 .1235  APPLICANT QUALIFICATIONS AND ASSURANCES
10A NCAC 15 .1236  FUNDING OF CLOSURE: STABILIZATION: INSTITUTIONAL CONTROLS
10A NCAC 15 .1237  RECORDS: REPORTS: TESTS: AND INSPECTIONS
10A NCAC 15 .1238  MAINTENANCE OF RECORDS: REPORTS AND TRANSFERS
10A NCAC 15 .1239  TESTS AT LAND DISPOSAL FACILITIES
10A NCAC 15 .1240  AGENCY INSPECTIONS OF LAND DISPOSAL FACILITIES
10A NCAC 15 .1241  INSPECTION
10A NCAC 15 .1242  NOTIFICATIONS AND REPORTS
SECTION .1300 - REQUIREMENTS FOR WIRELINE-SERVICE OPERATORS AND SUBSURFACE-TRACER STUDIES

Codifier's Note: 10 NCAC 03G .3400 was transferred to 15A NCAC 11 .1300 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .1301 WELL LOGGING, WIRELINE-SERVICE OPERATIONS, AND SUBSURFACE TRACER STUDIES: REQUIREMENTS FOR LICENSEES

(a) Persons using sources of radiation for well logging, wireline-service operations, mineral logging, radioactive markers, or subsurface tracer studies shall comply with the provisions of 10 CFR Part 39, except that 10 CFR 39.5, 39.8, 39.101, and 39.103 shall not apply.

(b) In addition to the terms defined in 10 CFR 39.2, the following definitions shall also apply to this Section:

1. "Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas;
2. "Well-bore" means a drilled hole in which wireline-service operations and subsurface-tracer studies are performed;
3. "Wireline" means a cable containing one or more electrical conductors that is used to lower and raise logging tools in the well-bore; and
4. "Wireline-service operations" means any evaluation or mechanical service that is performed in the well-bore using devices on a wireline.

(c) Applications required by 10 CFR 39.11 shall be made on forms provided by the agency, and the payment of fees required by 10 CFR Part 170 shall not apply. One copy of the application and supporting material shall be submitted to the agency by e-mail at Licensing.RAM@dhhs.nc.gov, or at the address shown in Rule .0111 of this Chapter in lieu of the NRC:

1. Persons applying for new radioactive materials licenses, or for the renewal of existing radioactive materials licenses, shall submit an Application for Radioactive Materials License. Items one through five on the application form shall be completed by the applicant, using additional sheets as necessary. The following information shall appear on the application:
   (A) legal business name and mailing address;
   (B) physical address(es) where radioactive material shall be used or possessed. The application shall indicate if radioactive materials shall be used at temporary jobsites;
   (C) the name, telephone number, and e-mail address of the Radiation Safety Officer;
   (D) the name, telephone number, and e-mail address of the individual to be contacted about the application. If this individual is same as the Radiation Safety Officer, the application may so state;
   (E) the application shall indicate if the application is for a new license or for the renewal of an existing license by marking the corresponding check box;
   (F) if the application is for the renewal of an existing license, the license number shall be provided on the application;
   (G) applicants shall indicate the type and category of license as shown on the form by marking the corresponding check box; and
   (H) the printed name, title, and signature of the certifying official. The certifying official shall be an individual employed by the business or licensee, who is authorized by the licensee to sign license applications on behalf of the business or licensee.

2. Persons applying for an amendment to an existing license shall submit an Application for Amendment of Radioactive Materials and Accelerator Licenses. Items one through seven on the application form shall be completed by the applicant, using additional sheets as necessary. The following information shall appear on the application:
   (A) the license number;
amendment number of the current license;
(C) expiration date of the license;
(D) licensee name as it currently appears on the license;
(E) the name, telephone number, and e-mail address of the Radiation Safety Officer;
(F) the name, telephone number, and e-mail address of the individual to be contacted about
the application. If this individual is same as the Radiation Safety Officer, item 5b on the
application may be left blank;
(G) applicants shall provide a description of the action requested by marking the corresponding
checkbox in item 6a. If the check box next to "Other" is marked in item 6a, provide a brief
description of the action requested in the space provided in item 6b;
(H) explanation of the action requested; and
(I) the printed name, title, and signature of the certifying official. The certifying official shall be
an individual employed by the business or licensee who is authorized by the licensee to sign
license applications on behalf of the business or licensee.

(3) Applications specified in this Rule are available free of charge at:

d) Persons conducting subsurface tracer studies using unsealed sources of radiation shall obtain agency approval prior
to injecting licensed material into the subsurface. Agency approval shall be obtained by submitting a license application
to the agency in accordance with Paragraph (c) of this Rule.

e) Notifications, authorization requests, and reports required by 10 CFR 39.77 shall be made to the agency at the
address shown in Rule .0111 of this Chapter in lieu of the NRC.

(f) Applications for exemptions to this Rule shall be submitted to the agency at the address shown in Rule .0111 of this
Chapter in lieu of the NRC.

(g) The regulations cited in this Rule from 10 CFR Part 39 are hereby incorporated by reference, including subsequent
amendments and editions. Copies of these regulations are available free of charge at https://www.nrc.gov/reading-
rm/doc-collections/cfr/part039/.

History Note: Authority G.S. 104E-3; 104E-7;
Eff. June 1, 1989;
Amended Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .1301 Eff. February 1, 2015;

10A NCAC 15 .1302 DEFINITIONS
10A NCAC 15 .1303 WRITTEN AGREEMENTS REQUIRED
10A NCAC 15 .1304 LIMITS ON LEVELS OF RADIATION
10A NCAC 15 .1305 STORAGE PRECAUTIONS
10A NCAC 15 .1306 TRANSPORT PRECAUTIONS
10A NCAC 15 .1307 RADIATION SURVEY INSTRUMENTS
10A NCAC 15 .1308 LEAK TESTING OF SEALED SOURCES
10A NCAC 15 .1309 QUARTERLY INVENTORY
10A NCAC 15 .1310 UTILIZATION RECORDS
10A NCAC 15 .1311 DESIGN: PERFORMANCE: AND CERTIFICATION CRITERIA
10A NCAC 15 .1312 LABELING
10A NCAC 15 .1313 INSPECTION AND MAINTENANCE
10A NCAC 15 .1314 TRAINING REQUIREMENTS
10A NCAC 15 .1315 OPERATING AND EMERGENCY PROCEDURES
10A NCAC 15 .1316 PERSONNEL MONITORING
10A NCAC 15 .1317 SECURITY
10A NCAC 15 .1318 HANDLING TOOLS
10A NCAC 15 .1319 SUBSURFACE-TRACER STUDIES
10A NCAC 15 .1320 PARTICLE ACCELERATORS
10A NCAC 15 .1321 RADIATION SURVEYS
10A NCAC 15 .1322 DOCUMENTS AND RECORDS REQUIRED AT FIELD STATIONS
10A NCAC 15 .1323 DOCUMENTS AND RECORDS REQUIRED AT TEMPORARY JOBSITEs
10A NCAC 15 .1324 NOTIFICATION OF INCIDENTS: ABANDONMENT: AND LOST SOURCES
10A NCAC 15 .1325 SUBJECTS IN TRAINING COURSES FOR LOGGING SUPERVISORS

History Note: Authority G.S. 20-167.1; 104E-7; 104E-10(b); 104E-12(a); 104E-12(a)(1); 104E-12(a)(2); 104E-15(a); 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540;
Eff. June 1, 1989;

10A NCAC 15 .1326 ENERGY COMPENSATION SOURCES

10A NCAC 15 .1327 TRITIUM NEUTRON GENERATOR TARGET SOURCES

History Note: Authority G.S. 104E-7;
Eff. January 1, 2005;
Transferred and Recodified from 15A NCAC 11 .1326 - .1327 Eff. February 1, 2015;

SECTION .1400 - TANNING FACILITIES

Codifier's Note: 10 NCAC 03G .3500 was transferred to 15A NCAC 11 .1400 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .1401 PURPOSE AND SCOPE
(a) This Section provides for the registration and regulation of facilities and equipment which employ ultraviolet and other lamps for the purpose of tanning the skin of the living human body through the application of ultraviolet radiation. (b) Except as otherwise provided in this Section, tanning facilities are exempt from the Rules in Sections .0100 through .1300 of this Chapter to the extent that such facilities do not receive, own, possess or use radioactive material or other sources of ionizing radiation as defined in G.S. 104E-5. (c) Nothing in this Section shall be interpreted as limiting the intentional exposure of patients to ultraviolet radiation for the purpose of treatment or therapy other than skin tanning, provided such treatment or therapy is supervised by a licensed practitioner of the healing arts in the lawful practice of their profession, in accordance with the requirements of their professional licensing board to prescribe and supervise such treatment.

History Note: Authority G.S. 104E-7(a)(7);
Eff. June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1401 Eff. February 1, 2015;

10A NCAC 15 .1402 COMPLIANCE WITH OTHER LAWS
Nothing in this Section shall relieve any person of responsibility for complying with other pertinent North Carolina laws and regulations.

History Note: Authority G.S. 104E-7(a)(7);
Eff. June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1402 Eff. February 1, 2015;

10A NCAC 15 .1403 DEFINITIONS
As used in this Section, the following definitions shall apply:
(1) "Agency" means the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section.
(2) "Consumer" means any individual who is provided access to a tanning facility that is required to be registered pursuant to provisions of this Section.
(3) "Formal Operator Training" is a course of study approved by this agency as meeting the requirements in Paragraph (i) of Rule .1418 in this Section.
"Individual" means any human being.

"Inspection" means an official examination or observation to determine compliance with the rules in this Section, and orders, requirements, and conditions of the agency.

"Minor" means any individual less than 18 years of age.

"Medical Lamps" means any lamp that is designed or labeled for medical use only.

"Operator" means any individual designated by the registrant to operate or to assist and instruct the consumer in the operation and use of the tanning facility or tanning equipment. Under this definition, the term "operator," includes any individual who conducts one or more of the following activities:

(a) determining consumer's skin type;
(b) determining the suitability of prospective consumers for tanning equipment use;
(c) informing the consumer of dangers of ultraviolet radiation exposure including photoallergic reactions and photosensitizing agents;
(d) assuring that the consumer reads and signs all forms as required by the rules in this Section;
(e) maintaining required consumer exposure records;
(f) recognizing and reporting consumer injuries or alleged injuries to the registrant;
(g) determining the consumer's exposure schedule;
(h) setting timers which control the duration of exposure; and
(i) instructing the consumer in the proper use of protective eyewear.

"Person," as defined in G.S. 104E-5(11), means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other State or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of these entities.

"Registrant" means any person who is registered with the agency as required by provisions of this Section.

"Registration" means registration with the agency in accordance with provisions of this Section.

"Tanning components" means any constituent tanning equipment part, to include ballasts, starters, lamps, reflectors, acrylic shields, timers, and airflow cooling systems.

"Tanning equipment" means ultraviolet or other lamps and equipment containing such lamps intended to induce skin tanning through the irradiation of any part of the living human body with ultraviolet radiation, e.g., beds, booths, facials, and wands.

"Tanning equipment services" means the installation, sales and servicing of tanning equipment and associated tanning components; calibration of equipment used in surveys to measure radiation and timer accuracy; tanning health physics consulting, e.g. radiation output measurements, design of safety programs, and training seminars for tanning operators and service personnel.

"Tanning facility" means any location, place, area, structure or business that provides consumers access to tanning equipment. For the purpose of this definition, tanning equipment registered to different persons at the same location and tanning equipment registered to the same person, but at separate locations, shall constitute separate tanning facilities.

"Ultraviolet radiation" means electromagnetic radiation with wavelengths in air between 200 nanometers and 400 nanometers.

**History Note:** Authority G.S. 104E-7(a)(7);
Eff. June 1, 1989;
Amended Eff. August 1, 2002; May 1, 1993; May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .1403 Eff. February 1, 2015;
Amended Eff. May 1, 2016;

**10A NCAC 15 .1404 EXEMPTIONS**

(a) Any person is exempt from the provisions of this Section to the extent that such person:

(1) uses equipment which emits ultraviolet radiation incidental to its proper operation, and
(2) does not use the equipment in Subparagraph (a)(1) of this Rule to deliberately expose parts of the living human body to ultraviolet radiation for the purpose of skin tanning.

(b) Any individual is exempt from the provisions of this Section to the extent that such individual owns tanning equipment exclusively for personal use.

(c) Tanning equipment while in transit or storage incidental thereto is exempt from the provisions of this Section.
10A NCAC 15 .1405  APPLICATION FOR REGISTRATION OF TANNING FACILITIES

(a) Each person having a tanning facility on the effective date of this Rule shall apply for registration of such facility no later than 60 days following the effective date of this Rule.

(b) Each person acquiring or establishing a tanning facility after the effective date of this Rule shall have a certificate of registration issued by the agency for such facility prior to beginning operation.

(c) The application required in Paragraphs (a) and (b) of this Rule shall be completed on forms provided by the agency.

(d) The agency shall require at least the following information on the forms provided for applying for registration of tanning facilities:

1. name, physical address, mail address and telephone number of the tanning facility;
2. name(s), mail address(es) and telephone number(s) of the owner(s) of the tanning facility;
3. each facility shall submit a copy of the tanning operator training certificate for each of the tanning facility operator(s) with the initial application in accordance with the provisions of the rules of this Section;
4. the manufacturer(s), model number(s) and type(s) of ultraviolet lamp(s) or tanning equipment located at the tanning facility;
5. name(s) of the tanning equipment supplier(s), installer(s) and service agent(s);
6. certification that the applicant has read and understands the requirements of the rules in this Section, such certification to be signed and dated by the manager and the owner of the tanning facility; and
7. certification that each person operating a tanning facility shall not allow any individual under 18 years of age to be the operator of tanning equipment.

10A NCAC 15 .1406  ISSUANCE OF CERTIFICATE OF REGISTRATION

(a) Upon determination that an application meets the requirements of this Section, the agency will issue a certificate of registration.

(b) The agency may incorporate in the certificate of registration, at the time of issuance or thereafter by appropriate rule or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of tanning equipment and tanning facilities as the agency deems appropriate or necessary.

10A NCAC 15 .1407  EXPIRATION OF CERTIFICATE OF REGISTRATION

Except as provided in Rule .1408(b) of this Section, each certificate of registration shall expire at midnight on the expiration date stated therein.

10A NCAC 15 .1408  RENEWAL OF CERTIFICATE OF REGISTRATION
(a) The registrant shall file applications for renewal in accordance with Rule .1405 of this Section.
(b) Provided that a registrant files with the agency an application for renewal in proper form for renewal by August 29 of each calendar year, such certificate of registration shall not expire pending final action on the application by the agency.

History Note: Authority G.S. 104E-7(a)(7);
Eff. June 1, 1989;
Amended Eff. August 1, 2002;
Transferred and Recodified from 15A NCAC 11 .1408 Eff. February 1, 2015;

10A NCAC 15 .1409 REPORT OF CHANGES
The registrant shall notify the agency in writing within 30 calendar days after making any change which would render the information contained in the application for registration or the certificate of registration no longer accurate.

History Note: Authority G.S. 104E-7(a)(7);
Eff. June 1, 1989;
Amended Eff. August 1, 2002;
Transferred and Recodified from 15A NCAC 11 .1409 Eff. February 1, 2015;

10A NCAC 15 .1410 TRANSFER OF CERTIFICATE OF REGISTRATION
No certificate of registration may be transferred from one person to another person or from one tanning facility to another tanning facility.

History Note: Authority G.S. 104E-7(a)(7);
Eff. June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1410 Eff. February 1, 2015;

10A NCAC 15 .1411 APPROVAL NOT IMPLIED
No person, in any advertisement, shall refer to the fact that such person or such person's facility is registered with the agency pursuant to the provisions of this Section, and no person shall state or imply that any activity under such registration has been approved by the agency.

History Note: Authority G.S. 104E-7(a)(7);
Eff. June 1, 1989;
Amended Eff. November 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1411 Eff. February 1, 2015;

10A NCAC 15 .1412 DENIAL: REVOCATION: TERMINATION OF REGISTRATION
(a) The agency may deny, suspend or revoke a certificate of registration applied for or issued pursuant to this Section:
   (1) for any material false statement in the application for registration or in any statement of fact required by provisions of this Section;
   (2) because of conditions revealed by the application or any report, record, inspection or other means which would warrant the agency to refuse to grant a certificate of registration on an original application;
   (3) for operation of the tanning facility in a manner that causes or threatens to cause hazard to the public health or safety;
   (4) for failure to allow authorized representatives of the agency to enter the tanning facility at reasonable times for the purpose of determining compliance with the provisions of this Section, conditions of the certificate of registration or an order of the agency;
   (5) for violation of or failure to observe any of the terms and conditions of the certificate of registration, the rules in this Section, or an order of the agency; or
for failure to pay a fee within 15 days of becoming delinquent as described in Paragraph (h) of Rule .1423 or for failure to correct payment of a fee in the form of a check or other instrument which is uncollectible from the paying institution within the timeframe specified in accordance with the provisions of the rules of this Section.

(b) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, prior to the institution of proceedings for suspension or revocation of a certificate of registration, the agency shall:

1. call to the attention of the registrant, in writing, the facts or conduct which may warrant such actions, and
2. provide reasonable opportunity for the registrant to demonstrate or achieve compliance with all lawful requirements.

(c) Any person aggrieved by a decision by the agency to deny a certificate of registration or to suspend or revoke a certificate of registration after issuance may request a hearing under provisions of G.S. 150B, Article 3.

(d) The agency may terminate a certificate of registration upon receipt of a written request for termination from the registrant.

History Note: Authority G.S. 104E-7(a)(7); 104E-11(a);
Eff. June 1, 1989;
Amended Eff. August 1, 2002: June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .1412 Eff. February 1, 2015;

10A NCAC 15 .1413 CONSTRUCTION AND OPERATION OF TANNING EQUIPMENT

Except as otherwise ordered or approved by the agency, each tanning facility shall be constructed, operated and maintained in accordance with the requirements in Rules .1414 to .1418 of this Section.

History Note: Authority G.S. 104E-7(a)(7);
Eff. June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1413 Eff. February 1, 2015;

10A NCAC 15 .1414 WARNING SIGNS REQUIRED

(a) The registrant shall post the warning sign described in Paragraph (b) of this Rule within one meter of each tanning station and in such a manner that the sign is clearly visible to consumers; not obstructed by any barrier, equipment, or other object; and may be easily viewed by the consumer before the tanning equipment is energized.

(b) The warning sign in Paragraph (a) of this Rule shall use upper and lower case letters that are at least seven millimeters and three and one-half millimeters in height, respectively, and shall state:

DANGER - ULTRAVIOLET RADIATION
UV – emitting tanning devices have been classified as "carcinogenic to humans."
ATTENTION: THIS DEVICE SHALL NOT BE USED BY PERSONS UNDER 18 YEARS OF AGE.

- Follow instruction.
- Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. REPEATED EXPOSURE MAY CAUSE PREMATURE AGING OF THE SKIN AND SKIN CANCER.
- Wear protective eyewear.

FAILURE TO USE PROTECTIVE EYEWEAR MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES.

Contraindications: This sunlamp product must not be used if skin lesions or open wounds are present.
Warning: This sunlamp product should not be used on individuals who have had skin cancer or have a family history of skin cancer.
Warning: Persons repeatedly exposed to ultraviolet sunlamp products should be regularly evaluated for skin cancer.
- Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult a physician before using sunlamp or tanning equipment if you are using medication or have a history of skin problems or believe yourself to be especially sensitive to sunlight. Consult your certified tanning operator for a list of cosmetics and products known to create sensitivity to light.

- If you do not tan in the sun, you are unlikely to tan from the use of this product.

- Consumers should report to the agency any injury for which medical attention is sought or obtained resulting from the use of registered tanning equipment. This report should be made within five working days after the occurrence.

(c) Warning signs shall include the current address and telephone number of the agency: Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section, 1645 Mail Service Center, Raleigh, NC 27699-1600, (919) 814-2250.

History Note: Authority G.S. 104E-7(a)(7); 104E-9.1; Eff. June 1, 1989;
Amended Eff. August 1, 2002; June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .1403 Eff. February 1, 2015;
Amended Eff. May 1, 2016;

10A NCAC 15 .1415 EQUIPMENT AND CONSTRUCTION REQUIREMENTS
(a) The registrant shall use only tanning equipment manufactured in accordance with the specifications set forth in 21 Code of Federal Regulations (CFR) Part 1040, Section 1040.20, and with 21 CFR Part 878.4635, which is herein incorporated by reference, including subsequent amendments and editions and may be accessed at http://www.ecfr.gov/cgi-bin/ECP?page=brow. The standard of compliance shall be the standards in effect at the time of manufacture as shown on the equipment identification label required by 21 CFR Part 1010, Section 1010.3. The registrant shall place an additional label on the bed that states "North Carolina state law prohibits the use of this device by persons under 18 years of age."
(b) Each assembly of tanning equipment shall be designed for use by only one consumer at a time.
(c) Each assembly of tanning equipment shall be equipped with a timer that complies with the requirements of 21 CFR Part 1040, Section 1040.20(c)(2). The maximum timer interval shall not exceed the manufacturer's maximum recommended exposure time. No timer interval shall have an error exceeding plus or minus 10 percent of the maximum timer interval for the product.
(d) Tanning equipment shall include physical barriers to protect consumers from injury induced by touching or breaking the lamps.
(e) All tanning equipment labeling required in Paragraph (a) of this Rule shall be easily read by the consumer while in the proximity of the tanning bed.
(f) The timer intervals shall be numerically indicated on the face of the timer.
(g) The timer shall not automatically reset and cause radiation emission to resume for a period greater than the unused portion of the timer cycle when emission from the tanning device has been interrupted.
(h) Each assembly of tanning equipment shall be provided with a control on the equipment to enable the consumer to manually terminate radiation emission from the equipment at any time without disconnecting the electrical plug or removing any ultraviolet lamp.
(i) The timer for the tanning devices shall be remotely located outside the room where the tanning equipment is located. The remote timer shall be set by a certified tanning operator.
(j) The registrant shall ensure that timer tests are performed annually on each assembly of tanning equipment and documented in writing for agency review during inspections to ensure the timer is accurate to within 10 percent as specified in Paragraph (c) of this Rule and the consumer is able to terminate the radiation manually in accordance with Paragraph (h) of this Rule.
(k) Medical lamps shall not be used for commercial cosmetic tanning purposes.

History Note: Authority G.S. 104E-7(a)(7); 104E-9.1;
Eff. June 1, 1989;
Amended Eff. August 1, 2002; June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .1415 Eff. February 1, 2015;
10A NCAC 15 .1416 ADDITIONAL REQUIREMENTS FOR STAND-UP BOOTHs

Tanning booths designed for stand-up use shall also comply with the following additional requirements:

(1) Booths shall have physical barriers or other means, such as handrails or floor markings, to indicate the proper exposure distance between ultraviolet lamps and the consumer's skin.

(2) Booths shall be constructed with sufficient strength and rigidity to withstand the stress of use and the impact of a falling person.

(3) Access to booths shall be of rigid construction with doors which are non-latching and open outwardly.

(4) Booths shall be equipped with handrails and non-slip floors.

History Note: Authority G.S. 104E-7(a)(7);
Eff. June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1416 Eff. February 1, 2015;

10A NCAC 15 .1417 PROTECTIVE EYEWEAR REQUIRED

(a) The registrant shall provide protective eyewear to each consumer for use during any use of tanning equipment.

(b) The protective eyewear in Paragraph (a) of this Rule shall meet the requirements of 21 CFR Part 1040, Section 1040.20(c)(4).

(c) Tanning facility operators shall instruct the consumer in the proper utilization of the protective eyewear required by this Rule.

(d) The registrant shall ensure that the protective eyewear required by this Rule is sanitized before each use and shall not rely upon exposure to the ultraviolet radiation produced by the tanning equipment itself to provide such sanitizing.

History Note: Authority G.S. 104E-7(a)(7);
Eff. June 1, 1989;
Amended Eff. August 1, 2002; November 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1417 Eff. February 1, 2015;

10A NCAC 15 .1418 RECORDS: REPORTS AND OPERATING REQUIREMENTS

(a) Prior to initial exposure, the registrant shall provide each consumer the opportunity to read a copy of the warning specified in Rule .1414(b) of this Section and have the consumer sign a statement that the information has been read and understood. For illiterate or visually impaired persons unable to read, the warning statement shall be read aloud by the operator to that individual, in the presence of a witness, and the witness and the operator shall sign the statement.

(b) The registrant shall maintain a record of each consumer's total number of tanning visits, including dates and durations of tanning exposures.

(c) The registrant shall determine each consumer's skin type using a method that distinguishes between six skin types and record the skin type on the client tan record.

(d) The registrant shall submit a written report of injury for which medical attention was sought or obtained from the use of registered tanning equipment to the Radiation Protection Section within five business days after occurrence. The report shall include:

   (1) the name of the affected individual;
   (2) the name and location of the tanning facility involved;
   (3) the nature of the actual or alleged injury; and
   (4) any other information relevant to the actual or alleged injury, including the date and duration of exposure and any documentation of medical attention sought or obtained.

(e) The registrant shall not allow individuals under the age of 18 to use tanning equipment.

(f) The registrant shall verify by checking legal identification that includes a driver's license, a passport, or military identification, each consumer is 18 years of age or older.

(g) The registrant shall not allow minors to remain in the tanning room while the tanning equipment is in operation.

(h) The registrant shall replace defective or burned out lamps, bulbs, or filters with a type intended for use in the affected tanning equipment as specified by the manufacturer's product label and having the same spectral distribution (certified equivalent lamp).
(i) The registrant shall replace ultraviolet lamps and bulbs that are not otherwise defective or damaged at such frequency or after such duration of use as is recommended by the manufacturer of such lamps and bulbs.

(j) The registrant shall maintain a record for inspection by authorized representatives of the agency of the number of hours that ultraviolet lamps and bulbs are used.

(k) The registrant shall certify that all tanning equipment operators are trained in the following:

1. the requirements of this Section;
2. procedures for correct operation of the tanning facility and tanning equipment;
3. recognition of injury or overexposure to ultraviolet radiation;
4. the tanning equipment manufacturer’s procedures for operation and maintenance of the tanning equipment;
5. the determination of skin type of customers and determination of duration of exposure to registered tanning equipment; and
6. emergency procedures to be followed in case of injury.

(l) The registrant shall allow operation of tanning equipment only by and in the physical presence of persons who have completed formal training courses that meet the requirements of Paragraph (k) of this Rule.

(m) The registrant shall maintain a record of operator training required in Paragraph (k) of this Rule for inspection by authorized representatives of the agency.

(n) No registrant shall possess, use, operate, or transfer tanning equipment or his or her ultraviolet radiation sources in such a manner as to cause any individual under 18 years of age to be exposed to radiation emissions from such equipment.

(o) Each registrant shall make available to all employees current copies of the following documents:

1. the facility’s certificate of registration with the Radiation Protection Section; and
2. conditions or documents incorporated into the registration by reference and amendments thereto.

History Note: Authority G.S. 104E-7(a)(7); 104E-9; 104E-9.1; 104E-12;
Eff. June 1, 1989;
Amended Eff. August 1, 2002; May 1, 1993; May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .1418 Eff. February 1, 2015;
Amended Eff. May 1, 2016;

10A NCAC 15 .1419 COMMUNICATIONS WITH THE AGENCY: AGENCY ADDRESS
Applications for registration, reports, notifications, and other communications required by this Section shall be mailed to the Radiation Protection Section, 1645 Mail Service Center, Raleigh, North Carolina 27699-1600 or delivered to the agency at its office located at 5505 Creedmoor Road, Suite 100, Raleigh, North Carolina 27612.

History Note: Authority G.S. 104E-7(a)(7);
Eff. June 1, 1989;
Amended Eff. August 1, 2002; May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .1419 Eff. February 1, 2015;
Amended Eff. May 1, 2016;

10A NCAC 15 .1420 PROPOSED SERVICING
Effective August 1, 1993, each person registered pursuant to Rule .1405 of this Section shall prohibit any person from furnishing tanning equipment services to their tanning equipment or facility until such person provides evidence that they are registered with the agency as a provider of services in accordance with the provisions of Rule .1421 of this Section.

History Note: Authority G.S. 104E-7(a)(7);
Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .1420 Eff. February 1, 2015;

10A NCAC 15 .1421 APPLICATION FOR REGISTRATION OF SERVICING OR SERVICES
(a) Each person who offers tanning equipment services to any agency registrant, shall apply for registration of such services with the agency within 60 days following the effective date of this Rule or, thereafter, prior to furnishing or offering to furnish any of these services.

(b) The application for registration required in Paragraph (a) of this Rule shall be completed on an approved agency form.

(c) Persons applying for registration under Paragraph (a) of this Rule shall certify that they have read and understand the requirements of the rules in this Section.

History Note: Authority G.S. 104E-7(a)(7); Eff. June 1, 1993; Transferred and Recodified from 15A NCAC 11 .1421 Eff. February 1, 2015; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1422 REPORTS AND INSTALLATION

(a) Persons registered pursuant to Rule .1421 of this Section, who sell, lease, transfer, lend, dispose of, assemble or install tanning equipment in this state shall, within 30 days after each calendar quarter, notify the agency at the address in Rule .1419 of this Section, of:

1. whether any tanning equipment was installed, transferred, or disposed of during the calendar quarter;
2. the name and address of persons who receive tanning equipment during the calendar quarter;
3. the manufacturer, model and serial number of tanning equipment transferred or otherwise disposed of; and
4. the date of transfer of any tanning equipment.

(b) No person shall make, sell, lease, transfer, lend, repair, assemble, or install tanning equipment or the supplies used in connection with such equipment unless such supplies and equipment when properly placed in operation and used shall meet the requirements of the rules in this Section and the regulations of 21 CFR 1040.20.

History Note: Authority G.S. 104E-7(a)(7); Eff. May 1, 1993; Amended Eff. August 1, 2002; Transferred and Recodified from 15A NCAC 11 .1422 Eff. February 1, 2015; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.

10A NCAC 15 .1423 FEES AND PAYMENT

(a) Annual fees established in this Rule shall be due on the first day of July of each year.

(b) Notwithstanding Paragraph (a) of this Rule, when a new registration is issued by the agency after the first day of July of any year, the initial fee is due on the date of issuance of the registration.

(c) The initial fee in Paragraph (b) of this Rule shall be computed as follows:

1. When any new registration is issued before the first day of January of any year, the initial fee is the full amount specified in this Rule; and
2. When any new registration is issued on or after the first day of January of any year, the initial fee is one-half of the amount specified in this Rule.

(d) Each registrant may pay all fees by cash, check, or money order as follows:

1. Checks or money orders shall be made payable to "Radiation Protection Section," and mailed to 1645 Mail Service Center, Raleigh, NC 27699-1600 or delivered to the agency office at 5505 Creedmoor Road, Suite 100, Raleigh, NC 27612; and
2. Cash payments shall be made only by appointment by calling the agency at 919/814-2250 and delivered to the agency office at 5505 Creedmoor Road, Suite 100, Raleigh, NC 27612.

(e) Within five days after the due dates established in Paragraphs (a) and (b) of this Rule, the agency shall mail to each registrant who has not already submitted payment a notice that indicates the due date, the amount of fees due, and the delinquent date.

(f) Payment of fees established in this Rule shall be delinquent if not received by the agency within 60 days after the due date specified in Paragraphs (a) and (b) of this Rule.

(g) If a registrant remits a fee in the form of a check or other instrument that is uncollectible from the paying institution, the agency shall notify the registrant by certified mail and allow the registrant 15 days to correct the matter, including payment of any fee charged to the agency by a banking institution.
(h) If payment of fees is uncollectible from the paying institution or not submitted to the agency by the delinquent date, the agency shall institute legal action to collect.

(i) Annual fees for persons registered pursuant to provisions of this Section are as listed in the following table:

<table>
<thead>
<tr>
<th>Type of registered facility</th>
<th>Letters appearing in registration number</th>
<th>Facility plus first piece of tanning equipment</th>
<th>Each additional piece of tanning equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tanning Facility</td>
<td>B</td>
<td>$200.00</td>
<td>$30.00</td>
</tr>
</tbody>
</table>

History Note: Authority G.S. 104E-9(a)(8); 104E-19(a);
Eff. July 1, 1994;
Amended Eff. July 1, 2011; August 1, 2007; August 1, 2002;
Transferred and Recodified from 15A NCAC 11 .1423 Eff. February 1, 2015;
Amended Eff. May 1, 2016;

SECTION .1500 - LICENSES FOR DISPOSAL SITE ACCESS

10A NCAC 15 .1501 PURPOSE AND SCOPE
10A NCAC 15 .1502 DEFINITIONS
10A NCAC 15 .1503 LICENSE REQUIRED
10A NCAC 15 .1504 APPLICATION FOR SITE ACCESS LICENSE: GENERAL REQUIREMENTS
10A NCAC 15 .1505 APPLICATION FOR SITE ACCESS LICENSE - WASTE GENERATORS
10A NCAC 15 .1506 CONTENT OF APPLICATION FOR WASTE COLLECTORS
10A NCAC 15 .1507 CONTENT OF APPLICATION FOR WASTE PROCESSORS
10A NCAC 15 .1508 CERTIFICATION OF COMPLIANCE WITH APPLICABLE REQUIREMENTS
10A NCAC 15 .1509 PRIOR NOTIFICATION FOR WASTE SHIPMENTS
10A NCAC 15 .1510 RADIOACTIVE SHIPMENT MANIFEST
10A NCAC 15 .1511 FINANCIAL QUALIFICATIONS AND REQUIREMENTS
10A NCAC 15 .1512 WASTE MANAGEMENT AND REDUCTION REQUIREMENTS
10A NCAC 15 .1513 ISSUANCE AND EXPIRATION OF SITE ACCESS LICENSES
10A NCAC 15 .1514 SITE ACCESS LICENSE RENEWAL
10A NCAC 15 .1515 SITE ACCESS LICENSE AMENDMENT
10A NCAC 15 .1516 MODIFICATION, REVOCATION, AND TERMINATION OF LICENSES
10A NCAC 15 .1517 TEMPORARY OR EMERGENCY ACCESS

History Note: Authority G.S. 104E-5; 104E-7; 104E-10.3; 104E-18; 104E-27; 104E-29; 132-1.2;
Eff. January 1, 1995;
Transferred and Recodified from 15A NCAC 11 .1501 -.1517 Eff. February 1, 2015;

SECTION .1600 - STANDARDS FOR PROTECTION AGAINST RADIATION

10A NCAC 15 .1601 STANDARDS FOR PROTECTION AGAINST RADIATION
(a) Persons registered with the agency pursuant to the rules in Section .0200 of this Chapter and persons licensed pursuant to the rules in Section .0300, .0900, .1200, or .1300 of this Chapter shall comply with the provisions of 10 CFR 20 as follows, which are hereby incorporated by reference including subsequent amendments and editions, except references to and requirements for 10 CFR 50, 52, 60, 63, 72, 73, and 76 shall not apply:

(1) 20.1001, "Purpose," except that non-ionizing radiation from radiation machines registered in accordance with the rules in Section .0200 of this Chapter shall also be regulated by this Rule;

(2) 20.1002, "Scope;"

(3) 20.1003, "Definitions," except that for persons registered with the agency pursuant to the rules in Section .0200 of this Chapter, the following terms used in 10 CFR 20 shall have the following substitutions:

(A) "license" shall have the same meaning as "registration" as defined in Rule .0104(131) of this Chapter;
(B) "licensed" means registered pursuant to the rules in Section .0200 of this Chapter;
(C) "licensed material" shall have the same meaning as "radiation machine" as defined in Rule .0104(122) of this Chapter, and
(D) "licensee" shall have the same meaning as "registrant" as defined in Rule .0104(130) of this Chapter;
(4) 20.1004, "Units of radiation dose;"
(5) 20.1005, "Units of radioactivity;"
(6) 20.1007, "Communications," except that licensees and registrants shall address communications regarding these rules, notifications, and reports to the agency as instructed by Rule .0111 of this Chapter in lieu of the NRC;
(7) 20.1101, "Radiation protection programs;"
(8) 20.1201, "Occupational dose limits for adults;"
(9) 20.1202, "Compliance with requirements for summation of external and internal doses;"
(10) 20.1203, "Determination of external dose from airborne radioactive material;"
(11) 20.1204, "Determination of internal exposure;"
(12) 20.1206, "Planned special exposures;"
(13) 20.1207, "Occupational dose limits for minors;"
(14) 20.1208, "Dose equivalent to an embryo/fetus;"
(15) 20.1301, "Dose limits for individual members of the public;"
(16) 20.1302, "Compliance with dose limits for individual members of the public;"
(17) 20.1401, "General provisions and scope;"
(18) 20.1402, "Radiological criteria for unrestricted use;"
(19) 20.1403, "Criteria for license termination under restricted conditions;"
(20) 20.1404, "Alternate criteria for license termination;"
(21) 20.1405, "Public notification and public participation," except the agency shall not publish a notice in the Federal Register;
(22) 20.1406, "Minimization of contamination," except that 20.1406(b) shall not apply;
(23) 20.1501, "General;"
(24) 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose;"
(25) 20.1601, "Control of access to high radiation areas;"
(26) 20.1602, "Control of access to very high radiation areas;"
(27) 20.1701, "Use of process or other engineering controls;"
(28) 20.1702, "Use of other controls;"
(29) 20.1703, "Use of individual respiratory protection equipment;"
(30) 20.1704, "Further restrictions on the use of respiratory equipment;"
(31) 20.1705, "Application for use of higher assigned protection factors;"
(32) 20.1801, "Security of stored material;"
(33) 20.1802, "Control of material not in storage;"
(34) 20.1901, "Caution signs;"
(35) 20.1902, "Posting requirements;"
(36) 20.1903, "Exceptions to posting requirements;"
(37) 20.1904, "Labeling containers;"
(38) 20.1905, "Exemptions to labeling requirements," except that 20.1905(g) shall not apply;
(39) 20.1906, "Procedures for receiving and opening packages;"
(40) 20.2001, "General requirements;"
(41) 20.2002, "Method for obtaining approval of proposed disposal procedures;"
(42) 20.2003, "Disposal by release to sanitary sewerage;"
(43) 20.2004, "Treatment or disposal by incineration;"
(44) 20.2005, "Disposal of specific wastes;"
(45) 20.2006, "Transfer for disposal and manifests;"
(46) 20.2007, "Compliance with environmental and health protection regulations;"
(47) 20.2008, "Disposal of certain byproduct material;"
(48) 20.2101, "General provisions;"
(49) 20.2102, "Records of radiation protection programs;"
(50) 20.2103, "Records of surveys;"
(51) 20.2104, "Determination of prior occupational dose;"
20.2105, “Records of planned special exposures;”
20.2106, “Records of individual monitoring results;”
20.2107, “Records of dose to individual members of the public;”
20.2108, “Records of waste disposal;”
20.2110, “Form of records;”
20.2201, “Reports of theft or loss of material.” Persons registered with the agency pursuant to the rules in Section .0200 of this Chapter shall make telephone reports of the theft or loss of radiation machines in accordance with 20.2201(a)(1)(i);
20.2202, “Notifications of incidents;”
20.2203, “Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits,” except that 20.2203(c) shall not apply;
20.2204, “Reports of planned special exposures;”
20.2205, “Reports to individuals exceeding dose limits;”
20.2206, “Reports of individual monitoring,” except that 20.2206(a)(1), and 20.2206(a)(3) through (a)(5) shall not apply. The report required by 20.2206(b) shall be submitted upon request by the agency in lieu of the requirements of 20.2206(c);
20.2207, “Reports of transactions involving nationally tracked sources.” Notwithstanding Subparagraph (a)(6) of this Rule, reports required by this Subparagraph shall be made in accordance with 20.2207(f) and (g);
20.2301, “Application for exemptions,” except that the request for exemption shall be made on the licensee’s or registrant’s business letterhead. Requests for exemptions from the requirements of this Rule shall be made to the agency at the addresses shown in Rule .0111(a) of this Chapter in lieu of the NRC or as otherwise instructed by the agency. To request an exemption, the following information shall be submitted to the agency:
(A) licensee or registrant name;
(B) license or registration number;
(C) name and contact information for the individual requesting the exemption;
(D) a description of the exemption being requested, and
(E) an explanation describing why the exemption is necessary;
20.2302, "Additional requirements;"
Appendix A to Part 20, "Assigned Protection Factors for Respirators;"
Appendix B to Part 20, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage;"
Appendix C to Part 20, "Quantities of Radioactive Material Requiring Labeling;"
Appendix E to Part 20, "Nationally Tracked Source Thresholds," and
Appendix G to Part 20, "Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests."
(b) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.
(c) Licensees and registrants shall continue to perform all activities required by the rules of this Chapter, license or registration condition, and shall pay annual fees as instructed on an invoice issued by the agency until the license or registration is terminated. Registrants shall maintain registration of all radiation machines under their control until those units are disposed.
(d) Nothing in the rules of this Chapter shall relieve any person of responsibility for complying with other applicable North Carolina laws and rules.
(e) Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part020/.

History Note: Authority G.S. 104E-7(a)(2);
Eff. January 1, 1994;
Amended Eff. August 1, 1998;
Transferred and Recodified from 15A NCAC 11 .1601 Eff. February 1, 2015;

10A NCAC 15 .1602 IMPLEMENTATION
10A NCAC 15 .1603 RADIATION PROTECTION PROGRAMS
10A NCAC 15 .1604 OCCUPATIONAL DOSE LIMITS FOR ADULTS
10A NCAC 15 .1605 REQUIREMENTS FOR SUMMATION OF EXTERNAL, INTERNAL DOSES
10A NCAC 15 .1606 EXTERNAL DOSE FROM AIRBORNE RADIOACTIVE MATERIAL
10A NCAC 15 .1607 DETERMINATION OF INTERNAL EXPOSURE
10A NCAC 15 .1608 PLANNED SPECIAL EXPOSURES
10A NCAC 15 .1609 OCCUPATIONAL DOSE LIMITS FOR MINORS
10A NCAC 15 .1610 DOSE EQUIVALENT TO AN EMBRYO/FETUS
10A NCAC 15 .1611 DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC
10A NCAC 15 .1612 COMPLIANCE WITH DOSE LIMITS FOR MEMBERS OF THE PUBLIC
10A NCAC 15 .1613 SURVEYS
10A NCAC 15 .1614 MONITORING OF EXTERNAL AND INTERNAL OCCUPATIONAL DOSE
10A NCAC 15 .1615 CONTROL OF ACCESS TO HIGH RADIATION AREAS
10A NCAC 15 .1616 CONTROL OF ACCESS TO VERY HIGH RADIATION AREAS
10A NCAC 15 .1617 ACCESS TO VERY HIGH RADIATION AREAS: IRRADIATORS
10A NCAC 15 .1618 USE OF PROCESS OR OTHER ENGINEERING CONTROLS
10A NCAC 15 .1619 USE OF OTHER CONTROLS TO RESTRICT INTERNAL EXPOSURE
10A NCAC 15 .1620 USE OF INDIVIDUAL RESPIRATORY PROTECTION EQUIPMENT
10A NCAC 15 .1621 RESTRICTIONS ON THE USE OF RESPIRATORY PROTECTION EQUIPMENT
10A NCAC 15 .1622 SECURITY OF SOURCES OF RADIATION
10A NCAC 15 .1623 CAUTION SIGNS
10A NCAC 15 .1624 POSTING REQUIREMENTS
10A NCAC 15 .1625 EXCEPTIONS TO POSTING REQUIREMENTS
10A NCAC 15 .1626 LABELING REQUIREMENTS AND EXEMPTIONS
10A NCAC 15 .1627 PROCEDURES FOR RECEIVING AND OPENING PACKAGES
10A NCAC 15 .1628 GENERAL REQUIREMENTS FOR WASTE DISPOSAL
10A NCAC 15 .1629 METHOD FOR OBTAINING APPROVAL OF DISPOSAL PROCEDURES
10A NCAC 15 .1630 DISPOSAL BY RELEASE INTO SANITARY SEWERAGE
10A NCAC 15 .1631 TREATMENT OR DISPOSAL BY INCINERATION
10A NCAC 15 .1632 DISPOSAL OF SPECIFIC WASTES
10A NCAC 15 .1633 TRANSFER FOR DISPOSAL AND MANIFESTS
10A NCAC 15 .1634 COMPLIANCE WITH ENV. AND HEALTH PROTECTION REGULATIONS
10A NCAC 15 .1635 GENERAL PROVISIONS FOR RECORDS
10A NCAC 15 .1636 RECORDS OF RADIATION PROTECTION PROGRAMS
10A NCAC 15 .1637 RECORDS OF SURVEYS
10A NCAC 15 .1638 DETERMINATION OF PRIOR OCCUPATIONAL DOSE
10A NCAC 15 .1639 RECORDS OF PLANNED EXPOSURES
10A NCAC 15 .1640 RECORDS OF INDIVIDUAL MONITORING RESULTS
10A NCAC 15 .1641 RECORDS OF DOSE TO INDIVIDUAL MEMBERS OF THE PUBLIC
10A NCAC 15 .1642 RECORDS OF WASTE DISPOSAL
10A NCAC 15 .1643 RECORDS OF TESTING ENTRY CONTROL DEVICES
10A NCAC 15 .1644 FORM OF RECORDS
10A NCAC 15 .1645 REPORTS OF THEFT OR LOSS OF LICENSED RADIOACTIVE MATERIAL
10A NCAC 15 .1646 NOTIFICATION OF INCIDENTS
10A NCAC 15 .1647 REPORTS OF RADIATION EXCEEDING THE LIMITS
10A NCAC 15 .1648 REPORTS OF PLANNED SPECIAL EXPOSURES
10A NCAC 15 .1649 REPORTS OF INDIVIDUAL MONITORING

History Note: Authority G.S. 104E-7(a)(2); 104E-7(a)(3); 104E-7(a)(5); 104E-12; 104E-12(a); 104E-15; 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R 7540; Eff. January 1, 1994; Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Amended Eff. October 1, 2013; November 1, 2007; May 1, 2006; January 1. 2005; August 1, 2002; April 1, 1999; August 1, 1998; May 1, 1995; Transferred and Recodified from 15A NCAC 11 .1602 - .1649 Eff. February 1, 2015; Amended Eff. March 1, 2017;

10A NCAC 15 .1650  CLASSIFICATION/RADIOACTIVE WASTE FOR NEAR-SURFACE DISPOSAL
10A NCAC 15 .1651  RADIOACTIVE WASTE CHARACTERISTICS
10A NCAC 15 .1652  LABELING

History Note:  Authority G.S. 104E-7(a)(2); Eff. January 1, 1994; Transferred and Recodified from 15A NCAC 11 .1650 -.1652 Eff. February 1, 2015; Repealed Eff. May 1, 2023.

10A NCAC 15 .1653  RADIOLOGICAL REQUIREMENTS FOR LICENSE TERMINATION

History Note:  Authority G.S. 104E-7(a)(2); 104E-10(b); Eff. April 1, 1999; Transferred and Recodified from 15A NCAC 11 .1653 Eff. February 1, 2015; Amended Eff. March 1, 2017; Repealed Eff. October 1, 2023.

SECTION .1700 – PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

10A NCAC 15 .1701  ADDITIONAL REQUIREMENTS FOR LICENSEES POSSESSING CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL
(a) Licensees possessing an aggregate category 1 or category 2 quantity of radioactive material, as defined in 10 CFR 37.5, shall comply with the requirements for the physical protection program listed in 10 CFR Part 37, which is hereby incorporated by reference, including any subsequent amendments and editions, except the following regulations are not incorporated:

(1) 10 CFR 37.1;
(2) 10 CFR 37.3;
(3) 10 CFR 37.7;
(4) 10 CFR 37.9;
(5) 10 CFR 37.11(a) and (b);
(6) 10 CFR 37.13;
(7) 10 CFR 37.105;
(8) 10 CFR 37.107; and
(9) 10 CFR 37.109.

(b) Licensee required reports of events or notifications in 10 CFR 37.23(b)(2), 37.41, 37.45, 37.57, 37.77(a) through (d), and 37.81 shall use the Agency contact information in Rule .0111 of this Chapter.
(c) The Code of Federal Regulations incorporated by this Rule are available free of charge at https://www.ecfr.gov/current/title-10/chapter-I/part-37.

History Note:  Authority G.S. 104E-7;
Eff. June 1, 2016;
Amended Eff. May 1, 2023.