

15A NCAC 11 .0104 is proposed to be amended as follows:

.0104 DEFINITIONS

As used in these Rules, the following definitions shall 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.
- (3) "Act" means North Carolina Radiation Protection Act as defined in G.S. 104E-1.
- (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 Environment and Natural Resources, Division of Radiation Protection.
- (7) "Agreement state" means any state with which the United States Nuclear Regulatory Commission has entered into an effective agreement under Subsection 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).
- (8) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.
- (9) "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 (DACs) 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 (ALI) or 12 DAC-hours.
- (10) "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.
- (11) "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. (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).
- (12) "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).
- (13) "Authorized representative" means an employee of the agency, or an individual outside the agency when the individual is specifically so designated by the agency under Rule .0112 of this Section.
- (14) "Authorized user" means an individual who is authorized by license or registration condition to use a source of radiation.
- (15) "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 contribute to background radiation and are not under the control of the licensee or registrant. "Background radiation" does not include sources of radiation regulated by the agency.
- (16) "Becquerel" is the SI unit of radioactivity. One becquerel is equal to one disintegration per second (s^{-1}).
- (17) "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.

(18) "Byproduct material" means any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material.

(19) "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:

CLASSIFICATION OF INHALED MATERIAL

<u>Class</u>	<u>Clearance half-time</u>
Class D (Day)	less than 10 days
Class W (Weeks)	10 days to 100 days
Class Y (Years)	greater than 100 days

(20) "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.

(21) "Commission" means the North Carolina Radiation Protection Commission.

(22) "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.

(23) "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 ($H_{E,50} = \sum w_T H_{T,50}$).

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

(25) "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.

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

(27) "Curie" is the special unit of radioactivity. One curie is equal to 3.7×10^{10} disintegrations per second = 3.7×10^{10} becquerels = 2.22×10^{12} disintegrations per minute.

(28) "Declared pregnant woman" means a woman who has voluntarily informed ~~her employer,~~ the licensee, 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.

(29) "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.

(30) "Deep-dose equivalent" (H_d), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of one cm (1000 mg/cm^2).

(31) "Department" means the North Carolina Department of Environment and Natural Resources.

(32) "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.

(33) "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 - 20.2041).

(34) "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).

- (35) "Diagnostic clinical procedures manual" means a collection of written procedures governing the use of radioactive material that describes each method by which the licensee performs diagnostic clinical procedures and includes other instructions and precautions. Each diagnostic clinical procedure including but not limited in content to the radiopharmaceutical, dosage and route of administration, shall be approved by an authorized user prior to inclusion in the manual. The radiation safety officer shall ensure that the manual includes the approved written procedure for all diagnostic clinical procedures performed at the facility.
- (36) "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 adequate measurement technology, survey and statistical techniques.
- (37) "Dose" (or radiation dose) is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, effective dose equivalent, or total effective dose equivalent, as defined in other Items of this Rule.
- (38) "Dose equivalent" (H_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).
- (39) "Dose limits" (see "Limits" defined in this Rule).
- (40) "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment.
- (41) "Effective dose equivalent" (H_E) is the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum w_T H_T$).
- (42) "Embryo/fetus" means the developing human organism from conception until the time of birth.
- (43) "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.
- (44) "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.
- (45) "Exposure" means being exposed to ionizing radiation or to radioactive material.
- (46) "Exposure rate" means the exposure per unit of time, such as R/min and mR/h.
- (47) "External dose" means that portion of the dose equivalent received from radiation sources outside the body.
- (48) "Extremity" means hand, elbow, arm, arm below the elbow, foot, knee, or leg below the knee.
- (49) "Eye dose equivalent" ~~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 centimeter (300 mg/cm²).~~ (See "Lens dose equivalent" as defined in this Rule).
- (50) "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. 2D11 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.
- (51) "Gray" (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule/kilogram (100 rads).
- (52) "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.
- (53) "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.
- (54) "Human use" means the internal or external administration of radiation or radioactive materials to human beings.
- (55) "Individual" means any human being.

- (56) "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 (see Bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or
 - (c) the assessment of dose equivalent by the use of survey data.
- (57) "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, ~~thermoluminescent~~ thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.
- (58) "Inhalation class" (see "Class" defined in this Rule).
- (59) "Inspection" means an official examination or observation to determine compliance with rules, orders, requirements and conditions of the agency or the Commission.
- (60) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.
- (61) "Lens dose equivalent" or "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).
- _____ (61) (62) "License", except where otherwise specified, means a license issued pursuant to Section .0300 of this Chapter.
- _____ (62) (63) "Licensee" means any person who is licensed by the agency pursuant to Section .0300 of this Chapter.
- _____ (63) (64) "Licensing state" means any state designated as such by the Conference of Radiation Control Program Directors, Inc. Unless the context clearly indicates otherwise, use of the term Agreement State in this Chapter shall be deemed to include licensing state with respect to naturally occurring and accelerator produced radioactive material (NARM).
- _____ (64) (65) "Limits" or "dose limits" means the permissible upper bounds of radiation doses.
- _____ (65) (66) "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.
- _____ (66) (67) "Lung class" (see "Class" as defined in this Rule).
- _____ (67) (68) "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.
- _____ (68) (69) "Member of the public" means any individual except when that individual is receiving an occupational dose.
- _____ (69) (70) "Minor" means an individual less than 18 years of age.
- _____ (70) (71) "Misadministration" means the administration of the following:
- (a) a diagnostic radiopharmaceutical dosage:
 - (i) involving a dose to the patient that exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ; and
 - (A) the wrong patient;
 - (B) the wrong radiopharmaceutical;
 - (C) the wrong route of administration; or
 - (D) an administered dosage that differs significantly from the prescribed dosage; or
 - (ii) for sodium iodide I-125 or I-131 involving:
 - (A) the wrong patient or wrong radiopharmaceutical; or
 - (B) an administered dosage that differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries;
 - (b) a therapeutic radiopharmaceutical dosage:
 - (i) involving:
 - (A) the wrong patient;

- (B) wrong radiopharmaceutical;
 - (C) wrong route of administration; or
 - (D) when the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage; or
 - (ii) when the administered dosage of sodium iodide I-125 or I-131 differs from the prescribed dosage by more than 20 percent of the prescribed dosage;
- (c) a teletherapy or accelerator radiation dose:
 - (i) involving:
 - (A) the wrong patient;
 - (B) the wrong mode of treatment; or
 - (C) wrong treatment site;
 - (ii) when the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;
 - (iii) when the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or
 - (iv) when the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose;
- (d) a brachytherapy radiation dose:
 - (i) involving:
 - (A) the wrong patient;
 - (B) the wrong radioisotope; or
 - (C) the wrong treatment site. This excludes, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site;
 - (ii) involving a sealed source that is leaking;
 - (iii) when, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or
 - (iv) when the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose; or
- (e) a gamma stereotactic radiosurgery radiation dose:
 - (i) involving the wrong patient or wrong treatment site; or
 - (ii) when the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.

- _____ (71) (72) "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.
- _____ (72) (73) "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.
- _____ (73) (74) "Natural radioactivity" means radioactivity of naturally occurring nuclides.
- _____ (74) (75) "Nonstochastic effect" means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect (also called a deterministic effect).
- _____ (75) (76) "NRC" means the United States Nuclear Regulatory Commission or its duly authorized representatives.
- _____ (76) (77) "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 dose 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 general public.

- (77) (78) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles.
- (78) (79) "Person" 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.
- (79) (80) "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 received by the individual.
- (80) (81) "Pharmacist" means an individual licensed by this state to compound and dispense drugs, prescriptions and poisons.
- (81) (82) "Physician" means an individual currently licensed to practice medicine in this state.
- (82) (83) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.
- (83) (84) "Prescribed dosage" means the quantity of radiopharmaceutical activity documented in a written directive by an authorized user.
- (84) (85) "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; or
 - (c) for gamma stereotactic radiosurgery, the total dose as documented in the written directive.
- (85) (86) "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 to 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.
- (86) (87) "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.
- (87) (88) "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.
- (88) (89) "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.
- (89) (90) "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).
- (90) (91) "Radiation" (ionizing radiation), except as otherwise defined in Section .1400 of this Chapter, means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions.
- (91) (92) "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.
- (92) (93) "Radiation dose" means dose.
- (93) (94) "Radiation machine" means any device capable of producing radiation except devices which produce radiation only from radioactive material.

- (94) (95) "Radiation safety officer" means one who has the knowledge and responsibility to apply appropriate radiation protection rules.
- (95) (96) "Radioactive material" means any material, solid, liquid, or gas, which emits radiation spontaneously.
- (96) (97) "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.
- (97) (98) "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.
- (98) (99) "Radioactivity" means the disintegration of unstable atomic nuclei by emission of radiation.
- (99) (100) "Radiobioassay" means bioassay.
- (100) (101) "Recordable event" means the administration of the following:
- (a) a radiopharmaceutical or radiation from a licensed source without a written directive where a written directive is required by Sub-items 145(a)(i) and 145(b)-(f) of this Rule;
 - (b) a radiopharmaceutical or radiation from a licensed source where a written directive is required by Sub-items 145(a)(i) and 145(b)-(f) of this Rule without recording each administered radiopharmaceutical dosage or radiation dose in the appropriate record on a daily basis;
 - (c) a radiopharmaceutical dosage of greater than 30 microcuries of sodium iodide I-125 and I-131 when:
 - (i) the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage; and
 - (ii) the difference between the administered dosage and prescribed dose exceeds 15 microcuries;
 - (d) a therapeutic dosage of any radiopharmaceutical dosage other than sodium iodide I-125 or I-131 when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;
 - (e) a teletherapy or accelerator radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose; or
 - (f) a brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.
- (101) (102) "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.
- (102) (103) "Registrant" means any person who is registered with the agency as required by provisions of these Rules or the Act.
- (103) (104) "Registration" means registration with the agency in accordance with these Rules.
- (104) (105) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189.
- (105) (106) "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:

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

<u>TYPE OF RADIATION</u>	<u>Quality Factor (Q)</u>	<u>Absorbed Dose Equal to a Unit Dose Equivalent^a</u>
X-, gamma or beta radiation	1	1

15A NCAC 11 .1403 is proposed to be amended as follows:

.1403 DEFINITIONS

As used in this Section, the following definitions shall apply:

- (1) "Agency" means the North Carolina Department of ~~Environment, Health, Environment~~ and Natural Resources.
- (2) "Consumer" means any individual who is provided access to a tanning facility which is required to be registered pursuant to provisions of this Section.
- (3) "Formal Operator Training" is a course of study that is offered by person(s) approved by this agency in accordance with the provisions of the rules in this Section.
- (3) (4) "Individual" means any human being.
- (5) "Inspection" means an official examination or observation to determine compliance with the rules in this Section, and orders, requirements and conditions of the agency.
- (6) "Minor" means any individual less than 18 years of age.
- (7) "Medical Lamps" means any lamp that is specifically designed or labeled for medical use only.
- (4) (8) "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, but is not limited to, any such 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 properly 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.
- (5) (9) "Person" 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.
- (6) (10) "Registrant" means any person who is registered with the agency as required by provisions of this Section.
- (7) (11) "Registration" means registration with the agency in accordance with provisions of this Section.
- (8) (12) "Tanning components" means any constituent tanning equipment part, to include ballasts, starters, lamps, reflectors, acrylic shields, timers, and airflow cooling systems.
- (9) (13) "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.
- (10) (14) "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, training seminars for tanning operators and service personnel.
- (11) (15) "Tanning facility" means any location, place, area, structure or business which 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.
- (12) (16) "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.

15A NCAC 11 .1405 is proposed to be amended as follows:

.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 ~~apply to the agency for~~ have a certificate of registration issued by the agency for of 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) ~~name(s) of the tanning facility operator(s) with a certification of each operator's training as provided in Rules .1418(g) and (h) of this Section;~~ 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) the geographic areas of the state to be covered, if the application is for a mobile tanning facility;~~
 - ~~(7) copies of any posted warnings or notices which are not required by this Section and which address the safety and proper use of tanning equipment and protective devices;~~
 - ~~(8) copies of the consent forms and statements which the consumer, parent or guardian will be required to sign pursuant to Paragraphs (a) and (d) of Rule .1418 of this Section;~~
 - ~~(9) procedures which the operator(s) will be required to follow for the correct use of tanning equipment to include: instructions to the consumer, use of protective eyewear, suitability of prospective consumers for tanning equipment use, determination of duration of tanning exposures, periodic testing of tanning equipment and timers, handling of complaints of injury from consumers, and records to be maintained on each consumer;~~
 - ~~(10)~~ (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
 - ~~(11)~~ (7) each person operating a tanning facility shall not allow any individual under 18 years of age to be the operator of tanning equipment; and equipment.
 - ~~(12) each person operating a tanning facility or tanning equipment shall meet one of the following educational requirements:~~
 - ~~(A) high school diploma;~~
 - ~~(B) high school equivalency; or~~
 - ~~(C) demonstrate basic literacy skills.~~

History Note: Authority G.S. 104E-7(a)(7);
Eff. June 1, 1989;
Amended Eff. August 1, 2002; June 1, 1993; May 1, 1992.

15A NCAC 11 .1408 is proposed to be amended as follows:

.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 ~~not less than 30 days prior to~~ by the expiration date stated on the certificate of registration, 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; 1989;
Amended Eff. August 1, 2002.

15A NCAC 11 .1409 is proposed to be amended as follows:

.1409 REPORT OF CHANGES

The registrant shall notify the agency in writing ~~before~~ 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~~, 1989;
Amended Eff. August 1, 2002.

15A NCAC 11 .1412 is proposed to be amended as follows:

.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; ~~or~~
 - (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~~; agency; ~~or~~
 - (6) 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.

15A NCAC 11 .0117 is proposed to be amended as follows:

.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, not obstructed by any barrier, equipment or other object, and can 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 which are at least ~~ten~~ seven millimeters and ~~five~~ three and half (3.5) millimeters in height, respectively, and shall have the following wording:

DANGER - ULTRAVIOLET RADIATION

-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.

-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.

-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 of the agency.

*History Note: Authority G.S. 104E-7(a)(7);
Eff. June 1, 1989;
Amended Eff. August 1, 2002; June 1, 1993.*

15A NCAC 11 .1415 is proposed to be amended as follows:

.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, "Sunlamp products and ultraviolet lamps intended for use in sunlamp products". 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.
- (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 which 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 ten 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 legible and accessible to view.
- (f) The timer intervals shall be numerically indicated on the face of the timer.
- (g) The time 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. Effective two years after the effective date of this Rule, all tanning facilities shall be equipped with remote timers.

(j) The registrant shall ensure that 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 Rule .1415 of this Section and the consumer is able to terminate the radiation manually in accordance with this Rule.

(k) Medical lamps shall not be used for commercial cosmetic tanning purposes.

*History Note: Authority G.S. 104E-7(a)(7);
Eff. June 1, 1989;
Amended Eff. August 1, 2002; June 1, 1993.*

15A NCAC 11 .1417 is proposed to be amended as follows:

.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(e)(5)~~; 1040.20(c)(4).
- (c) ~~Tanning facility operators shall ensure that consumers wear the protective eyewear required by this Rule by means of post exposure observation.~~ 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 properly 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.*

15A NCAC 11 .1419 is proposed to be amended as follows:

.1419 COMMUNICATIONS WITH THE AGENCY: AGENCY ADDRESS

Applications for registration, reports, notifications and other communications required by this Section shall be mailed to the Division of Radiation Protection ~~P. O. Box 27687, Mail Service Center 1645, Raleigh, North Carolina 27611-7687~~ 27699-1645 or delivered to the agency at its office located at 3825 Barrett Drive, Raleigh, North Carolina 27609-7221.

*History Note: Authority G.S. 104E-7(a)(7);
Eff. June 1, 1989;
Amended Eff. August 1, 2002; May 1, 1992.*

15A NCAC 11 .1422 is proposed to be amended as follows:

.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; 1993;
Amended Eff. August 1, 2002.*

15A NCAC 11 .1423 is proposed to be amended as follows:

.1423 FEES AND PAYMENT

- (a) This Rule establishes initial, annual and reinstatement fees ~~on~~ for persons registered pursuant to the provisions of this Section to cover the anticipated costs of tanning equipment inspection and enforcement activities of the agency.
- (b) ~~All annual~~ Annual fees established in this Rule shall be due on the effective date of this Rule and on the first day of July of each subsequent ~~year~~; reinstatement fees shall be paid prior to reinstatement.
- (c) Notwithstanding Paragraph (b) of this Rule, when a new registration is issued by the agency after the first day of July of any year, the initial fee shall be due on the date of issuance of the registration.
- (d) The initial fee in Paragraph (c) 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 shall be 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 shall be one-half of the amount specified in this Rule.
- (e) All fees received by the agency pursuant to provisions of this Rule shall be nonrefundable.
- (f) Each registrant may pay all fees by cash, check or money order provided:
 - (1) Checks or money orders shall be made payable to "Division of Radiation Protection", and mailed to ~~P.O. Box 27687, 1645 Mail Service Center, Raleigh, NC 27611-7687~~ 27699-1645 or delivered to the agency office at 3825 Barrett Drive, Raleigh, NC 27609-7221; and
 - (2) Cash payments shall be made only by appointment by calling the agency at 919/571-4141 and delivered to the agency office at 3825 Barrett Drive, Raleigh, NC 27609-7221.
- (g) Within five days after the due dates established in Paragraphs (b) and (c) of this Rule, the agency shall mail to each registrant, who has not already submitted payment, a notice which indicates the due date, ~~delinquent date~~ and the amount of fees due; ~~due, the delinquent date and the amount of the reinstatement fee if not paid by the delinquent date.~~
- (h) 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 (b) and (c) of this Rule.
- (i) If a 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 registrant by certified mail and allow the registrant 15 days to correct the matter.
- (j) If payment of fees is uncollectible from the paying institution or not submitted to the agency by the delinquent date, the agency may institute appropriate legal action to collect.
- (k) Annual fees for persons registered pursuant to provisions of this Section are as listed in the following table:

Type of registered facility	Letters appearing in registration number	Facility plus first Piece of Tanning Equipment	Each additional Piece of Tanning Equipment
Tanning Facility	B	\$100.00	\$16.00
Tanning Equipment Services	F	\$100.00	NA

- (l) ~~When fees become delinquent as specified in this Rule, in addition to any delinquent fee owed to the agency, the registrant shall pay to the agency a reinstatement fee of one hundred fifty dollars (\$150).~~

History Note: Authority G.S. 104E-9(a)(8); 104E-19(a);
 Eff. July 1, 1994. 1994;
 Amended Eff. August 1, 2002.

15A NCAC 11 .1608 is proposed to be amended as follows:

.1608 PLANNED SPECIAL EXPOSURES

A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in Rule .1604 of this Section provided that each of the following conditions is satisfied:

- (1) The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the ~~higher exposure~~ dose estimated to result from the planned exposure are unavailable or impractical.
- (2) The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.
- (3) Before a planned special exposure, the licensee or registrant ensures that the individuals involved are:
 - (a) informed of the purpose of the planned operation;
 - (b) informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and
 - (c) instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.
- (4) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by Rule .1638(b) of this Section during the lifetime of the individual for each individual involved.
- (5) Subject to Rule .1604(b) of this Section, the licensee or registrant does not authorize a planned special exposure that would cause an individual to receive a dose such that the individual's dose from all planned special exposures and all doses in excess of the limits would exceed:
 - (a) the numerical values of any of the dose limits in Rule .1604(a) of this Section in any year; and
 - (b) five times the annual dose limits in Rule .1604(a) of this Section during the individual's lifetime.
- (6) The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with Rule .1639 of this Section and submits a written report in accordance with Rule .1648 of this Section.
- (7) The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures is not to be considered in controlling future occupational dose of the individual under Rule .1604(a) of this Section but is to be included in evaluations required by Items (4) and (5) of this Rule.

History Note: Authority G.S. 104E-7(a)(2); 104E-12;
Eff. January 1, 1994. 1994;
Amended Eff. August 2, 2002.

15A NCAC 11 .1610 is proposed to be amended as follows:

.1610 DOSE EQUIVALENT TO AN EMBRYO/FETUS

- (a) The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). Recordkeeping requirements for doses to an embryo/fetus are provided in Rule .1640 of this Section.
- (b) The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in Paragraph (a) of this Rule.
- (c) The dose equivalent to an embryo/fetus shall be taken as the sum of:
 - (1) the deep-dose equivalent to the declared pregnant woman; and
 - (2) the dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

- (d) If the dose equivalent to the embryo/fetus is found to have exceeded 0.45 rem (4.5 mSv) by the time the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with Paragraph (a) of this Rule if the additional dose to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

*History Note: Authority G.S. 104E-7(a)(2);
Eff. January 1, 1994, 1994;
Amended Eff. August 1, 2002.*

15A NCAC 11 .1613 is proposed to be amended as follows:

.1613 SURVEYS

- (a) Each licensee or registrant shall make or cause to be made, surveys that:
- (1) may be necessary for the licensee or registrant to comply with the rules in this Section; and
 - (2) are reasonable under the circumstances to evaluate:
 - (A) the magnitude and extent of radiation levels;
 - (B) concentrations or quantities of radioactive material; and
 - (C) the potential radiological hazards that could be present.
- (b) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated periodically for the radiation measured.
- (c) All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees or registrants to comply with Rule .1604 of this Section, with other applicable provisions of this Chapter, or with conditions specified in a license shall be processed and evaluated by a dosimetry processor:
- (1) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and
 - (2) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.
- (d) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

*History Note: Authority G.S. 104E-7(a)(2);
Eff. January 1, 1994, 1994;
Amended Eff. August 1, 2002.*

15A NCAC 11 .1614 is proposed to be amended as follows:

.1614 MONITORING OF EXTERNAL AND INTERNAL OCCUPATIONAL DOSE

Each licensee or registrant shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this Section. As a minimum:

- (1) Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:
 - (a) adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in Rule .1604(a) of this ~~Section~~, Section;
 - (b) ~~minors and declared pregnant women~~ likely to receive, in one year year, from sources ~~external to the body~~, a dose ~~in excess of 10 percent of any of the applicable limits in Rules .1609 or .1610 of this Section; and~~ of radiation, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent in excess of 0.5 rem (5 mSv);
 - (c) declared pregnant women likely to receive, during the entire pregnancy, from sources of radiation external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv); and
 - (e) (d) individuals entering a high or very high radiation area.

- (2) Each licensee shall monitor the occupational intake of radioactive material by and assess the committed effective dose equivalent to:
- (a) adults likely to receive, in one year, an intake in excess of 10 percent of the applicable ALI(s) in Table 1, Columns 1 and 2, of Appendix B to 10 CFR §§ 20.1001 - 20.2401; 20.2402; and
 - (b) minors and declared pregnant women likely to receive, in ~~± one~~ year, a committed effective dose equivalent in excess of ~~0.05 rem (0.5 mSv)~~; 0.1 rem (1mSv).

History Note: Authority G.S. 104E-7(a)(2);
 Eff. January 1, 1994; 1994;
 Amended Eff. August 1, 2002.

15A NCAC 11 .1625 is proposed to be amended as follows:

.1625 EXCEPTIONS TO POSTING REQUIREMENTS

- (a) A licensee is not required to post caution signs in areas or rooms containing radioactive materials for periods of less than eight hours, if each of the following conditions is met:
 - (1) The materials are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to radiation or radioactive materials in excess of the limits established in the rules in this Section; and
 - (2) The area or room is subject to the licensee's control.
- (b) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to Rule .1624 of this Section provided that:
 - (1) The patient is being treated with sealed sources or has been treated with unsealed radioactive material in quantities less than 30 millicuries (110 MBq), or the measured dose rate at one meter from the patient is less than 0.005 rem (0.05 mSv) per hour; and
 - (2) There are personnel in attendance who will take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the limits established in this Section and to operate within the ALARA provisions of the licensee's radiation protection program.
- (c) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the source container or housing does not exceed 0.005 rem (0.05 mSv) per hour.
- (d) Rooms or other areas in medical facilities that are occupied by patients while being treated with radiation from an accelerator are not required to be posted with a caution sign pursuant to Rule .1624(c) of this Section provided that:
 - (1) access to the room or area is posted in accordance with Rule .1624(b) of this Section; and
 - (2) there are personnel in attendance who shall provide assurance that:
 - (A) continuous audio and visual observation of the patient is maintained during treatment;
 - (B) all provisions of Subparagraph (b)(2) of this Rule are met; and
 - (C) the accelerator is secured in the "beam off" status at the end of each patient's treatment.
- (e) Rooms or other areas in medical facilities that are occupied by patients while being treated with radiation from a teletherapy source are not required to be posted with a caution sign pursuant to Rule .1624(c) of this Section provided that:
 - (1) access to the room or area is posted in accordance with Rule .1624(b) of this Section; and
 - (2) there are personnel in attendance who shall take the necessary precautions to prevent the inadvertent exposures of workers, other patients, and members of the public to radiation in excess of the limits established in the rules 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(a)(2);
 Eff. January 1, 1994;
 Amended Eff. August 1, 2002; May 1, 1995.

15A NCAC 11 .1627 is proposed to be amended as follows:

.1627 PROCEDURES FOR RECEIVING AND OPENING PACKAGES

- (a) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in Rule .0104 of this Chapter, shall make arrangements to receive:
- (1) the package when the carrier offers it for delivery; or
 - (2) notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.
- (b) Each licensee, upon receipt of a package containing radioactive material, shall ~~monitor the external surfaces of the package for radioactive contamination and radiation levels if the package:~~ monitor:
- (1) ~~is labeled external surfaces of a package labeled as containing radioactive material; or material for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR § 71.4;~~
 - (2) ~~has evidence of potential contamination, such as packages that are crushed, wet, or damaged. external surfaces of a package labeled as containing radioactive material for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR § 71.4 and Appendix A to Part 71; and~~
 - (3) all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.
- (c) The licensee shall perform the monitoring required by Paragraph (b) of this Rule as soon as practicable after receipt of the package, but not later than three hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.
- (d) The licensee shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the agency when:
- (1) removable radioactive surface contamination exceeds the limits of 10 CFR § 71.87(i); or
 - (2) external radiation levels exceed the limits of 10 CFR § 71.47.
- (e) Each licensee shall:
- (1) establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and
 - (2) ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.
- (f) Licensees transferring special form sources in licensee-owned or licensee-operated vehicles to and from a work site are exempt from the contamination monitoring requirements of Paragraph (b) of this Rule, but are not exempt from the survey requirement in Paragraph (b) of this Rule for measuring radiation levels that is required to ensure that the source is still properly lodged in its shield.

History Note: Authority G.S. 104E-7(a)(2); 104E-12(a);
Eff. January 1, 1994. 1994;
Amended Eff. August 1, 2002.

15A NCAC 11 .1635 is proposed to be amended as follows:

.1635 GENERAL PROVISIONS FOR RECORDS

- (a) Each licensee or registrant shall use the units: curie, rad and rem, including multiples and subdivisions thereof, and shall clearly indicate the units of all quantities on records required by this Section.
- (b) Notwithstanding the requirements of Paragraph (a) of this Rule, when recording information on shipping manifests, as required by Rule .1633 of this Section and Appendix G to 10 CFR 20, information shall be recorded in the International System of Units (SI) or SI and units as specified in Paragraph (a) of this Rule. For records other than shipping manifests, the licensee or registrant may record quantities in SI units in parenthesis following each of the units specified in Paragraph (a) of this Rule; however all quantities shall be recorded as stated in Paragraph (a) of this Rule.
- (c) The licensee or registrant shall make a clear distinction whether the quantities entered on the records required by this Section are total effective dose equivalent, shallow-dose equivalent, eye dose equivalent, deep-dose equivalent, or committed effective dose equivalent.

- (d) The discontinuance or curtailment of activities does not relieve the licensee or registrant of responsibility for retaining all records required by the rules in this Section.

History Note: Authority G.S. 104E-7(a)(2); 104E-12(a);
Eff. January 1, 1994;
Amended Eff. August 1, 2002; April 1, 1999.

15A NCAC 11 .1640 is proposed to be amended as follows:

.1640 RECORDS OF INDIVIDUAL MONITORING RESULTS

- (a) Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to Rule .1614 of this Section, and records of doses received during planned special exposures, accidents, and emergency conditions. These records shall include, when applicable:
- (1) the deep-dose equivalent to the whole body, eye dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities;
 - (2) the estimated intake ~~or body burden~~ of radionuclides (see Rule .1605 of this Section);
 - (3) the committed effective dose equivalent assigned to the intake or body burden of radionuclides;
 - (4) the specific information used to calculate the committed effective dose equivalent pursuant to Rule .1607(c) of this Section; Section and when required by Rule .1614 of this Section;
 - (5) the total effective dose equivalent when required by Rule .1605 of this Section; and
 - (6) the total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose.
- (b) The licensee or registrant shall make entries of the records specified in Paragraph (a) of this Rule at least annually.
- (c) The licensee or registrant shall maintain the records specified in Paragraph (a) of this Rule on the agency form for recording occupational radiation doses, in accordance with the instructions provided with the form, or in clear and legible records containing all the information required by the agency form for recording occupational radiation doses.
- (d) Assessments of dose equivalent and records made using units in effect before the licensee's or registrant's adoption of the rules in this Section need not be changed.
- (e) The records required under this Rule may be protected from public disclosure because of their personal privacy nature; however, the limitations in this Paragraph are subject to, and do not limit federal and state laws that may require disclosure.
- (f) The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy shall also be kept on file, but may be maintained separately from the dose records.
- (g) The licensee or registrant shall retain each required form or record until the agency terminates each pertinent license or registration requiring the record.

History Note: Authority G.S. 104E-7(a)(2); 104E-12(a);
Eff. January 1, 1994. 1994;
Amended Eff. August 1, 2002.

dilution and excretion. This group does not include the use of any radiopharmaceutical disapproved by the North Carolina Radiation Protection Commission or involving imaging, tumor localization or therapy.

(2) Group II includes radiopharmaceuticals for which a New Drug application has been approved by the U.S. Food and Drug Administration for diagnostic studies involving imaging and tumor localizations. This group does not include the use of any radiopharmaceutical disapproved by the North Carolina Radiation Protection Commission.

(3) Group III includes the use of generators and reagent kits for which a New Drug application has been approved by the U.S. Food and Drug Administration for the preparation of radiopharmaceuticals for certain diagnostic uses. This group does not include any generator or reagent kit disapproved by the North Carolina Radiation Protection Commission.

(4) Group IV includes radiopharmaceuticals for which a New Drug application has been approved by the U.S. Food and Drug Administration for therapeutic uses which do not normally require hospitalization for purposes of radiation safety. This group does not include any radiopharmaceutical disapproved by the North Carolina Radiation Protection Commission.

(c) Any licensee who is authorized to use radioactive material in one or more groups pursuant to Paragraph (a) of this Rule is subject to the following conditions:

(1) For Groups I, II and IV, no licensee shall receive, possess, or use radioactive materials except as a radiopharmaceutical manufactured in the form to be administered to the patient, labeled, packaged, and distributed in accordance with:

(A) a specific license issued by the U.S. Nuclear Regulatory Commission, pursuant to Section 32.72 of 10 CFR Part 32; or

(B) a specific license issued by the agency or an agreement state pursuant to equivalent regulations.

(2) For Group III, no licensee shall receive, possess, or use generators or reagent kits containing radioactive material or shall use reagent kits that do not contain radioactive material to prepare radiopharmaceuticals containing radioactive material, except:

(A) reagent kits, not containing radioactive material, that are approved by the U.S. Nuclear Regulatory Commission, the U.S. Atomic Energy Commission, or an agreement state for use by persons licensed for Group III pursuant to Paragraph (a) of this Rule or equivalent regulations of an agreement state or the U.S. Nuclear Regulatory Commission;

(B) generators or reagent kits containing radioactive material that are manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or by the agency or an agreement state pursuant to equivalent regulations;

(C) any licensee who uses generators or reagent kits shall elute the generator or process radioactive material with the reagent kit in accordance with instructions which are approved by the U.S. Nuclear Regulatory Commission or an agreement state and are furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.

(3) For Groups I, II and III, any licensee using radioactive material for clinical procedures other than those specified in the product labeling package insert shall comply with the product labeling regarding:

(A) chemical and physical form;

(B) route of administration; and

(C) dosage range.

(4) Any licensee who is licensed pursuant to Paragraph (a) of this Rule for one or more of the medical use groups also is authorized to use radioactive material under the general license in Rule .0314 of this Section for the specified IN VITRO uses without filing agency form as required by Rule .0314(b) of this Section, provided that the licensee is subject to the other provisions of Rule .0314 of this Section.

(5) Any licensee who is licensed pursuant to Paragraph (a) of this Rule for one or more of the medical use groups in Paragraph (a) of this Rule also is authorized, subject to the provisions of Parts (c)(5)(E) and (F) of this Rule, to receive, possess, and use for calibration and reference standards:

(A) Any radioactive material listed in Group I, Group II, or Group III of this Rule with a half-life not longer than 100 days, in amounts not to exceed 15 millicuries total;

(B) Any radioactive material listed in Group I, Group II, or Group III of this Rule with half-life greater than 100 days in individual amounts not to exceed 200 microcuries total;

(C) Technetium-99m in individual amounts not to exceed 50 millicuries;

(D) Any radioactive material in amounts not to exceed 15 millicuries per source contained in calibration or reference sources that have been manufactured, labeled, packaged, and distributed in accordance with:

(i) a specific license issued to the manufacturer by an agreement state pursuant to equivalent state regulations;

(ii) a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.74 of 10 CFR, Part 32; or

(iii) an application filed with the U.S. Atomic Energy Commission pursuant to Section 32.74 of 10 CFR, part 32; or

(iv) an application filed with an agreement state pursuant to equivalent state regulations on or before October 15, 1974 for a license to manufacture a source that the applicant distributed commercially on or before August 16, 1974, on which application the U.S. Atomic Energy Commission or the U.S. Nuclear Regulatory Commission or the agreement state has not acted.

(E) Any licensee who possesses sealed sources as calibration or reference sources pursuant to Subparagraph (c)(5) of this Rule shall cause each sealed source containing radioactive material other than hydrogen-3 with a half-life greater than 30 days in any form other than gas to be tested for leakage or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, the sealed source shall not be used until tested. No leak tests are required when:

(i) The source contains 100 microcuries or less of beta or gamma emitting material or ten microcuries or less of alpha emitting material.

(ii) The sealed source is stored and is not being used.

Such source shall be tested for leakage prior to any use or transfer unless they have been leak tested within six months prior to the date of use or transfer.

(F) The leak test shall be capable of detecting the presence of 0.005 microcuries of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which contamination might be expected to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the agency.

(G) If the leak test reveals the presence of 0.005 microcuries or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission rules. A report shall be filed within five days of the test with the agency address in Rule .0111 of this Chapter describing the equipment involved, the test results, and the corrective action taken.

(H) Any licensee who possesses and uses calibration and reference sources pursuant to Subparagraph (c)(5) of this Rule shall:

(i) 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;

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

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

- (d) Current lists of the radiopharmaceuticals, generators, reagent kits, and associated uses in Group I to IV are available from the agency at the address in Rule .0111 of this Chapter.

History Note: Authority G.S. 104E-7; 104E-10(b);

Eff. February 1, 1980;

Amended Eff. August 1, 2002; April 1, 1999; May 1, 1993.

15A NCAC 11 .0359 is proposed to be amended as follows:

.0359 MEASUREMENTS/DOSAGES OF UNSEALED RADIOACTIVE MATERIAL FOR MEDICAL USE

- (a) A licensee shall possess and use a dose calibrator to measure the radioactivity of dosages of photon-emitting radionuclides prior to administration to each individual. A licensee shall:
- (1) develop, maintain, and implement written procedures for use of the dose calibrator;
 - (2) check dose calibrator for constancy at the beginning of each day of use. To satisfy the requirements of this Subparagraph, the check shall be done on a frequently used setting with a sealed source of not less than 10 microcuries (0.37 megabecquerel (MBq) of radium-226 or 50 microcuries (1.85 MBq) of any other photon-emitting radionuclide;
 - (3) test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least two sealed sources containing different radionuclides ~~who~~ whose activity the manufacturer has determined within five percent of this stated activity, whose activity is at least 10 microcuries (0.37 MBq) for radium-226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;
 - (4) test each dose calibrator for linearity upon installation and at least quarterly thereafter over a range ~~with~~ from the highest dosage that will be administered to a patient or human research subject to 30 microcuries (1.1 MBq); and
 - (5) test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.
- (b) A licensee shall also perform appropriate checks and tests required by this Rule following repair of the dose calibrator.
- (c) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (.37 MBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.
- (d) A licensee shall retain a record of each check and test required by this Rule for three years. The records required in Subparagraphs (a)(2)-(a)(5) of this Rule shall include:
- (1) For Subparagraph (a)(2) of this Rule, the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the initials of the individual who performed the check;
 - (2) For Subparagraph (a)(3) of this Rule, the model and serial number of the dose calibrator, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the identity of the individual performing the test;
 - (3) For Subparagraph (a)(4) of this Rule, the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the identify of the individual performing the test; and
 - (4) For Subparagraph (a)(5) of this Rule, the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the identity of the individual performing the test.

History Note: Authority G.S. 104E-7; 104E-10(b); 104E-12;

Eff. April 1, ~~1999~~ 1999;

Amended Eff. August 1, 2002.

15A NCAC 11 .0362 is proposed to be amended as follows:

.0362 DECAY-IN-STORAGE

- (a) A licensee may hold radioactive material with a physical half-life of less than 165 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 the date of the disposal, the date on which radioactive material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose ~~rate used, rate,~~ and the dose rate measured at the surface of each waste container.

History Note: Authority G.S. 104E-7(a)(2); 104E-10(b);
 Eff. April 1, 1999, 1999;
 Amended Eff. August 1, 2002.

15A NCAC 11 .0507 is proposed to be amended as follows:

.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 transferor 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 ~~0.005 uCi~~ 0.005 uCi (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. August 1, 2002; April 1, 1999; May 1, 1995; June 1, 1993.

15A NCAC 11 .0511 is proposed to be amended as follows:

.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 ~~of~~ of 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: 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. August 1, 2002; April 1, 1999; May 1, 1995; October 1, 1980.

15A NCAC 11 .0520 is proposed to be amended as follows:

.0520 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~~ 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: 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. October 1, 1980;

Amended Eff. August 1, 2002; April 1, 1999; May 1, 1995; January 1, 1994.

15A NCAC 11 .1007 is proposed to be amended as follows:

.1007 REQUESTS FOR INSPECTIONS

- (a) Any worker or representative of workers who believes that a violation of the Act, provisions of this Chapter or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Director of the Division of Radiation Protection, ~~P.O. Box 27687, 1645 Mail Service Center,~~ Raleigh, North Carolina ~~27611-7687, 27699-1645~~. Any such notice shall be in writing, shall set forth the specified grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the Director of the Division of Radiation Protection no later than at the time of inspection except that, upon request of the worker giving such notice, his name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the agency, except for good cause shown.
- (b) If, upon receipt of such notice, the Director of the Division of Radiation Protection determines that the complaint meets the requirements set forth in Paragraph (a) of this Rule and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he shall cause an inspection to be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this Rule need not be limited to matters referred to in the complaint.
- (c) No licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under this Chapter or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by this Section.

History Note: Authority G.S. 104E-7; 104E-10;
Eff. February 1, 1980;
Amended Eff. August 1, 2002; May 1, 1992; November 1, 1989.

15A NCAC 11 .1008 is proposed to be amended as follows:

.1008 INSPECTIONS NOT WARRANTED

- (a) If the Director of the Division of Radiation Protection determines, with respect to a complaint under Rule .1007 of this Section that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Director of the Division of Radiation Protection shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the Secretary, Department of ~~Environment, Health,~~ Environment and Natural Resources, ~~P.O. Box 27687, 1601 Mail Service Center,~~ Raleigh, North Carolina ~~27611-7687, 27699-1601~~ who will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the Secretary, Department of ~~Environment, Health,~~ Environment and Natural Resources who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the Secretary, Department of ~~Environment, Health,~~ Environment and Natural Resources may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written or oral views presented, the Secretary, Department of ~~Environment, Health,~~ Environment and Natural Resources shall affirm, modify, or reverse the determination of the Director of the Division of Radiation Protection and furnish the complainant and the licensee or registrant a written notification of his decision and the reason therefor.
- (b) If the Director of the Division of Radiation Protection determines that an inspection is not warranted because the requirements of Rule .1007(a) of this Section have not been met, he shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of Rule .1007(a) of this Section.

History Note: Authority G.S. 104E-7; 104E-10;
Eff. February 1, 1980;
Amended Eff. August 1, 2002; May 1, 1992; November 1, 1989.

15A NCAC 11 .1102 is proposed to be amended as follows:

.1102 PAYMENT DUE

- (a) All fees established in this Section shall be due on the effective date of this Rule and on the first day of July of each subsequent year.
- (b) Notwithstanding Paragraph (a) of this Rule, when a new license or registration is issued by the agency after the first day of July of any 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 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 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 by check or money order made payable to "Division of Radiation Protection" and mail such payment to: Division of Radiation Protection, North Carolina Department of Environment, Health, Environment and Natural Resources, ~~P. O. Box 27687~~, 1645 Mail Service Center, Raleigh, North Carolina ~~27611-7687~~; 27699-1645. Such payment may be delivered to the agency at its office located at 3825 Barrett Drive, Raleigh, North Carolina 27609-7221.

*History Note: Authority G.S. 104E-9(8); 104E-19(a);
 Eff. July 1, 1982;
 Amended Eff. August 1, 2002; May 1, 1993; May 1, 1992; July 1, 1989.*

15A NCAC 11 .1105 is proposed to be amended as follows:

.1105 FEE AMOUNTS

- (a) Annual fees for persons registered pursuant to provisions of Section .0200 of this Chapter are as listed in the following table:

Type of Registered Facility	Letters appearing in registration number	Facility plus first X-ray tube		Each additional X-ray Tube to a maximum of 40 additional X-ray tubes	
Clinics	A	\$ 70.00	\$ 90.00	\$ 12.50	\$ 16.25
Chiropractors	C	\$ 70.00	\$ 90.00	\$ 12.50	\$ 16.25
Dentists	D	\$ 70.00	\$ 90.00	\$ 12.50	\$ 16.25
Educational	E	\$ 50.00	\$ 65.00	\$ 10.00	\$ 13.00
Government	G	\$ 50.00	\$ 65.00	\$ 10.00	\$ 13.00
Podiatrists	H	\$ 70.00	\$ 90.00	\$ 12.50	\$ 16.25
Industrial	I	\$ 70.00	\$ 90.00	\$ 12.50	\$ 16.25
Industrial Medical Health Departments	IM	\$100.00	\$130.00	\$ 17.50	\$ 22.75
Hospitals	M	\$150.00	\$195.00	\$ 22.50	\$ 29.25
Physicians	P	\$ 70.00	\$ 90.00	\$ 12.50	\$ 16.25
Industrial Radiography Services	R	\$150.00	\$195.00	\$ 22.50	\$ 29.25
Veterinarians	S	\$100.00	\$130.00	\$ 0.00	
	V	\$ 50.00	\$ 65.00	\$ 10.00	\$ 13.00
Other	Z	\$ 70.00	\$ 90.00	\$ 12.50	\$ 16.25

- (b) Annual fees for persons licensed pursuant to provisions of Section .0300 of this Chapter are as listed in the following table:

Type of Radioactive Material License	Annual Fee	
Specific license of broad scope		
-medical or academic	\$ 925.00	<u>\$1,200.00</u>
-other	\$ 325.00	<u>\$ 425.00</u>
Specific license		
-industrial radiography (with temporary subsites)	\$1,175.00	<u>\$1,525.00</u>
-industrial radiography (in plant only)	\$ 600.00	<u>\$ 780.00</u>
-manufacture or distribution	\$ 325.00	<u>\$ 425.00</u>
-medical institution other than teletherapy	\$ 275.00	<u>\$ 360.00</u>
-medical private practice	\$ 200.00	<u>\$ 260.00</u>
-medical teletherapy with one teletherapy unit and	\$ 225.00	<u>\$ 300.00</u>
-each additional teletherapy unit	\$ 50.00	<u>\$ 65.00</u>
-industrial gauges	\$ 175.00	<u>\$ 225.00</u>
-moisture-density gauges	\$ 75.00	<u>\$ 100.00</u>
-gas chromatographs	\$ 75.00	<u>\$ 100.00</u>
-educational institutions	\$ 275.00	<u>\$ 360.00</u>
-services/consultants	\$ 75.00	<u>\$ 100.00</u>
-other	\$ 125.00	<u>\$ 160.00</u>
General licenses		
-industrial gauges	\$ 75.00	<u>\$ 100.00</u>
-IN VITRO testing and others	\$ 75.00	<u>\$ 100.00</u>

- (c) Annual fees for persons licensed pursuant to provisions of Section .0900 of this Chapter are as listed in the following table:

Description of Fee	Annual Fee	
-Facility with one accelerator	\$225.00	<u>\$ 300.00</u>
- each additional accelerator	\$ 50.00	<u>\$ 65.00</u>

- (d) Annual fees for certain out-of-state persons granted permission to use sources of radiation in this state pursuant to provisions of Rules .0211 and .0345 of this Chapter are the same as that provided for in the applicable category specified in Paragraphs (a), (b), and (c) of this Rule. Only those out-of-state persons granted reciprocal recognition for the purpose of industrial radiography, portable gauge use and use that involves intentional exposures to individuals for medical purposes are subject to the payment of the prescribed fees contained in this Rule. Such fees are due when application for reciprocal recognition of certain out-of-state license or registration is made in the same manner as for a new license or registration as specified in Rule .1102.

History Note: Authority G.S. 104E-9(8); 104E-19(a);
 Eff. July 1, 1982;
 Amended Eff. August 1, 2002; July 1, 1989.

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

<u>TYPE OF RADIATION</u>	<u>Quality Factor (Q)</u>	<u>Absorbed Dose Equal to a Unit Dose Equivalent^a</u>
Alpha particles; multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

^aAbsorbed 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:

MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

	<u>Neutron Energy (MeV)</u>	<u>Quality Factor^a (Q)</u>	<u>Fluence per Unit Dose Equivalent^b (neutrons cm⁻² rem⁻¹)</u>
(thermal)	2.5 x 10 ⁻⁸	2	980 x 10 ⁶
	1 x 10 ⁻⁷	2	980 x 10 ⁶
	1 x 10 ⁻⁶	2	810 x 10 ⁶
	1 x 10 ⁻⁵	2	810 x 10 ⁶
	1 x 10 ⁻⁴	2	840 x 10 ⁶
	1 x 10 ⁻³	2	980 x 10 ⁶
	1 x 10 ⁻²	2.5	1010 x 10 ⁶
	1 x 10 ⁻¹	7.5	170 x 10 ⁶
	5 x 10 ⁻¹	11	39 x 10 ⁶
	1	11	27 x 10 ⁶
	2.5	9	29 x 10 ⁶
	5	8	23 x 10 ⁶
	7	7	24 x 10 ⁶
	10	6.5	24 x 10 ⁶
	14	7.5	17 x 10 ⁶
	20	8	16 x 10 ⁶
	40	7	14 x 10 ⁶
	60	5.5	16 x 10 ⁶
	1 x 10 ²	4	20 x 10 ⁶
	2 x 10 ²	3.5	19 x 10 ⁶
	3 x 10 ²	3.5	16 x 10 ⁶

MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

Neutron Energy (MeV)	Quality Factor ^a (Q)	Fluence per Unit Dose Equivalent ^b (neutrons cm ⁻² rem ⁻¹)
4 x 10 ²	3.5	14 x 10 ⁶

^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.

—————(106) (107) "Research and development" means:

- (a) theoretical analysis, exploration, or experimentation; or
- (b) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

—————(107) (108) "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if the burials were made in accordance with the provisions of Section .1600 of this Chapter.

—————(108) (109) "Respiratory protective device" means an apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

—————(109) (110) "Restricted area" means an area, access to which is controlled by the licensee or registrant for purposes of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

—————(110) (111) "Roentgen" (R) means the special unit of exposure. One roentgen equals 2.58 x 10⁻⁴ coulombs/kilogram of air.

—————(111) (112) "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

—————(112) (113) "Sealed source" means radioactive material that is permanently bonded, fixed or encapsulated so as to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

—————(113) (114) "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).

—————(114) (115) "Shallow-dose equivalent" (H_s), which applies to the external exposure of the skin or an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm²) averaged over an area of one square centimeter.

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

—————(116) (117) "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).

- (117) (118) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.
- (118) (119) "Source material" means:
- (a) uranium or thorium or any combination of uranium and thorium in any physical or chemical form; or
 - (b) ores which contain, by weight, 0.05 percent or more of uranium, thorium, or any combination thereof. Source material does not include special nuclear material.
- (119) (120) "Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.
- (120) (121) "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.
- (121) (122) "Special nuclear material" means:
- (a) plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the United States Nuclear Regulatory Commission, pursuant to the provisions of Section 51 of the Atomic Energy Act of 1954 (42 U.S.C. 2D11 et seq.), determines to be special nuclear material, but does not include source material; or
 - (b) any material artificially enriched by any of the foregoing but does not include source material.
- (122) (123) "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 unity. For example, the following quantities in combination would not exceed the limitations and are within the formula, as follows:
- $$\frac{175 \text{ (gram contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} \text{ is } < \text{ or } = 1$$
- (123) (124) "State" means the State of North Carolina.
- (124) (125) "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.
- (125) (126) "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.
- (126) (127) "These Rules" means Chapter 11 of this Title.

- (127) (128) "To the extent practicable" means to the extent feasible or capable of being done or carried out with reasonable effort.
- (128) (129) "Total effective dose equivalent" (TEDE) means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).
- (129) (130) "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 15A NCAC 13A .0102(a).
- (130) (131) "Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in Rule .0113 of this Section or may be determined by procedures described in Rule .0113 of this Section. All quantities of radioactive material greater than a Type A quantity are Type B.
- (131) (132) "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.
- (132) (133) "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.
- (133) (134) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant.
- (134) (135) "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).
- (135) (136) "Waste" means low-level radioactive waste as defined in G.S. 104E-5(9a) and includes 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.
- (136) (137) "Waste, Class A" is defined in Rule .1650 of this Chapter.
- (137) (138) "Waste, Class B" is defined in Rule .1650 of this Chapter.
- (138) (139) "Waste, Class C" is defined in Rule .1650 of this Chapter.
- (139) (140) "Week" means seven consecutive days starting on Sunday.
- (140) (141) "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

<u>Organ or Tissue</u>	<u>w_T</u>
Gonads	0.25
Breast	0.15
Red Bone Marrow	0.12
Lung	0.12
Thyroid	0.03
Bone Surfaces	0.03
Remainder	0.30 ^a
Whole Body	1.00 ^b

^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.

- (141) (142) "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.
- (142) (143) "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.
- (143) (144) "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 1.3×10^5 MeV of potential alpha particle energy.
- (144) (145) "Working level month" (WLM) means an exposure to one working level for 170 hours.
- (145) (146) "Written directive" means an order in writing for a specific patient, 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 following information:
- (a) for the diagnostic administration of a radiopharmaceutical:
 - (i) if greater than 30 microcuries of sodium iodide I-125 or I-131, the dosage to be administered in accordance with the diagnostic clinical procedures manual; or
 - (ii) if not subject to Sub-item (a)(i) of this Item, the type of study to be performed in accordance with the diagnostic clinical procedures manual;
 - (b) for the therapeutic administration of a radiopharmaceutical:
 - (i) radiopharmaceutical;
 - (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) overall treatment period;
 - (d) for high-dose-rate remote afterloading brachytherapy:
 - (i) radioisotope;
 - (ii) treatment site; and
 - (iii) total dose;
 - (e) for all other brachytherapy:
 - (i) prior to implantation:
 - (A) radioisotope;
 - (B) number of sources to be implanted; and
 - (C) source strengths in millicuries; and
 - (ii) after implantation but prior to completion of the procedure:
 - (A) radioisotope;
 - (B) treatment site; and
 - (C) either:
 - (I) total source strength and exposure time; or
 - (II) total dose;
 - (f) for gamma stereotactic radiosurgery:
 - (i) target coordinates;
 - (ii) collimator size;
 - (iii) plug pattern; and
 - (iv) total dose.
- (146) (147) "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: 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);
Eff. February 1, 1980;
Amended Eff. November 1, 1989; June 1, 1989; October 1, 1984;
Transferred and Recodified from 10 NCAC 3G .2204 Eff. January 4, 1990;
Amended Eff. August 1, 2002; April 1, 1999; August 1, 1998; May 1, 1995; January 1, 1994;
May 1, 1992.

15A NCAC 11 .0111 is proposed to be amended as follows:

.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 Division of Radiation Protection, ~~3825 Barrett Drive, 1645 Mail Service Center~~, Raleigh, North Carolina ~~27609-7221~~ 27699-1645 or delivered to the agency at its office located at ~~the same address: 3825 Barrett Drive, Raleigh, North Carolina 27609-7221.~~
- (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) 571-4141 from 8:00 a.m. to 5:30 p.m. on workdays.

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

15A NCAC 11 .0117 is proposed to be amended as follows:

.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) 10 CFR Part 21, 10 CFR Part 30.1, 30.10, 10 CFR Part 31, 10 CFR Part 32, 10 CFR Part 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, 35.960, 35.970, 35.971, 35.972, 10 CFR Part 36, 10 CFR Part 40 and 10 CFR Part 50;
 - (3) 10 CFR Part 61, 10 CFR Part 70, 10 CFR Part 71, 10 CFR Part 73, 10 CFR Part 110, 10 CFR Part 140 and 10 CFR Part 150;
 - (4) 21 CFR Part 1010, 21 CFR Part 1020 and 21 CFR Part 1040;
 - (5) 39 CFR Part 14 and 39 CFR Part 15;
 - (6) Postal Service Manual (Domestic Mail Manual) Section 124.3 [incorporated by reference in 39 CFR Section 111.11];
 - (7) 40 CFR Part 261;
 - (8) 49 CFR Parts 100-189;
 - (9) "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;
 - (10) "Standards and Specifications for Geodetic Control Networks (September 1984);
 - (11) "Geometric Geodetic Survey Accuracy Standards and Specifications for Geodetic Surveys Using GPS Relative Positioning Techniques";
 - (12) "Reference Man: Anatomical, Physiological and Metabolic Characteristics" (ICRP Publication No. 23) of the International Commission on Radiological Protection;
 - (13) "10 CFR, Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 FR 7540"; and
 - (14) American National Standard N432-1980 "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 Department of Environment and Natural Resources, Division of Radiation Protection 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 Division of Radiation Protection;
 - (2) Twenty-five dollars (\$25.00) for the regulations listed in Subparagraph (a)(2) of this Rule in a volume containing 10 CFR Parts 0-50;
 - (3) Eighteen dollars (\$18.00) for the regulations listed in Subparagraph (a)(3) of this Rule in a volume containing 10 CFR Parts 51-199;
 - (4) Eighteen dollars (\$18.00) for the regulations listed in Subparagraph (a)(4) of this Rule in a volume containing 21 CFR Parts 800-1299;
 - (5) Sixteen dollars (\$16.00) 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;
 - (7) Thirty-one dollars (\$31.00) 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) Twenty-three dollars (\$23.00) for a volume containing 49 CFR Parts 100-177; and
 - (B) Seventeen dollars (\$17.00) 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 Division of Radiation Protection;
 - (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) One hundred and five dollars (\$105.00) 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 Division of Radiation Protection; and
 - (14) Thirty-eight dollars plus five dollars shipping and handling (\$43.00) for the American National Standard N432-1980 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-25(a) and (b).

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-15(a); 150B-21.6;

Eff. June 1, 1993;

Amended Eff. August 1, 2002; April 1, 1999; August 1, 1998; May 1, 1995.

15A NCAC 11 .0320 is proposed to be amended as follows:

.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 will 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 extensive experience in the proposed use, the handling and administration of radioisotopes, and where applicable, the clinical management of radioactive patients; and
 - (5) the physician(s) shall furnish 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.
- (b) The agency will 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.
- (c) The agency will approve an application by an individual physician or group of physicians for a specific license to receive, possess, or use radioactive materials covered under Rule .0321 of this Section if:
- (1) the applicant has appointed a medical isotopes committee of at least three members to evaluate all proposals for diagnostic or therapeutic use of radioisotopes within the facility; and
 - (2) membership of the committee includes an authorized user from each department where radioactive material is used, a representative of the institution's management and a person trained in radiation safety.

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

15A NCAC 11 .0321 is proposed to be amended as follows:

.0321 SPECIFIC LICENSES: GROUPS OF DIAGNOSTIC USES

- (a) An application for a specific license pursuant to Rule .0318 of this Section for any diagnostic or therapeutic use of radioactive material specified in groups established in Paragraph (b) of this Rule shall be approved for all of the diagnostic or therapeutic uses within the group which include the use specified in the application 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 specified in the appropriate group;
 - (3) the physicians designated in the application as individual users, have clinical experience in the types of uses included in the group or groups incorporated by reference in 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 radioactive material appropriate to their participation in the uses included in the group or groups incorporated by reference in Rule .0117(a)(2) of this Chapter;
 - (5) the applicant has detailed radiation safety operating procedures for handling and disposal of the radioactive material involved in the uses included in the group or groups that provide protection to the workers, the public and the environment from radiation exposure and radioactive contamination.
- (b) The groups of diagnostic and therapeutic radiopharmaceutical uses are established as follows:
- (1) Group I includes radiopharmaceuticals for which a New Drug application has been approved by the U.S. Food and Drug Administration for diagnostic studies involving measurement of uptake,