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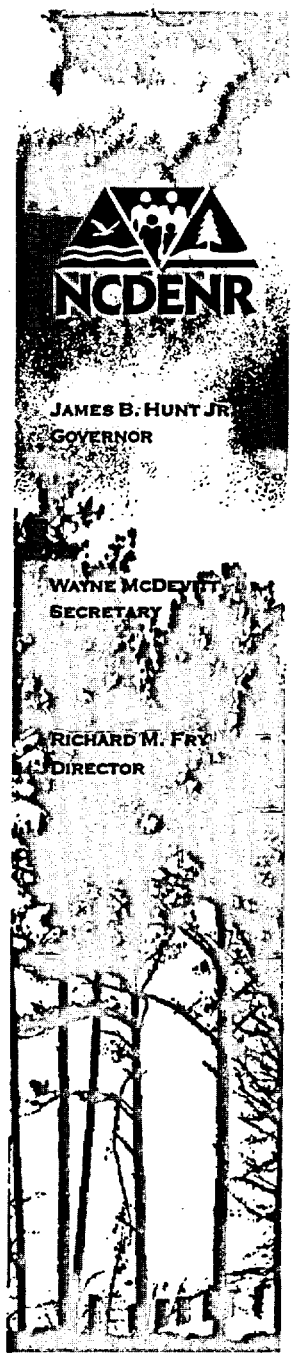

NORTH CAROLINA DEPARTMENT OF
ENVIRONMENT AND NATURAL RESOURCES
DIVISION OF RADIATION PROTECTION

November 5, 1999

Tom O'Brien
Office of State Programs
U.S. NRC
Washington, DC 20555-0001

Dear Mr. O'Brien

As requested in SP-99-074 "Request for Technical Information," attached are copies of North Carolina's definitions from our statutes and regulations and a written statement on our radiological criteria for unrestricted release.

Also enclosed is the information requested on release of solid materials.

Should you have any questions concerning the enclosed materials, please feel free to contact me or Robin Haden, Chief, Radioactive Materials Section of this Division.

Sincerely,

RM Fry

Richard M. Fry, CHP

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OSP

SP-A-4
SP-AG-21

3825 BARRETT DR. RALEIGH, NORTH CAROLINA 27609-7221
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FROM North Carolina General Statutes - Chapter 104-E

§ 104E-5. Definitions.

Unless a different meaning is required by the context, the following terms as used in this Chapter shall have the meanings hereinafter respectively ascribed to them:

(1) "Agreement materials" means those materials licensed by the State under agreement with the United States Nuclear Regulatory Commission and which include by-product, source or special nuclear materials in a quantity not sufficient to form a critical mass, as defined by the Atomic Energy Act of 1954 as amended.

(2) "Agreement state" means any state which has consummated an agreement with the United States Nuclear Regulatory Commission under the authority of section 274 of the Atomic Energy Act of 1954 as amended, as authorized by compatible state legislation providing for acceptance by that state of licensing authority for agreement materials and the discontinuance of such licensing activities by the United States Nuclear Regulatory Commission.

(3) "Atomic energy" means all forms of energy released in the course of nuclear fission or nuclear fusion or other atomic transformations.

(4) "By-product 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.

(5) "Commission" means the Radiation Protection Commission.

(6) "Department" means the State Department of Environment, Health, and Natural Resources.

(7) "Emergency" means any condition existing outside the bounds of nuclear operating sites owned or licensed by a federal agency, and further any condition existing within or outside of the jurisdictional confines of a facility licensed by the Department and arising from the presence of by-product material, source material, special nuclear materials, or other radioactive materials, which is endangering or could reasonably be expected to endanger the health and safety of the public, or to contaminate the environment.

(7a) "Engineered barrier" means a man-made structure or device that is intended to improve a disposal facility's ability to meet (i) the performance objectives of Subpart C, Title 10, Code of Federal Regulations Part 61 in effect on 1 January 1987, (ii) other requirements set out in G.S. 104E-25, and (iii) requirements of rules adopted by the Commission under this Chapter.

(8) "General license" means a license effective pursuant to regulations promulgated under the provisions of this Chapter without the filing of an

application to transfer, acquire, own, possess, or use quantities of, or devices or equipment utilizing by-product, source, special nuclear materials, or other radioactive materials occurring naturally or produced artificially.

(9) "Ionizing radiation" means gamma rays and x-rays, alpha and beta particles, high speed electrons, protons, neutrons, and other nuclear particles; but not sound or radio waves, or visible, infrared, or ultraviolet light.

(9a) "Low-level radioactive waste" means low-level radioactive waste as defined in the Low-Level Radioactive Waste Policy Amendments Act of 1985, Pub. L. 99-240, 99 Stat. 1842, 42 U.S.C. 2021b et seq. and other waste, including waste containing naturally occurring and accelerator produced radioactive material, which is not regulated by the United States Nuclear Regulatory Commission or other agency of the federal government and which is determined to be low-level radioactive waste by the North Carolina Radiation Protection Commission.

(9b) "Low-level radioactive waste facility" means a facility for the storage, collection, processing, treatment, recycling, recovery, or disposal of low-level radioactive waste.

(9c) "Low-level radioactive waste disposal facility" means any low-level radioactive waste facility or any portion of such facility, including land, buildings, and equipment, which is used or intended to be used for the disposal of low-level radioactive waste on or in land in accordance with rules promulgated under this Chapter.

(10) "Nonionizing radiation" means radiation in any portion of the electromagnetic spectrum not defined as ionizing radiation, including, but not limited to, such sources as laser, maser or microwave devices.

(11) "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 the foregoing, other than the United States Nuclear Regulatory Commission, or any successor thereto, and other than federal government agencies licensed by the United States Nuclear Regulatory Commission, or any successor thereto.

(12) "Radiation" means gamma rays and x-rays, alpha and beta particles, high speed electrons, protons, neutrons, and other nuclear particles, and electromagnetic radiation consisting of associated and interacting electric and magnetic waves including those with frequencies between three times 10 to the eighth power cycles per second and three times 10 to the twenty-

fourth power cycles per second and wavelengths between one times 10 to the minus fourteenth power centimeters and 100 centimeters.

(13) "Radiation machine" means any device designed to produce or which produces radiation or nuclear particles when the associated control devices of the machine are operated.

(14) "Radioactive material" means any solid, liquid, or gas which emits ionizing radiation spontaneously.

(14a) "Shallow land burial" means disposal of low-level radioactive waste in subsurface trenches without the additional confinement of the waste as described in G.S. 104E-25.

(14b) "Secretary" means the Secretary of Environment, Health, and Natural Resources.

(15) "Source material" means (i) uranium, thorium, or any other material which the Department declares to be source material after the United States Nuclear Regulatory Commission, or any successor thereto has determined the material to be such; or (ii) ores containing one or more of the foregoing materials, in such concentration as the Department declares to be source material after the United States Nuclear Regulatory Commission, or any successor thereto, has determined the material in such concentration to be source material.

(16) "Special nuclear material" means (i) plutonium, uranium 233, uranium 235, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Department declares to be special nuclear material after the United States Nuclear Regulatory Commission, or any successor thereto, has determined the material to be such, but does not include source material; or (ii) any material artificially enriched by any of the foregoing, but does not include source material.

(17) "Specific license" means a license, issued after application, to use, manufacture, produce, transfer, receive, acquire, own or process quantities of, or devices or equipment utilizing by-product, source, special nuclear materials, or other radioactive materials occurring naturally or produced artificially. Nothing in this Chapter shall require the licensing of individual natural persons involved in the use of radiation machines or radioactive materials for medical diagnosis or treatment.

(18) Repealed by Session Laws 1987, c. 850, s. 3.

§ 104E-6. Designation of State radiation protection agency.

The Department is hereby designated the State agency to administer a statewide radiation protection program consistent with the provisions of this Chapter.(1975, c. 718, s. 1.)

§ 104E-6.1. Conveyance of land used for low-level radioactive waste disposal facility to State.

CHAPTER 11 - RADIATION PROTECTION

SECTION .0100 - GENERAL PROVISIONS

.0101 SCOPE

(a) Except as otherwise specifically provided these Rules apply to all persons who receive, possess, use, transfer, own or acquire any source of radiation within the State of North Carolina.

(b) Nothing in these Rules shall apply to any person to the extent any person is subject to regulation by the United States Nuclear Regulatory Commission.

(c) Regulation by the State of North Carolina of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the "Agreement Between the United States Atomic Energy Commission and the State of North Carolina for Discontinuance of Certain Commission Regulatory and Responsibility within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended" under provisions of Public Law 86-373, as amended, and 10 CFR Part 150.

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

.0102 COMPLIANCE WITH LAWS

Nothing in these Rules shall relieve any person of responsibility for complying with other pertinent North Carolina laws and rules.

History Note: Statutory Authority G.S. 104E-7;
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2202
Eff. January 4, 1990;
Amended Eff. May 1, 1993.

.0103 INTENTIONAL EXPOSURE

Nothing in Sections .0100 to .1000 of this Chapter shall be interpreted as limiting the intentional exposure of patients to radiation for the purposes of medical diagnosis and therapy.

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

.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, Health, and Natural Resources.

(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 a year by the reference man that would result in a committed 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 at intervals not to exceed 12 consecutive months.

(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.

"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

Class	Clearance half-time
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 ($H_{E,50} = \Sigma w_T H_{T,50}$).

(24) "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.

(25) "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.

(26) "Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

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

(28) "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).

(29) "Department" means the North Carolina Department of Environment, Health, and Natural Resources.

(30) "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.

(31) "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).

(32) "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).

(33) "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.

(34) "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.

(35) "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).

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

(37) "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.

(38) "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 ($H_E = \Sigma w_T H_T$).

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

(40) "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.

(41) "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.

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

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

(44) "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

(45) "Extremity" means hand, elbow, arm, arm below the elbow, foot, knee, or leg below the knee.

(46) "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/cm^2).

(47) "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.

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

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

(50) "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.

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

(52) "Individual" means any human being.

(53) "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.

(54) "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 dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

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

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

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

(58) "License", except where otherwise specified, means a license issued pursuant to Section .0300 of this Chapter.
(59) "Licensee" means any person who is licensed by the agency pursuant to Section .0300 of this Chapter.
(60) "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).
(61) "Limits" or "dose limits" means the permissible upper bounds of radiation doses.
(62) "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.
(63) "Lung class" (see "Class" as defined in this Rule).
(64) "Member of the public" means an individual in a controlled or unrestricted area; however, an individual is not a member of the public during any period in which the individual receives an occupational dose.
(65) "Minor" means an individual less than 18 years of age.
(66) "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.

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

(68) "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.

(69) "Natural radioactivity" means radioactivity of naturally occurring nuclides.

(70) "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).

(71) "NRC" means the United States Nuclear Regulatory Commission or its duly authorized representatives.

(72) "Occupational dose" means the dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to radiation or licensed radioactive material, 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 voluntary participation in medical research programs, or as a member of the general public.

(73) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged

particles.

(74) "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.

(75) "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.

(76) "Pharmacist" means an individual licensed by this state to compound and dispense drugs, prescriptions and poisons.

(77) "Physician" means an individual currently licensed to practice medicine in this state.

(78) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.

(79) "Prescribed dosage" means the quantity of radiopharmaceutical activity documented in a written directive by an authorized user.

(80) "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.

(81) "Public dose" means the dose received by a member of the public from exposure to radiation and to radioactive material released by a licensee or registrant, or to another source of radiation either within a licensee's or registrant's controlled area or in unrestricted areas. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, or from voluntary participation in medical research programs.

(82) "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.

(83) "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.

(84) "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).

(85) "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.

(86) "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.

(87) "Radiation dose" means dose.

(88) "Radiation machine" means any device capable of producing radiation except devices which produce radiation only from radioactive material.

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

(90) "Radioactive material" means any material, solid, liquid, or gas, which emits radiation spontaneously.

(91) "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.

(92) "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.

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

(94) "Radiobioassay" means bioassay.

(95) "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 (136)(a)(i) and (136)(b)-(f) of this Rule;

(b) a radiopharmaceutical or radiation from a licensed source where a written directive is required by Sub-items (136)(a)(i) and (136)(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.

(96) "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.

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

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

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

(100) "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

TYPE OF RADIATION	Quality Factor Q	Absorbed Dose Equal to a Unit Dose Equivalent[a]
X-, gamma, or beta radiation	1	1
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

[a]Absorbed dose in rad equal to one rem or the absorbed dose in gray equal to one sievert.

If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, one rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of the rules of this Chapter, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from the following table to convert a measured tissue dose in rads to dose equivalent in rems:

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})

(thermal)	2.5×10^{-8}	2	980×10^{6}
	1×10^{-7}	2	980×10^{6}
	1×10^{-6}	2	810×10^{6}
	1×10^{-5}	2	810×10^{6}
	1×10^{-4}	2	840×10^{6}
	1×10^{-3}	2	980×10^{6}
	1×10^{-2}	2.5	1010×10^{6}
	1×10^{-1}	7.5	170×10^{6}
	5×10^{-1}	11	39×10^{6}
	1	11	27×10^{6}
	2.5	9	29×10^{6}
	5	8	23×10^{6}
	7	7	24×10^{6}
	10	6.5	24×10^{6}
	14	7.5	17×10^{6}
	20	8	16×10^{6}
	40	7	14×10^{6}
	60	5.5	16×10^{6}
	1×10^{2}	4	20×10^{6}
	2×10^{2}	3.5	19×10^{6}
	3×10^{2}	3.5	16×10^{6}
	4×10^{2}	3.5	14×10^{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.

(101) "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.

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

(103) "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.

(104) "Roentgen" (R) means the special unit of exposure. One roentgen equals 2.58×10^{-4} coulombs/kilogram of air.

(105) "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.

(106) "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.

(107) "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/cm^2) averaged over an area of one square centimeter.

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

(109) "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).

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

(111) "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.

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

(113) "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.

(114) "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.

(115) "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:

$$\frac{175 \text{ (gram contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} \text{ is } < \text{ or} = 1$$

(116) "State" means the State of North Carolina.

(117) "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.

(118) "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.

(119) "These Rules" means Chapter 11 of this Title.

(120) "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).

(121) "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 .0002(a).

(122) "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.

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

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

(125) "Very high radiation area" means an area, accessible to individuals, in which radiation levels 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).

(126) "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.

(127) "Waste, Class A" is defined in Rule .1650 of this Chapter.

(128) "Waste, Class B" is defined in Rule .1650 of this Chapter.

(129) "Waste, Class C" is defined in Rule .1650 of this Chapter.

(130) "Week" means seven consecutive days starting on Sunday.

(131) "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

Organ or Tissue	W_T
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. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

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

(133) "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.

(134) "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.

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

(136) "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.

(137) "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;
Statutory 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. May 1, 1995; January 1, 1994; May 1, 1992.

.0105 OTHER DEFINITIONS

Definitions of certain other words and phrases as used in these Rules are set forth in Sections .0500, .0600, .0800, .1200, .1300, .1400, and .1500 of this Chapter.

History Note: Statutory Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Transferred and Recodified from 10 NCAC 3G .2205 Eff. January 4, 1990;
Amended Eff. May 1, 1993.

.0106 EXEMPTIONS

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

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

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

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

system will make use of selected processes and structures, such as compaction, solidification, packaging in high-integrity containers, placement of wastes, use of concrete for walls or fill, special trench covers, drainage systems, or other devices. The facility design objectives are to minimize contact of water with wastes, facilitate detection of water and contamination, retard release of radioactive materials, suppress the migration of wastes in the geologic medium, and accommodate timely recovery of wastes if necessary. Account is to be taken of radiation dose limits for facility workers and the public, and efforts are to be made to reduce costs without sacrificing safety.
The concept of "reasonable assurance" is used throughout this Section. Reasonable assurance is to be understood as placing primary emphasis on protection of public health and the environment. The cost of achieving reasonable assurance will be only a secondary consideration.

(e) Persons licensed pursuant to the provisions of this Section are also subject to the rules in Sections .0100, .0300, .1000, .1100, and .1600 of this Chapter, except as provided otherwise in this Section.

History Note: Statutory Authority G.S. 104E-2; 104E-3; 104E-7; 104E-10; 104E-10.1; 104E-10.2; 104E-25; 104E-26;
Eff. December 1, 1987;
Amended Eff. January 1, 1994.

.1202 DEFINITIONS

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

(1) "Active maintenance" means any significant remedial activity needed during the period of institutional control to maintain a reasonable assurance that the performance objectives in Rules .1223 and .1224 of this Section are met. Such active maintenance includes ongoing activities such as the pumping and treatment of water from a disposal unit or one-time measures such as replacement of a disposal unit cover. Active maintenance does not include custodial activities such as repair of fencing, repair or replacement of monitoring equipment, revegetation, minor additions to soil cover, minor repair of disposal unit covers, and general disposal site upkeep such as mowing grass.

(2) "Buffer zone" is a portion of the disposal site that is controlled by the licensee and that lies under the disposal units and between the disposal units and the boundary of the site.

(3) "Chelating agent" means amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxy-carboxylic acids, and polycarboxylic acids (e.g., citric acid, carbolic acid, and gluconic acid).

(4) "Commencement of construction" means clearing of land, excavation, or other substantial action that would adversely affect the environment of a land disposal facility. The term does not mean disposal site exploration, necessary roads for disposal site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the disposal site or the protection of

environmental values.

(5) "Custodial agency" means the North Carolina Low-Level Radioactive Waste Management Authority.

(6) "Disposal" means the isolation of waste from the biosphere inhabited by man and his food chains by emplacement in a land disposal facility.

(7) "Disposal site" means that portion of a land disposal facility which is used for disposal of waste. It consists of disposal units and a buffer zone.

(8) "Disposal system" means the components relied on to ensure that the land disposal facility meets the performance objectives and other requirements of this Section. These components include the site and its characteristics, the facility and disposal unit design, and engineered barriers therein, the waste, facility operations and closure, intruder barriers and institutional control.

(9) "Disposal unit" means a discrete portion of the disposal site into which waste is placed for disposal. For near-surface disposal, the disposal unit is usually a trench.

(10) "Engineered barrier" means engineered barrier as defined in G.S. 104E-5(7a).

(11) "Explosive material" means any chemical compound, mixture, or device, which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

(12) "Government agency" means any executive department, commission, independent establishment, or corporation, wholly or partly owned by the United States of America or the State of North Carolina and which is an instrumentality of the United States or the State of North Carolina; or any board, bureau, department, division, service, office, officer, authority, administration, or other establishment in the executive branch of the government.

(13) "Hazardous waste" means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

(14) "Hydrogeologic unit" means any soil or rock unit or zone which by virtue of its porosity or permeability, or lack thereof, has a distinct influence on the storage or movement of groundwater.

(15) "Inadvertent intruder" means a person who might occupy the disposal site after closure and engage in normal activities, such as agriculture, dwelling construction, or other pursuits in which the person might be unknowingly exposed to radiation from the waste.

(16) "Intruder barrier" means a sufficient depth of cover over the waste that inhibits contact with waste and helps to ensure that radiation exposures to an inadvertent intruder will meet the performance objectives set forth in this Section, or engineered structures that provide equivalent protection to the inadvertent intruder.

(17) "Institutional control" means control of the site after the site is closed and stabilized and responsibility for all disposed waste and site maintenance is assumed by the custodial agency.

(18) "Land disposal facility" means low-level radioactive waste

disposal facility as defined in G.S. 104E-5(9c).

(19) "Low-level radioactive waste" means low-level radioactive waste as defined in G.S. 104E-5(9a) and includes 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, and is suitable for land disposal under the provisions in this Section.

(20) "Mixed waste" means waste that satisfies the definition of low-level radioactive waste in Item (19) of this Rule and contains hazardous waste that either:

(a) is listed as a hazardous waste in Subpart D of 40 CFR Part 261 or

(b) causes the low-level radioactive waste to exhibit any of the hazardous waste characteristics identified in Subpart C of 40 CFR Part 261.

(21) "Monitoring" means observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site.

(22) "Near-surface disposal facility" means a land disposal facility in which waste is disposed of within approximately the upper 30 meters of the earth's surface.

(23) "Reconnaissance level information" is any information or analysis that can be retrieved or generated without the performance of new comprehensive site-specific investigations. Reconnaissance level information includes but is not limited to drilling records required by state agencies, other Divisions of this Department, and other relevant published scientific literature.

(24) "Retrieval" means a remedial action for removal of Class B and C waste from a disposal unit.

(25) "Shallow land burial" means shallow land burial as defined in G.S. 104E-5(14a).

(26) "Site closure and stabilization" means those actions that are taken upon completion of operations that prepare the disposal site for custodial care and that assure that the disposal site will remain stable and will not need ongoing active maintenance.

(27) "State" means the State of North Carolina.

(28) "Surveillance" means monitoring and observation of the disposal site for purposes of visual detection of need for maintenance, custodial care, evidence of intrusion, and compliance with other license and regulatory requirements.

(29) "Waste" means low-level radioactive waste that is acceptable for disposal in a land disposal facility. For the purpose of this Section, the words "waste" and "low-level radioactive waste" have the same meaning.

History Note: Statutory Authority G.S. 104E-5; 104E-7; 104E-10; 104E-25;
Eff. December 1, 1987;
Amended Eff. May 1, 1993; May 1, 1992; June 1, 1989.

.1203 LICENSE REQUIRED

(a) No person may receive, possess, and dispose of waste from other persons at a land disposal facility unless authorized by a license issued by the agency pursuant to the rules in this

.1502 DEFINITIONS

(a) As used in this Section, the following definitions shall apply.

(1) "Carrier" means any person transporting radioactive waste in North Carolina for the purpose of disposal at a low-level radioactive waste disposal facility located in North Carolina.

(2) "Collector" means any person who collects or consolidates prepared packages of low-level radioactive waste from another site access licensee and arranges for the transportation of such waste to a disposal facility located in North Carolina.

(3) "Generator" means any person who produces low-level radioactive waste which will be transferred for disposal at a low-level radioactive waste disposal facility located in North Carolina, including indirect transfer through collectors or processors.

(4) "Low-level radioactive waste" means low-level radioactive waste as defined in Rule .1202 of this Chapter.

(5) "Low-Level radioactive waste disposal facility" means any facility operated pursuant to G.S. 104G for the purpose of low-level radioactive waste disposal and licensed pursuant to Section .1200 of this Chapter.

(6) "Manifest" means the document used for identifying the quantity, composition, origin and destination of low-level radioactive waste during its transport to a disposal facility.

(7) "Processor" means any person who receives low-level radioactive waste or radioactively contaminated material from another site access licensee for the purpose of repackaging or treatment, including, but not limited to, compaction, incineration, decontamination or resource recovery, prior to transfer to a disposal facility located in North Carolina.

(8) "Radioactive material license" means any license issued by the agency, an agreement state or the U. S. Nuclear Regulatory Commission which authorizes activities which may generate waste.

(9) "Shipment" means the total low-level radioactive waste transported in a single conveyance as defined in 49 CFR § 173.403.

(10) "Shipper" means any person who holds a valid site access license and prepares low-level radioactive waste for transport to a low-level radioactive waste disposal facility located in North Carolina.

(11) "Site access license" means a license issued pursuant to the rules in this Section.

(12) "Solidifying" means that process by which liquid wastes or wastes containing liquids are converted into an acceptable stable form as defined in Rule .1651 of this Chapter.

(13) "Southeast Compact" means the Southeast Interstate Low-Level Radioactive Waste Management Compact as set out in G.S. 104F.

(14) "Stabilizing" means that process by which radioactive wastes are prepared to meet the stability requirements as defined in Rule .1651 of this Chapter.

(15) "Transport" means the movement of low-level radioactive waste in North Carolina for the purpose of disposal at a low-level radioactive waste disposal facility located in North Carolina.

(16) "Waste" means "low-level radioactive waste".

(b) Definitions of other words and phrases used in this Section are set forth in other sections of this Chapter.

History Note: Statutory Authority G.S. 104E-5; 104E-7; 104E-10.3; 104E-27;
Eff. January 1, 1995.

.1503 LICENSE REQUIRED

(a) No person shall ship or transfer waste to a low-level radioactive waste disposal facility located in North Carolina, except as authorized by a valid site access license issued, prior to shipment or transfer, pursuant to the rules in this Section.

(b) A separate site access license is required for each generator, collector and processor facility from which waste, which will be transferred to a low-level radioactive waste disposal facility located in North Carolina, is shipped.

(c) The agency shall not issue any site access license authorizing disposal of waste generated outside the Southeast Compact region unless:

(1) the U.S. Nuclear Regulatory Commission has granted emergency access as authorized under the Low-Level Radioactive Waste Policy Amendments Act of 1985, provided that access shall be limited to that granted by the U.S. Nuclear Regulatory Commission and complies with Rule .1517 of this Section; or

(2) access has been granted by the Southeast Compact Commission in accordance with provisions of G.S. 104F and complies with all rules of this Section.

History Note: Statutory Authority G.S. 104E-10.3; 104E-27;
Eff. January 1, 1995.

.1504 APPLICATION FOR SITE ACCESS LICENSE: GENERAL REQUIREMENTS

(a) Each applicant for a site access license shall file a completed agency application form. The completed application shall include the following information:

(1) name, address, telephone number, and description of the business of the applicant;

(2) a list of radioactive material licenses issued to the applicant along with the name of the regulatory agency that issued each license;

(3) name, address and telephone number of the facility for which a site access license is requested;

(4) name and telephone number of the person who is responsible for the applicant's waste management plan;

(5) organization chart which depicts the relationship among senior level management, managers of waste generating and waste management activities, and the person identified in Subparagraph (a)(4) of this Rule;

(6) general transportation routing information, within the State of North Carolina, of waste shipments, including but not limited to waste transported for processing and waste transported for disposal at the North Carolina

Radiological Criteria for Unrestricted Release of Solid Material

For guidance, the NRC criteria as stated in Reg Guide 1.86 is used to determine when solid material may be released for unrestricted use. Our goal is to release only those materials and facilities that have no activity that is distinguishable above background. When laboratory data is available the NRCP test between the differences in two means is used, i.e. background mean vs sample mean. For other monitoring instruments, our standard has been that material can be released if the activity is not distinguishable above background. In practicality, this is that the readings are not above twice background. This guidance is applied on a case-by-case basis with professional health physics judgement that the amount of radioactivity involved is sufficiently low as to not be of any public health and safety or environmental concern. No specific criteria exist to differentiate between surficial and volumetric contamination.

Information Requested on Release of Solid Materials

1. Our radiological criteria for the unrestricted release of solid materials are based on Reg Guide 1.86 as applicable on a case-by-case basis, and they apply to all radioactive materials we regulate.

2. These criteria are used as guidance and are adapted as need to deal with specific situations based on the professional judgement of our health physicists.

3. We use the MARSSIM document again as guidance that will be adapted to fit the circumstances involved.

4. We select the type of instrumentation with which to survey based on the materials involved and the type of radioactivity expected. Where possible laboratory type counting equipment is preferred; however, sensitive portable monitoring equipment is also acceptable. The actual MDL's involved are dependent on the type of equipment used and is dictated by the circumstances present in the case-by-case determination.

5. The determination of no activity present is normally based on a test of the laboratory data that determines that there is no difference between the background mean and the sample mean. When portable survey instruments are used the test is a determination that the levels present are not distinguishable from background. That test is most normally a determination that radiation levels are not present that give any indications above twice background on a portable rate meter.

6. To my knowledge, North Carolina has not licensed anyone with a volumetric release authorization. In general our criteria have been to release materials that have activity that cannot be distinguished from background levels of radioactivity. When we have done pathway analyses, we have considered exposures of one millirem per year or less as trivial and sufficiently protective of public health and safety and the environment.