

**NORTH CAROLINA REGULATIONS
FOR PROTECTION AGAINST RADIATION**

ADOPTED BY

THE NORTH CAROLINA RADIATION PROTECTION COMMISSION

15A NCAC 11

**N.C. DEPARTMENT OF ENVIRONMENT
AND NATURAL RESOURCES
DIVISION OF RADIATION PROTECTION
RALEIGH, NORTH CAROLINA**

EFFECTIVE APRIL 1, 1999

INTRODUCTION

The North Carolina Radiation Protection Act (G.S. 104E) established the North Carolina Radiation Protection Commission with the power to "... adopt, promulgate, amend and repeal such rules, regulations and standards relating to the manufacture, production, transportation, use, handling, servicing, installation, storage, sale, lease, or other disposition of radioactive materials and machines ..." and to "... provide by rule and regulation for an electronic product safety program to protect the public health and safety, which program may authorize regulation and inspection of sources of non-ionizing radiation throughout the state.

The North Carolina Radiation Protection Commission adopted new state rules for protection against radiation at its meeting on November 30, 1979. These Rules became effective February 1, 1980. These basic rules have been subsequently amended on separate occasions and these amendments are incorporated into the rules, publication dated September 1997.

With the passage of House Bill 480 by the North Carolina 1989 General Assembly, the Radiation Protection Section was renamed as the Division of Radiation Protection and became part of the Department of Environment, Health, and Natural Resources. Similarly, the North Carolina Radiation Protection Commission also became a part of the new department. These changes were made retroactive to July 1, 1989. The Division of Radiation Protection's rules were originally adopted and codified in 10 NCAC 3G. With reorganization and the Division of Radiation Protection becoming a part of the new department, the rules were recodified in 15A NCAC 11 effective January 1, 1990.

Effective July 1, 1997, the N.C. Department of Environment, Health, and Natural Resources was reorganized. The Division of Radiation Protection is now a part of the N.C. Department of Environment and Natural Resources.

This book includes all adoptions and amendments effective April 1, 1999.

These Rules were promulgated to protect and promote the public health and safety. All licensees and registrants of the Division of Radiation Protection, North Carolina Department of Environment and Natural Resources, should study and fully understand these Rules as they apply to their particular regulated activities.

Rules and amendments are not copyrighted and may be reproduced without prior permission; however, additional copies of the North Carolina Regulations for Protection Against Radiation are available from the Division of Radiation Protection for \$10.00 per copy.

Copies of the tanning rules may be purchased separately as follows:

Section .1400 Tanning Facilities

Containing the rules concerning facilities and equipment which employ ultraviolet and other lamps for the purpose of tanning the skin of humans.

Price \$1.00

Questions concerning radiation protection in the state of North Carolina should be directed to:

Department of Environment and Natural Resources

Division of Radiation Protection

3825 Barrett Drive

Raleigh, North Carolina 27609-7221

Phone: (919) 571-4141

FAX (919) 571-4148

Additionally, the physical location of our office is the same as our mailing address.

April 1, 1999

NORTH CAROLINA ADMINISTRATIVE CODE
TITLE 15A
DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES
DIVISION OF RADIATION PROTECTION
CHAPTER 11 - RADIATION PROTECTION

SECTION .0100 - GENERAL PROVISIONS

- .0101 SCOPE
- .0102 COMPLIANCE WITH LAWS
- .0103 INTENTIONAL EXPOSURE
- .0104 DEFINITIONS
- .0105 OTHER DEFINITIONS
- .0106 EXEMPTIONS
- .0107 INSPECTIONS
- .0108 ADDITIONAL REQUIREMENTS-VIOLATIONS REPEALED 11/01/89
- .0109 IMPOUNDING
- .0110 PROHIBITED USES
- .0111 COMMUNICATIONS
- .0112 DESIGNATION OF AUTHORIZED REPRESENTATIVE OF THE AGENCY
- .0113 CLASSIFICATION OF RADIOACTIVE MATERIAL
- .0114 TESTS FOR SPECIAL FORM
- .0115 RECORDS
- .0116 TESTS
- .0117 INCORPORATION BY REFERENCE
- .0118 OPTIONAL EARLY COMPLIANCE WITH SECTION .1600

SECTION .0200 -REGISTRATION OF RADIATION MACHINE FACILITIES AND SERVICES

- .0201 PURPOSE AND SCOPE
- .0202 EXEMPTIONS
- .0203 APPLICATION: REGISTRATION: RADIATION MACHINES: FACILITIES
- .0204 PROHIBITED SERVICES AND INSTALLATION
- .0205 APPLICATION FOR REGISTRATION OF SERVICES
- .0206 REPORTS OF INSTALLATION
- .0207 ISSUANCE OF NOTICE OF REGISTRATION
- .0208 PRIOR NOTIFICATION OF TRANSFER
- .0209 REPORT OF CHANGES
- .0210 OTHER PROHIBITED ACTIVITIES
- .0211 OUT-OF-STATE RADIATION MACHINES
- .0212 MODIFICATIONS: REVOCATION: TERMINATION OF REGISTRANTS
- .0213 ADDITIONAL REQUIREMENTS: REGISTERED SERVICES
- .0214 TRAINING AND EDUCATIONAL REQUIREMENTS FOR EQUIPMENT SERVICES

SECTION .0300 - LICENSING OF RADIOACTIVE MATERIAL

- .0301 PURPOSE AND SCOPE
- .0302 EXEMPTIONS FOR SOURCE MATERIAL
- .0303 EXEMPT CONCENTRATIONS: OTHER THAN SOURCE MATERIAL
- .0304 EXEMPT QUANTITIES: OTHER THAN SOURCE MATERIAL

.0305 EXEMPT ITEM CONTAINING OTHER THAN SOURCE MATERIAL
.0306 TYPES OF LICENSES: GENERAL AND SPECIFIC
.0307 GENERAL LICENSES: SOURCE MATERIAL
.0308 GENERAL LICENSES: OTHER THAN SOURCE MATERIAL
.0309 GENERAL LICENSES: MEASURING GAUGING: CONTROLLING DEVICES
.0310 GENERAL LICENSES: INSTALL GENERALLY LICENSED DEVICES
.0311 GENERAL LICENSES: LUMINOUS SAFETY DEVICES
.0312 GENERAL LICENSES: CALIBRATION AND REFERENCE
.0313 OWNERSHIP OF RADIOACTIVE MATERIAL
.0314 GENERAL LICENSES: IN VITRO CLINICAL OR LABORATORY TESTING
.0315 GENERAL LICENSES: ICE DETECTION DEVICES
.0316 GENERAL LICENSES: TRANSPORTATION
.0317 SPECIFIC LICENSES: FILING APPLICATION & GENERAL REQUIREMENT
.0318 SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE
.0319 SPECIFIC LICENSES: HUMAN USE IN HOSPITALS
.0320 SPECIFIC LICENSES: HUMAN USE BY INDIVIDUAL PHYSICIANS
.0321 SPECIFIC LICENSES: GROUPS OF DIAGNOSTIC USES
.0322 SPECIFIC LICENSES: HUMAN USE OF SEALED SOURCES
.0323 SPECIFIC LICENSES: SEALED SOURCES IN INDUSTRIAL RADIOGRAPHY
.0324 SPECIFIC LICENSES: BROAD SCOPE
.0325 SPECIFIC LICENSES: PRODUCTS WITH EXEMPT CONCENTRATIONS
.0326 SPECIFIC LICENSES: EXEMPT DISTRIBUTION
.0327 SPECIFIC LICENSES: EXEMPT GAS AND AEROSOL DETECTORS
.0328 SPECIFIC LICENSES: MANUFACTURE DEVICES TO PERSONS LICENSED
.0329 SPECIFIC LICENSES: LUMINOUS SAFETY DEVICES IN AIRCRAFT
.0330 SPECIFIC LICENSES: MANUFACTURE OF CALIBRATION SOURCES
.0331 SPECIFIC LICENSES: MANUFACTURE OF IN VITRO TEST KITS
.0332 SPECIFIC LICENSES: MANUFACTURE OF ICE DETECTOR DEVICES
.0333 SPECIFIC LICENSES: MANUFACTURE OF RADIOPHARMACEUTICALS
.0334 SPECIFIC LICENSES: GENERATORS AND REAGENT KITS
.0335 SPECIFIC LICENSES: PRODUCTS CONTAINING DEPLETED URANIUM
.0336 COPIES OF APPLICABLE FEDERAL REGULATIONS (REPEALED 05/01/93)
.0337 ISSUANCE OF SPECIFIC LICENSES
.0338 SPECIFIC TERMS AND CONDITIONS OF LICENSES
.0339 EXPIRATION AND TERMINATION OF LICENSES AND DECOMMISSIONING
.0340 RENEWAL OF LICENSES
.0341 AMENDMENT OF LICENSES AT REQUEST OF LICENSEE
.0342 AGENCY ACTION ON APPLICATIONS TO RENEW OR AMEND
.0343 TRANSFER OF MATERIAL
.0344 MODIFICATION: REVOCATION: AND TERMINATION OF LICENSES
.0345 RECIPROCAL RECOGNITION OF LICENSES
.0346 PREPARATION OF RADIOACTIVE MATERIAL FOR TRANSPORT
.0347 SECURITY REQUIREMENTS (REPEALED 05/01/92)
.0348 SPECIFIC LICENSES: CERTAIN INCINERATOR FACILITIES
.0349 EXEMPTIONS: WASTE MANAGEMENT BY GENERATORS
.0350 RECORDS AND REPORTS OF MISADMINISTRATION
.0351 SPECIFIC LICENSES: MOBILE NUCLEAR MEDICINE SERVICES
.0352 EMERGENCY PLANS
.0353 FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING
.0354 METHODS OF FINANCIAL ASSURANCE FOR DECOMMISSIONING

- .0355 FIN. TESTS- PARENT COMPANY GUARANTEES: DECOMMISSIONING FUNDING
- .0356 QUALITY MANAGEMENT PROGRAM
- .0357 REPORTING REQUIREMENTS
- .0358 RELEASE OF PATIENTS CONTAINING RADIOPHARMACEUTICALS OR PERMANENT IMPLANTS
- .0359 MEASUREMENTS/DOSAGES OF UNSEALED RADIOACTIVE MATERIAL FOR MEDICAL USE
- .0360 SURVEYS OF RADIOPHARMACEUTICAL AREAS FOR CONTAMINATION AND RADIATION EXPOSURE RATE
- .0361 MEDICAL USE OF UNSEALED RADIOACTIVE MATERIAL
- .0362 DECAY-IN-STORAGE

SECTION .0400 - STANDARDS FOR PROTECTION AGAINST RADIATION

Repealed August 1, 1998

SECTION .0500 - SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHY

OPERATIONS

- .0501 PURPOSE AND SCOPE
- .0502 DEFINITIONS
- .0503 EQUIPMENT RADIATION LEVEL LIMITS
- .0504 RADIOGRAPHIC EXPOSURE DEVICES AND STORAGE CONTAINERS
- .0505 STORAGE, LABELS AND TRANSPORTATION PRECAUTIONS
- .0506 SURVEY INSTRUMENTS
- .0507 LEAK TESTING AND REPLACEMENT OF SEALED SOURCES
- .0508 QUARTERLY INVENTORY
- .0509 UTILIZATION LOGS
- .0510 LIMITATIONS
- .0511 INSPECTION AND MAINTENANCE
- .0512 PERSONNEL MONITORING
- .0513 OPERATING AND EMERGENCY PROCEDURES
- .0514 SECURITY
- .0515 RADIATION SURVEYS AND SURVEY RECORDS
- .0516 POSTING
- .0517 SUPERVISION OF RADIOGRAPHERS' ASSISTANTS
- .0518 RADIATION MACHINES
- .0519 SUBJECTS TO BE COVERED DURING INSTRUCTION OF RADIOGRAPHERS
- .0520 PERMANENT RADIOGRAPHIC INSTALLATIONS
- .0521 PERFORMANCE REQUIREMENTS FOR RADIOGRAPHY EQUIPMENT
- .0522 REPORTING REQUIREMENTS
- .0523 RECORDS OF INDUSTRIAL RADIOGRAPHY
- .0524 SPECIFIC LICENSE FOR INDUSTRIAL RADIOGRAPHY
- .0525 RADIOGRAPHER CERTIFICATION

SECTION .0600 - X-RAYS IN THE HEALING ARTS

- .0601 PURPOSE AND SCOPE
- .0602 DEFINITIONS
- .0603 GENERAL REQUIREMENTS
- .0604 GENERAL REQUIREMENTS FOR ALL DIAGNOSTIC SYSTEMS
- .0605 FLUOROSCOPIC X-RAY SYSTEMS
- .0606 SYSTEMS OTHER THAN FLUOROSCOPIC AND DENTAL INTRAORAL

- .0607 INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS
- .0608 THERAPEUTIC X-RAY INSTALLATIONS: LESS THAN ONE MeV
- .0609 X-RAY ELECTRON THERAPY INSTALLATIONS ONE MeV AND ABOVE
- .0610 VETERINARY MEDICINE RADIOGRAPHIC INSTALLATIONS

SECTION .0700 - USE OF SEALED RADIOACTIVE SOURCES IN THE HEALING ARTS

- .0701 SCOPE
- .0702 INTERSTITIAL: INTRACAVITARY AND SUPERFICIAL APPLICATIONS
- .0703 TELETHERAPY

SECTION .0800 - REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

- .0801 PURPOSE AND SCOPE
- .0802 DEFINITIONS
- .0803 EQUIPMENT REQUIREMENTS
- .0804 AREA REQUIREMENTS
- .0805 OPERATING REQUIREMENTS
- .0806 PERSONNEL REQUIREMENTS

SECTION .0900 - REQUIREMENTS FOR PARTICLE ACCELERATORS

- .0901 PURPOSE AND SCOPE
- .0902 LICENSING REQUIREMENTS
- .0903 REQUIREMENTS FOR ISSUANCE OF A LICENSE FOR ACCELERATORS
- .0904 LIMITATIONS
- .0905 SHIELDING AND SAFETY DESIGN
- .0906 CONTROLS AND INTERLOCK SYSTEMS
- .0907 WARNING DEVICES
- .0908 OPERATING PROCEDURES
- .0909 RADIATION MONITORING REQUIREMENTS
- .0910 VENTILATION SYSTEMS

SECTION .1000 - NOTICES: INSTRUCTIONS: REPORTS AND INSPECTION

- .1001 SCOPE
- .1002 POSTING OF NOTICES TO WORKERS
- .1003 INSTRUCTIONS TO WORKERS
- .1004 NOTIFICATIONS AND REPORTS TO INDIVIDUALS
- .1005 PRESENCE OF REPRESENTATIVES DURING INSPECTIONS
- .1006 CONSULTATION WITH WORKERS
- .1007 REQUEST FOR INSPECTIONS
- .1008 INSPECTIONS NOT WARRANTED

SECTION .1100 - FEES

- .1101 PURPOSE AND SCOPE
- .1102 PAYMENT DUE
- .1103 NOTICES OF PAYMENT DUE
- .1104 DELINQUENT AND UNCOLLECTIBLE FEES
- .1105 FEE AMOUNTS

SECTION .1200 - LAND DISPOSAL OF RADIOACTIVE WASTE

- .1201 PURPOSE AND SCOPE
- .1202 DEFINITIONS

- .1203 LICENSE REQUIRED
- .1204 CONTENT OF APPLICATION
- .1205 GENERAL INFORMATION
- .1206 SPECIFIC TECHNICAL INFORMATION
- .1207 ENVIRONMENTAL INFORMATION
- .1208 TECHNICAL AND ENVIRONMENTAL ANALYSES
- .1209 INSTITUTIONAL INFORMATION
- .1210 FINANCIAL INFORMATION
- .1211 FILING AND DISTRIBUTION OF APPLICATION
- .1212 ELIMINATION OF REPETITION
- .1213 UPDATING OF APPLICATION
- .1214 STANDARDS FOR ISSUANCE OF A LICENSE
- .1215 CONDITIONS OF LICENSE
- .1216 AMENDMENT OF LICENSE
- .1217 APPLICATION FOR RENEWAL OR CLOSURE
- .1218 CONTENTS OF APPLICATION FOR CLOSURE
- .1219 POST-CLOSURE OBSERVATION AND MAINTENANCE
- .1220 TRANSFER OF LICENSE
- .1221 TERMINATION OF LICENSE
- .1222 PERFORMANCE OBJECTIVES - GENERAL REQUIREMENT
- .1223 PROTECTION OF POPULATION FROM RELEASES OF RADIOACTIVITY
- .1224 PROTECTION OF INDIVIDUALS FROM INADVERTENT INTRUSION
- .1225 PROTECTION OF INDIVIDUALS DURING OPERATIONS
- .1226 STABILITY OF THE DISPOSAL SITE AFTER CLOSURE
- .1227 TECHNICAL REQUIREMENTS FOR LAND DISPOSAL FACILITIES
- .1228 DISPOSAL SITE SUITABILITY REQUIREMENTS
- .1229 SITE DESIGN FOR LAND DISPOSAL
- .1230 FACILITY OPERATION AND DISPOSAL SITE CLOSURE
- .1231 ENVIRONMENTAL MONITORING
- .1232 VARIANCE- REPEALED 07/01/90
- .1233 WASTE CLASSIFICATION AND CHARACTERISTICS
- .1234 INSTITUTIONAL REQUIREMENTS
- .1235 APPLICANT QUALIFICATIONS AND ASSURANCES
- .1236 FUNDING OF CLOSURE: STABILIZATION: INSTITUTIONAL CONTROLS
- .1237 RECORDS: REPORTS: TESTS: AND INSPECTIONS
- .1238 MAINTENANCE OF RECORDS: REPORTS AND TRANSFERS
- .1239 TESTS AT LAND DISPOSAL FACILITIES
- .1240 AGENCY INSPECTIONS OF LAND DISPOSAL FACILITIES
- .1241 INSPECTION
- .1242 NOTIFICATIONS AND REPORTS

**SECTION .1300 - REQUIREMENTS FOR WIRELINE-SERVICE OPERATORS AND
SUBSURFACE TRACER STUDIES**

- .1301 PURPOSE AND SCOPE
- .1302 DEFINITIONS
- .1303 WRITTEN AGREEMENTS REQUIRED
- .1304 LIMITS ON LEVELS OF RADIATION
- .1305 STORAGE PRECAUTIONS
- .1306 TRANSPORT PRECAUTIONS
- .1307 RADIATION SURVEY INSTRUMENTS

- .1308 LEAK TESTING OF SEALED SOURCES
- .1309 QUARTERLY INVENTORY
- .1310 UTILIZATION RECORDS
- .1311 DESIGN: PERFORMANCE: AND CERTIFICATION CRITERIA
- .1312 LABELING
- .1313 INSPECTION AND MAINTENANCE
- .1314 TRAINING REQUIREMENTS
- .1315 OPERATING AND EMERGENCY PROCEDURES
- .1316 PERSONNEL MONITORING
- .1317 SECURITY
- .1318 HANDLING TOOLS
- .1319 SUBSURFACE-TRACER STUDIES
- .1320 PARTICLE ACCELERATORS
- .1321 RADIATION SURVEYS
- .1322 DOCUMENTS AND RECORDS REQUIRED AT FIELD STATIONS
- .1323 DOCUMENTS AND RECORDS REQUIRED AT TEMPORARY JOBSITES
- .1324 NOTIFICATIONS OF INCIDENTS: ABANDONMENT: AND LOST SOURCES
- .1325 SUBJECTS IN TRAINING COURSES FOR LOGGING SUPERVISORS

SECTION .1400 - TANNING FACILITIES

- .1401 PURPOSE AND SCOPE
- .1402 COMPLIANCE WITH OTHER LAWS
- .1403 DEFINITIONS
- .1404 EXEMPTIONS
- .1405 APPLICATION FOR REGISTRATION OF TANNING FACILITIES
- .1406 ISSUANCE OF CERTIFICATE OF REGISTRATION
- .1407 EXPIRATION OF CERTIFICATE OF REGISTRATION
- .1408 RENEWAL OF CERTIFICATE OF REGISTRATION
- .1409 REPORT OF CHANGES
- .1410 TRANSFER OF CERTIFICATE OF REGISTRATION
- .1411 APPROVAL NOT IMPLIED
- .1412 DENIAL: REVOCATION: TERMINATION OF REGISTRATIONS
- .1413 CONSTRUCTION AND OPERATION OF TANNING EQUIPMENT
- .1414 WARNING SIGNS NOT POSTED
- .1415 EQUIPMENT AND CONSTRUCTION REQUIREMENTS
- .1416 ADDITIONAL REQUIREMENTS FOR STAND-UP BOOTHS
- .1417 PROTECTIVE EYEWEAR REQUIRED
- .1418 RECORDS: REPORTS AND OPERATING REQUIREMENTS
- .1419 COMMUNICATIONS WITH THE AGENCY: AGENCY ADDRESS
- .1420 PROPOSED SERVICING
- .1421 APPLICATION FOR REGISTRATION OF SERVICING OR SERVICES
- .1422 REPORTS AND INSTALLATION
- .1423 FEES AND PAYMENT

SECTION .1500 - LICENSES FOR DISPOSAL SITE ACCESS

- .1501 PURPOSE AND SCOPE
- .1502 DEFINITIONS
- .1503 LICENSE REQUIRED
- .1504 APPLICATION FOR SITE ACCESS LICENSE - GENERAL REQUIREMENTS
- .1505 APPLICATION FOR SITE ACCESS LICENSE - WASTE GENERATORS

- .1506 CONTENT OF APPLICATION FOR WASTE COLLECTORS
- .1507 CONTENT OF APPLICATION FOR WASTE PROCESSORS
- .1508 CERTIFICATION OF COMPLIANCE WITH APPLICABLE REQUIREMENTS
- .1509 PRIOR NOTIFICATION FOR WASTE SHIPMENTS
- .1510 RADIOACTIVE SHIPMENT MANIFEST
- .1511 FINANCIAL QUALIFICATIONS AND REQUIREMENTS
- .1512 WASTE MANAGEMENT AND REDUCTION REQUIREMENTS
- .1513 ISSUANCE AND EXPIRATION OF SITE ACCESS LICENSES
- .1514 SITE ACCESS LICENSE RENEWAL
- .1515 SITE ACCESS LICENSE AMENDMENT
- .1516 MODIFICATION, REVOCATION, AND TERMINATION OF LICENSES
- .1517 TEMPORARY OR EMERGENCY ACCESS

SECTION .1600 - STANDARDS FOR PROTECTION AGAINST RADIATION

- .1601 PURPOSE AND SCOPE
- .1602 IMPLEMENTATION
- .1603 RADIATION PROTECTION PROGRAMS
- .1604 OCCUPATIONAL DOSE LIMITS FOR ADULTS
- .1605 REQUIREMENTS FOR SUMMATION OF EXTERNAL, INTERNAL DOSE
- .1606 EXTERNAL DOSE FROM AIRBORNE RADIOACTIVE MATERIAL
- .1607 DETERMINATION OF INTERNAL EXPOSURE
- .1608 PLANNED SPECIAL EXPOSURES
- .1609 OCCUPATIONAL DOSE LIMITS FOR MINORS
- .1610 DOSE TO AN EMBRYO/FETUS
- .1611 DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC
- .1612 COMPLIANCE WITH DOSE LIMITS FOR MEMBERS OF THE PUBLIC
- .1613 SURVEYS
- .1614 MONITORING OF EXTERNAL AND INTERNAL OCCUPATIONAL DOSE
- .1615 CONTROL OF ACCESS TO HIGH RADIATION AREAS
- .1616 CONTROL OF ACCESS TO VERY HIGH RADIATION AREAS
- .1617 ACCESS TO VERY HIGH RADIATION AREAS: IRRADIATORS
- .1618 USE OF PROCESS OR OTHER ENGINEERING CONTROLS
- .1619 USE OF OTHER CONTROLS TO RESTRICT INTERNAL EXPOSURE
- .1620 USE OF INDIVIDUAL RESPIRATORY PROTECTION EQUIPMENT
- .1621 RESTRICTIONS ON THE USE OF RESPIRATORY PROTECTION EQUIPMENT
- .1622 SECURITY OF SOURCES OF RADIATION
- .1623 CAUTION SIGNS
- .1624 POSTING REQUIREMENTS
- .1625 EXCEPTIONS TO POSTING REQUIREMENTS
- .1626 LABELING REQUIREMENTS AND EXEMPTIONS
- .1627 PROCEDURES FOR RECEIVING AND OPENING PACKAGES
- .1628 GENERAL REQUIREMENTS FOR WASTE DISPOSAL
- .1629 METHOD FOR OBTAINING APPROVAL OF DISPOSAL PROCEDURES
- .1630 DISPOSAL BY RELEASE INTO SANITARY SEWERAGE
- .1631 TREATMENT OR DISPOSAL BY INCINERATORS
- .1632 DISPOSAL OF SPECIFIC WASTES
- .1633 TRANSFER FOR DISPOSAL AND MANIFESTS
- .1634 COMPLIANCE WITH ENV. AND HEALTH PROTECTION REGULATIONS
- .1635 GENERAL PROVISIONS FOR RECORDS
- .1636 RECORDS OF RADIATION PROTECTION PROGRAMS

- .1637 RECORDS OF SURVEYS
- .1638 DETERMINATION OF PRIOR OCCUPATIONAL DOSE
- .1639 RECORDS OF PLANNED EXPOSURE
- .1640 RECORDS OF INDIVIDUAL MONITORING RESULTS
- .1641 RECORDS OF DOSE TO INDIVIDUAL MEMBERS OF THE PUBLIC
- .1642 RECORDS OF WASTE DISPOSAL
- .1643 RECORDS OF TESTING ENTRY CONTROL DEVICES
- .1644 FORM OF RECORDS
- .1645 RECORDS OF THEFT OR LOSS OF LICENSED RADIOACTIVE MATERIAL
- .1646 NOTIFICATION OF INCIDENTS
- .1647 REPORTS OF RADIATION EXCEEDING THE LIMITS
- .1648 REPORTS OF PLANNED SPECIAL EXPOSURES
- .1649 REPORTS OF INDIVIDUAL MONITORING
- .1650 CLASSIFICATION/RADIOACTIVE WASTE FOR NEAR-SURFACE DISPOSAL
- .1651 RADIOACTIVE WASTE CHARACTERISTICS
- .1652 LABELING
- .1653 RADIOLOGICAL REQUIREMENTS FOR LICENSE TERMINATION

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: 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: 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: 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 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, in writing, of her pregnancy and the estimated date of conception.
- (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/cm^2).
 - (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 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 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) "License", except where otherwise specified, means a license issued pursuant to Section .0300 of this Chapter.
- (62) "Licensee" means any person who is licensed by the agency pursuant to Section .0300 of this Chapter.
- (63) "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) "Limits" or "dose limits" means the permissible upper bounds of radiation doses.
- (65) "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) "Lung class" (see "Class" as defined in this Rule).
- (67) "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) "Member of the public" means any individual except when that individual is receiving an occupational dose.
- (69) "Minor" means an individual less than 18 years of age.
- (70) "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) "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.
- (72) "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) "Natural radioactivity" means radioactivity of naturally occurring nuclides.
- (74) "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) "NRC" means the United States Nuclear Regulatory Commission or its duly authorized representatives.
- (76) "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) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles.
- (78) "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) "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) "Pharmacist" means an individual licensed by this state to compound and dispense drugs, prescriptions and poisons.
- (81) "Physician" means an individual currently licensed to practice medicine in this state.
- (82) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.
- (83) "Prescribed dosage" means the quantity of radiopharmaceutical activity documented in a written directive by an authorized user.
- (84) "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) "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) "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) "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) "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) "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) "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) "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) "Radiation dose" means dose.
 - (93) "Radiation machine" means any device capable of producing radiation except devices which produce radiation only from radioactive material.
 - (94) "Radiation safety officer" means one who has the knowledge and responsibility to apply appropriate radiation protection rules.
 - (95) "Radioactive material" means any material, solid, liquid, or gas, which emits radiation spontaneously.
 - (96) "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) "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) "Radioactivity" means the disintegration of unstable atomic nuclei by emission of radiation.
 - (99) "Radiobioassay" means bioassay.
 - (100) "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) "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) "Registrant" means any person who is registered with the agency as required by provisions of these Rules or the Act.
 - (103) "Registration" means registration with the agency in accordance with these Rules.
 - (104) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189.
 - (105) "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</u>	<u>Absorbed Dose Equal to a Unit Dose Equivalent^a</u>
	<u>Q</u>	
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

^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

2×10^2	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.

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

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

(111) "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) "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) "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) "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.

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

(116) "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 ($1 \text{ Sv} = 100 \text{ rems}$).

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

- (118) "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) "Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.
- (120) "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) "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) "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:
- $$\frac{175 \text{ (gram contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} \text{ is } \leq 1$$
- (123) "State" means the State of North Carolina.
- (124) "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) "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) "These Rules" means Chapter 11 of this Title.
- (127) "To the extent practicable" means to the extent feasible or capable of being done or carried out

with reasonable effort.

- (128) "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) "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) "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) "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) "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.
- (133) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant.
- (134) "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).
- (135) "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) "Waste, Class A" is defined in Rule .1650 of this Chapter.
- (137) "Waste, Class B" is defined in Rule .1650 of this Chapter.
- (138) "Waste, Class C" is defined in Rule .1650 of this Chapter.
- (139) "Week" means seven consecutive days starting on Sunday.
- (140) "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) "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.
- (142) "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) "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) "Working level month" (WLM) means an exposure to one working level for 170 hours.
- (145) "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) "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. April 1, 1999; August 1, 1998; 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: 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;
- (2) prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;

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

*History Note: Authority G.S. 104E-2; 104E-7; 104E-15;
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2206 Eff. January 4, 1990;
Amended Eff. June 1, 1993.*

.0107 INSPECTIONS

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

*History Note: Authority G.S. 104E-7; 104E-11(a);
Eff. February 1, 1980;
Amended Eff. November 1, 1989;
Transferred and Recodified from 10 NCAC 3G .2207 Eff. January 4, 1990;
Amended Eff. May 1, 1993.*

.0108 ADDITIONAL REQUIREMENTS

(a) The agency may, by license condition, registration condition, or order, when not in conflict with any law, waive any requirement in these Rules or impose additional requirements in accordance with 46 FR 7540 as it deems appropriate or necessary to minimize danger to public health, safety or property. Such additional requirements are subject to appeal procedures contained in Section 15A NCAC 1B .0200.

(b) The Commission may by rule require radioactive material licensees to procure and file with the department such bond, insurance or other security as the Commission deems necessary to protect the state from costs for emergency response and perpetual maintenance.

*History Note: Authority G.S. 104E-7; 104E-18; 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540;
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2208 Eff. January 4, 1990;
Amended Eff. June 1, 1993.*

.0109 IMPOUNDING

Sources of radiation are subject to impounding by authorized representatives of the agency pursuant to provisions of the Act.

*History Note: Authority G.S. 104E-14;
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2210 Eff. January 4, 1990.*

.0110 PROHIBITED USES

- (a) Hand-held fluoroscopic screens shall not be used.

- (b) Shoe-fitting fluoroscopic devices shall not be used.
- (c) Effective February 1, 1981, plastic pointed position indicating devices on intraoral dental systems shall not be used.
- (d) Effective February 1, 1983, mechanical timers on intraoral dental machines shall not be used.
- (e) Dental fluoroscopy without image intensification shall not be used.
- (f) Non-intensified photofluorographic equipment shall not be used.

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

.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, Raleigh, North Carolina 27609-7221 or delivered to the agency at its office located at the same address.

(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. 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.*

.0112 DESIGNATION OF AUTHORIZED REPRESENTATIVE OF THE AGENCY

(a) When an employee of the agency is qualified and is specifically designated by the agency, the employee shall be an authorized representative of the agency to conduct inspections, or tests, or surveys.

(b) When a public employee of other than the agency is determined by the agency to be qualified, the agency may designate the employee as an authorized representative of the agency to conduct specified inspections, or tests, or surveys.

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

.0113 CLASSIFICATION OF RADIOACTIVE MATERIAL

For a single radionuclide of known identity, the values of A_1 and A_2 used for determining Type A quantity in the rules of this Chapter are taken from Appendix A of 10 CFR 71 as revised at 48 Federal Register 35600, August 5, 1983, and corrections at 48 Federal Register 38449, August 24, 1983.

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

.0114 TESTS FOR SPECIAL FORM

Special form radioactive material as defined in Rule .0104 of this Section must satisfactorily pass the following tests:

- (1) a free drop through a distance of 30 feet onto a flat essentially unyielding horizontal surface, striking the surface in such a position as to suffer maximum damage;
- (2) impact of the flat circular end of a one-inch diameter steel rod weighing three pounds, dropped through a distance on a sheet of lead, of hardness number 3.5 to 4.5 on the Vickers scale, and not more than one inch thick supported by a smooth essentially unyielding surface;
- (3) heating in air to a temperature of 1,475° F. and remaining at that temperature for a period of ten minutes;
- (4) immersion for 24 hours in water at room temperature at pH 6 to pH 8, with a maximum conductivity of ten micromhos per centimeter.

*History Note: Authority G.S. 104E-15;
Eff. February 1, 1980;
Amended Eff. November 1, 1989;
Transferred and Recodified from 10 NCAC 3G .2215 Eff. January 4, 1990;
Amended Eff. May 1, 1993.*

.0115 RECORDS

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

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

.0116 TESTS

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

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

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

.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 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. April 1, 1999; August 1, 1998; May 1, 1995.

.0118 OPTIONAL EARLY COMPLIANCE WITH SECTION .1600

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

- (1) implement all rules in Section .1600 of this Chapter, except as exempted by the provisions of Rule .1602(c) of this Chapter;
- (2) comply with the rules in Section .1600 of this Chapter in lieu of any rule in Section .0400 of this Chapter that is cited in license or registration conditions, except as otherwise provided in Rule .1602 of this Chapter; and
- (3) provide written notification of implementation to the agency at the address in Rule .0111 of this Section.

History Note: Authority G.S. 104E-7(a)(2); 104E-12(a);
Eff. May 1, 1993.

SECTION .0200
REGISTRATION OF RADIATION MACHINES: FACILITIES AND SERVICES

This Section .0200, Chapter 11 of Title 15A of the North Carolina Administrative Code (T15A.11 .0200); REGISTRATION OF RADIATION MACHINES: FACILITIES AND SERVICES; has been transferred and recodified from Section .2300, Subchapter 3G of Title 10 of the North Carolina Administrative Code (T10.03G .2300), effective January 4, 1990. The recodification was pursuant to G.S. 143B-279.3.

.0201 PURPOSE AND SCOPE

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

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

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

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

(e) In addition to the requirements of this Section, all registrants are subject to the annual fee provisions contained in Section .1100 of this Chapter.

*History Note: Authority G.S. 104E-7; 104E-9(8); 104E-19(a);
Eff. February 1, 1980;
Amended Eff. May 1, 1993; July 1, 1982.*

.0202 EXEMPTIONS

(a) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this Section provided that the dose equivalent rate average over an area of ten square centimeters does not exceed 0.5 mrem per hour at five centimeters from any accessible surface of the equipment when any external shielding is removed. The production, testing, or factory servicing of such equipment are not exempt.

(b) Radiation machines while in transit or storage incident thereto are exempt from the requirements of this Section.

(c) Domestic television receivers are exempt from the requirements of this Section.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980.*

.0203 APPLICATION: REGISTRATION: RADIATION MACHINES: FACILITIES

(a) Each person having an unregistered radiation machine or facility shall:

(1) apply for registration of such facility and each radiation machine within 30 days following initial operation of that facility and each radiation machine. Application for registration shall be completed on agency forms and shall contain all information required by the forms and accompanying instructions. The registration of the first radiation machine at a facility constitutes registration of the facility itself.

(2) designate on the application form an individual who shall be responsible for radiation protection.

(b) Agency forms described in Subparagraph (a)(1) of this Rule require the following and other information:

(1) name, address and telephone number of the radiation machine facility;

(2) name of the person responsible for radiation protection in the facility;

- (3) name, training and experience of the person designated in Subparagraph (a)(2) of this Rule;
- (4) the manufacturer, model number, serial number and type of each radiation machine located within the facility;
- (5) the date of the application and the signatures of the persons specified in Subparagraphs (b)(2) and (3) of this Rule.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. May 1, 1992.*

.0204 PROHIBITED SERVICES AND INSTALLATION

(a) Except as provided in Paragraph (b) of this Rule or otherwise authorized in writing by the agency, each person registered pursuant to Rule .0203 of this Section shall prohibit any person from furnishing equipment services described in Rule .0205(d) of this Section to his facility until such person provides evidence that he is currently registered with the agency as a provider of such services in accordance with Rule .0205 of this Section.

(b) No person registered pursuant to the provisions of Rule .0203 of this Section shall perform any services listed in Rule .0205(d) of this Section in his facility unless such person satisfies the applicable requirements in Rules .0205, .0213, and .0214 of this Section and has received written authorization from the agency to perform such services.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. June 1, 1989.*

.0205 APPLICATION FOR REGISTRATION OF SERVICES

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

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

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

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

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

- (1) direct sale and transfer of radiation machines and machine components to end users;
- (2) installation or servicing of radiation machines and associated radiation machine components;
- (3) diagnostic radiographic facility and shielding design;
- (4) diagnostic fluoroscopic facility and shielding design;

- (5) diagnostic area radiation survey, e.g., shielding evaluation;
- (6) radiation instrument calibration;
- (7) therapeutic facility and shielding design, area radiation survey or calibration;
- (8) personnel dosimetry services; and
- (9) general health physics consulting, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs and radiation safety training programs, non-healing arts facility and shielding design and area radiation surveys.

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

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. June 1, 1993; May 1, 1992; June 1, 1989.*

.0206 REPORTS OF INSTALLATION

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

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

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

*History Note: Authority G.S. 104E-7; 104E-12;
Eff. February 1, 1980.*

.0207 ISSUANCE OF NOTICE OF REGISTRATION

(a) The agency shall issue a notice of registration upon a determination that an applicant:

- (1) is qualified by reason of education, training or experience in the use and hazards of radiation sources described in the application for registration;
- (2) has facilities and equipment which meet the requirements in these Rules;
- (3) has established a radiation protection program, appropriate to the registered activities, which assures compliance with radiation protection requirements in these Rules; and
- (4) meets the applicable requirements in this Chapter.

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

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

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. June 1, 1993; June 1, 1989.*

.0208 PRIOR NOTIFICATION OF TRANSFER

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

(b) The notification shall include:

- (1) the name and address of the transferee, and
- (2) the manufacturer, model number and serial number of the radiation machine to be transferred.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980.*

.0209 REPORT OF CHANGES

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

*History Note: Authority G.S. 104E-7; 104E-12;
Eff. February 1, 1980.*

.0210 OTHER PROHIBITED ACTIVITIES

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

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

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

*History Note: Authority G.S. 104E-7; 104E-20;
Eff. February 1, 1980;
Amended Eff. May 1, 1993; June 1, 1989.*

.0211 OUT-OF-STATE RADIATION MACHINES

(a) No person shall bring any radiation machine into the state, for any temporary use, unless such person has given a written notice to the agency at least five working days before the machine is to be used in the state. The notice shall include the type of radiation machine; the nature, duration, and scope of use; and the exact location(s) where the radiation machine is to be used. If, for a specific case, the five working day period would impose an undue hardship on the person, he may, upon application to the agency, obtain permission to proceed sooner.

(b) The person in Paragraph (a) of this Rule shall:

- (1) comply with all applicable rules in this Chapter, including registration pursuant to Rule .0203 of this Section; and

- (2) supply the agency with such other information as the agency may reasonably request.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. June 1, 1989.*

.0212 MODIFICATIONS: REVOCATION: TERMINATION OF REGISTRANTS

(a) The terms and conditions of all registrations are subject to amendment, revision or modification and all registrations are subject to suspension or revocation by reason of:

- (1) rules adopted pursuant to provisions of the Act; or
- (2) orders issued by the agency pursuant to provisions of the Act and rules adopted pursuant to provisions of the Act.

(b) Any registration may be revoked, suspended or modified in whole or in part:

- (1) for any material false statement in the application or in any statement of fact required by provisions of this Section;
- (2) because of conditions which would warrant the agency to refuse to grant a registration on original application revealed by:
 - (A) the application;
 - (B) any statement of fact;
 - (C) any report, record, inspection or other means; or
- (3) for violations of, or failure to observe any of the terms and conditions of the Act, the registration, the rules of this Chapter, or order of the agency.

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, prior to the institution of proceedings for modification, revocation or suspension of a registrant, the agency shall:

- (1) call to the attention of the registrant in writing the facts or conduct which may warrant these actions, and
- (2) provide an opportunity for the registrant to demonstrate or achieve compliance with all lawful requirements.

(d) Before any order is entered suspending, revoking or modifying a registration, the agency shall give notice and grant a hearing as provided in Chapter 150B of the North Carolina General Statutes.

(e) The agency may terminate a registration upon written request submitted by the registrant to the agency.

*History Note: Authority G.S. 104E-7; 104E-13;
Eff. June 1, 1989;
Amended Eff. June 1, 1993.*

.0213 ADDITIONAL REQUIREMENTS: REGISTERED SERVICES

(a) An applicant for registration of diagnostic area radiation survey, diagnostic radiation output measurements or therapeutic calibration services pursuant to Rule .0205 of this Section shall meet the following additional requirements:

- (1) The applicant shall have adequate radiation survey and radiation measurement equipment appropriate to the services requested for authorization.
- (2) The applicant shall ensure that the equipment in Subparagraph (a)(1) of this Rule is calibrated at least every 12 months by persons registered to provide such services pursuant to Rule .0205 of this Section, except as provided in Subparagraph (a)(3) of this Rule. The agency may approve less frequent calibration of equipment used for therapy calibration, provided the applicant satisfies the agency that the proposed frequency and procedures will provide equivalent or better assurance of proper calibration.

- (3) The applicant may perform the equipment calibrations required in Subparagraph (a)(2) of this Rule provided that:
 - (A) such calibrations are currently traceable to the National Institute of Standards and Technology;
 - (B) the calibration procedures are approved by the agency;
 - (C) the radiation sources used for such calibration are licensed or registered as required by the rules in this Chapter; and
 - (D) the equipment is labeled to indicate the date of calibration and records of the calibration are maintained.
 - (4) The applicant shall submit:
 - (A) a description of the procedures that will be used in performing area radiation surveys including a list of all guides and references to be employed;
 - (B) a copy of all forms, reports and documents that will be supplied to customers;
 - (C) samples of three different types of surveys;
 - (D) samples of three reports of diagnostic radiation output measurements; and
 - (E) samples of three therapeutic calibration reports.
- (b) An applicant for registration of services pursuant to Rule .0205 of this Section who proposes to provide diagnostic radiographic, fluoroscopic and therapeutic facility and shielding design services shall meet the following additional requirements:
- (1) The applicant shall submit examples of the facility and shielding design which will be provided to clients.
 - (2) The applicant shall submit examples of the calculations which will be performed as part of the facility and shielding design along with any guides, occupancy factor rationales, and workload estimation rationales which will be used.
 - (3) The applicant shall ensure that the facility and shielding design services provided to licensees and registrants of the agency satisfy the applicable requirements in this Chapter.

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

.0214 TRAINING AND EDUCATIONAL REQUIREMENTS FOR EQUIPMENT SERVICES

- (a) Each person registered pursuant to Rule .0205 of this Section shall be qualified by reason of education, training and experience to provide the services for which registration is requested. The following are minimum qualifications for specific types of services:
- (1) Class I - sales of radiation machines and machine components to end users: The applicant must certify knowledge of familiarity with the rules which govern the possession, installation and use of radiation machines in North Carolina.
 - (2) Class II - installation and service of radiation machines and machine components including the making of diagnostic radiation output measurements to verify performance associated with the installation or service:
 - (A) manufacturer's equipment school for service, maintenance and installation for the type of machine use (e.g. dental intraoral, medical diagnostic or medical fluoroscopic) or equivalent training;
 - (B) training in principles of radiation protection; and
 - (C) three months of experience in installation and service of radiation machines and machine components.
 - (3) Class III - diagnostic radiographic facility and shielding design:
 - (A) training in principles of radiation protection;
 - (B) training in shielding design; and

- (C) one year of experience in diagnostic radiographic facility and shielding design for the specific type of machine application.
- (4) Class IV - diagnostic fluoroscopic facility and shielding design:
 - (A) training in principles of radiation protection;
 - (B) training in shielding design; and
 - (C) one year of experience in diagnostic fluoroscopic facility and shielding design for the specific type of machine application.
- (5) Class V - diagnostic area radiation survey, e.g., shielding evaluation:
 - (A) training in basic radiological health;
 - (B) training in shielding evaluation; and
 - (C) one year of experience performing area radiation surveys.
- (6) Class VI - radiation instrument calibration: The applicant must possess a current radioactive materials license or registration authorizing radiation instrument calibration.
- (7) Class VII - therapeutic facility and shielding design, area radiation survey, or calibration:
 - (A) certification by the American Board of Radiology in therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, or x-ray and radium physics; or certification by the American Board of Medical Physics; or
 - (B) having the following minimum training and experience:
 - (i) a master's degree in physics, biophysics, radiological physics or health physics;
 - (ii) one year of full-time training in therapeutic radiological physics
 - (iii) one year of full-time experience in a therapeutic facility including personal calibration and spot-check of at least one machine;
 - (C) shall submit a description of the procedures that will be utilized in performing therapeutic calibrations including a list of all guides and references to be employed;
 - (D) shall submit a copy of all forms, reports and documents that will be supplied to customers; and
 - (E) shall submit one sample of each specific type, e.g., teletherapy, accelerator.
- (8) Class VIII - personnel dosimetry service: The applicant must hold current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology or use NVLAP accredited dosimetry.
- (9) Class IX - general health physics consulting, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs, and radiation safety training programs, non-healing arts facility and shielding design, and area radiation surveys:
 - (A) baccalaureate degree in a physical science (e.g. physics, chemistry or radiologic science), engineering or related field and two years of progressive experience in medical or health physics; graduate training in medical or health physics may be substituted on a year for year basis; or
 - (B) certification by the American Board of Radiology in therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, or x-ray and radium physics; certification by the American Board of Health Physics in health physics or certification by the American Board of Medical Physics.

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

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

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

*History Note: Authority G.S. 104E-7; 104E-13;
Eff. June 1, 1989;
Amended Eff. June 1, 1993.*

SECTION .0300 - LICENSING OF RADIOACTIVE MATERIAL

This Section .0300, Chapter 11 of Title 15A of the North Carolina Administrative Code (T15A.11 .0300); LICENSING OF RADIOACTIVE MATERIAL; has been transferred and recodified from Section .2400, Subchapter 3G of Title 10 of the North Carolina Administrative Code (T10.03G .2400), effective January 4, 1990. The recodification was pursuant to G.S. 143B-279.3.

.0301 PURPOSE AND SCOPE

(a) This Section provides for the licensing of radioactive material. No person shall receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to, or as otherwise provided in, this Section.

(b) In addition to the requirements of this Section,

- (1) All licensees are subject to the requirements of Sections .1000 and .1600 of this Chapter, except as otherwise provided in the rules of this Section;
- (2) Licensees engaged in industrial radiographic operations are subject to the requirements of Section .0500 of this Chapter;
- (3) Licensees using sealed sources in the healing arts are subject to the requirements of Section .0700 of this Chapter;
- (4) Licensees engaged in the operation of radioactive waste disposal facilities are subject to the requirements of Section .1200 of this Chapter;
- (5) Licensees engaged in well-logging operations are subject to the requirements of Section .1300 of this Chapter; and
- (6) Licensees engaged in the operation of panoramic and underwater irradiators are subject to the requirements of Section .0100 of this Chapter.

(c) In addition to the requirements of this Section, all licensees are subject to the annual fee provisions contained in Section .1100 of this Chapter.

(d) The rules in this Section do not apply to persons licensed pursuant to the rules in Section .1200 of this Chapter except as specifically provided otherwise in Section .1200.

*History Note: Authority G.S. 104E-7; 104E-9(8); 104E-10(b); 104E-19;
Eff. February 1, 1980;*

Amended Eff. August 1, 1998; January 1, 1994; May 1, 1992; June 1, 1989; July 1, 1982.

.0302 EXEMPTIONS FOR SOURCE MATERIAL

(a) Any person is exempt from licensure to the extent that any person receives, possesses, uses, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 0.05 percent of the mixture, compound, solution, or alloy.

(b) Any person is exempt from licensure to the extent that any person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, no person shall refine or process ore containing source material.

(c) Any person is exempt from licensure to the extent that any person receives, possesses, uses, or transfers:

- (1) any quantities of thorium contained in:
 - (A) incandescent gas mantles;
 - (B) vacuum tubes;
 - (C) welding rods;
 - (D) electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium;
 - (E) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium;

- (F) rare earth metals and compounds, mixtures, and products containing not more than 0.04 percent by weight thorium, uranium or any combination of these;
- (G) personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;
- (2) source material contained in the following products:
 - (A) glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material;
 - (B) glassware containing not more than ten percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass, or ceramic used in construction;
 - (C) piezoelectric ceramic containing not more than two percent by weight source material;
 - (D) glass enamel or glass enamel frit containing not more than ten percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States before July 25, 1983;
- (3) photographic film, negatives, and prints containing uranium or thorium;
- (4) any finished product or part fabricated of, or containing, tungsten or magnesium-thorium alloys; provided that the thorium content of the alloy does not exceed four percent by weight and that the exemption contained in this Rule shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of the product or part;
- (5) uranium contained in counterweights installed in aircraft, rockets, projectiles and missiles, or stored or handled in connection with installation or removal of the counterweights when:
 - (A) the counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 CFR 40;
 - (B) each counterweight has been impressed with the following legend clearly legible through any plating or other covering, which states, "DEPLETED URANIUM";
 - (C) each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED";
 - (D) the exemption contained in this Subparagraph shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any counterweights other than repair or restoration of any plating or other covering;
 - (E) the requirements specified in Subparagraphs (c)(5)(B) and (C) of this Rule need not be met by counterweights manufactured prior to December 31, 1969; provided, that the counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM";
- (6) natural or depleted uranium metal used as shielding constituting part of any shipping container; provided that:
 - (A) The shipping container is conspicuously and legibly impressed with the legend, "CAUTION - RADIOACTIVE SHIELDING - URANIUM"; and
 - (B) The uranium metal is encased in mild steel or equally fire resistant metal with a minimum wall thickness of one-eighth inch or 3.2 mm;
- (7) thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium; and that the exemption contained in this Subparagraph shall not be deemed to authorize either:
 - (A) the shaping, grinding, or polishing of the lens or manufacturing processes other than the assembly of the lens into optical systems and devices without any alteration of the lens; or
 - (B) the receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eye pieces in binoculars or other optical instruments;
- (8) uranium contained in detector heads for use in fire detection units, provided that each detector

- head contains not more than 0.005 microcurie of uranium;
- (9) thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:
- (A) The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide);
- (B) The thorium content in the nickel-thoria alloy does not exceed four percent by weight.

*History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. June 1, 1989; October 1, 1984; October 1, 1980.*

.0303 EXEMPT CONCENTRATIONS: OTHER THAN SOURCE MATERIAL

(a) No person shall introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under Paragraph (b) of this Rule or equivalent regulations of the U.S. Nuclear Regulatory Commission or any agreement state, except in accordance with a specific license issued pursuant to Rule .0325 of this Section.

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

EXEMPT CONCENTRATIONS

Element (atomic number)	Isotope	Column I Gas concentration microcurie/ml	Column II Liquid and solid concentration microcurie/ml
Antimony (51)	Sb 122		3×10^{-4}
	Sb 124		2×10^{-4}
	Sb 125		1×10^{-3}
Argon (18)	Ar 37	1×10^{-3}	
	Ar 41	4×10^{-7}	
Arsenic (33)	As 73		5×10^{-3}
	As 74		5×10^{-4}
	As 76		2×10^{-4}
	As 77		8×10^{-4}
Barium (56)	Ba 131		2×10^{-3}
	Ba 140		3×10^{-4}
Beryllium (4)	Be 7		2×10^{-2}
Bismuth (83)	Bi 206		4×10^{-4}
Bromine (35)	Br 82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd 109		2×10^{-3}
	Cd 115m		3×10^{-4}
	Cd 115		3×10^{-4}
Calcium (20)	Ca 45		9×10^{-5}
	Ca 47		5×10^{-4}
Carbon (6)	C 14	1×10^{-6}	8×10^{-3}

Cerium (58)	Ce 141		9×10^{-4}
	Ce 143		4×10^{-4}
	Ce 144		1×10^{-4}
Cesium (55)	Cs 131		2×10^{-2}
	Cs 134m		6×10^{-2}
	Cs 134		9×10^{-5}
Chlorine (17)	Cl 38	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr 51		2×10^{-2}
Cobalt (27)	Co 57		5×10^{-3}
	Co 58		1×10^{-3}
	Co 60		5×10^{-4}
Copper (29)	Cu 64		3×10^{-3}
Dysprosium (66)	Dy 165		4×10^{-3}
	Dy 166		4×10^{-4}
	Er 169		9×10^{-4}
Erbium (68)	Er 171		1×10^{-3}
	Eu 152		6×10^{-4}
Europium (63)	(T1/2 =9.2 Hrs.)		
	Eu 155		2×10^{-3}
Fluorine (9)	F 18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd 153		2×10^{-3}
	Gd 159		8×10^{-4}
Gallium (31)	Ga 72		4×10^{-4}
Germanium (32)	Ge 71		2×10^{-2}
Gold (79)	Au 196		2×10^{-3}
	Au 198		5×10^{-4}
	Au 199		2×10^{-3}
Hafnium (72)	Hf 181		7×10^{-4}
Hydrogen (1)	H 3	5×10^{-6}	3×10^{-2}
Indium (49)	In 113m		1×10^{-2}
	In 114m		2×10^{-4}
Iodine (53)	I 126	3×10^{-9}	2×10^{-5}
	I 131	3×10^{-9}	2×10^{-5}
	I 132	8×10^{-8}	6×10^{-4}
	I 133	1×10^{-8}	7×10^{-5}
	I 134	2×10^{-7}	1×10^{-3}
Iridium (77)	Ir 190		2×10^{-3}
	Ir 192		4×10^{-4}
	Ir 194		3×10^{-4}
Iron (26)	Fe 55		8×10^{-3}
	Fe 59		6×10^{-4}
Krypton (36)	Kr 85m		1×10^{-6}
	Kr 85		3×10^{-6}
Lanthanum (57)	La 140		2×10^{-4}
Lead (82)	Pb 203		4×10^{-3}
Lutetium (71)	Lu 177		1×10^{-3}
Manganese (25)	Mn 52		3×10^{-4}
	Mn 54		1×10^{-3}
	Mn 56		1×10^{-3}
Mercury (80)	Hg 197m		2×10^{-3}

	Hg 197	3×10^{-3}
	Hg 203	2×10^{-4}
Molybdenum (42)	Mo 99	2×10^{-3}
Neodymium (60)	Nd 147	6×10^{-3}
	Nd 149	3×10^{-4}
Nickel (28)	Ni 65	1×10^{-3}
Niobium (Columbium)(41)	Nb 95	1×10^{-3}
	Nb 97	9×10^{-3}
Osmium (76)	Os 185	7×10^{-4}
	Os 191m	3×10^{-2}
	Os 191	2×10^{-3}
	Os 193	6×10^{-4}
Palladium (46)	Pd 103	3×10^{-3}
	Pd 109	9×10^{-4}
Phosphorus (15)	P 32	2×10^{-4}
Platinum (78)	Pt 191	1×10^{-3}
	Pt 193m	1×10^{-2}
	Pt 197m	1×10^{-2}
	Pt 197	1×10^{-3}
Polonium (84)	Po 210	7×10^{-6}
Potassium (19)	K 42	3×10^{-3}
Praseodymium (59)	Pr 142	3×10^{-4}
	Pr 143	5×10^{-4}
Promethium (61)	Pm 147	2×10^{-3}
	Pm 149	4×10^{-4}
Radium (88)	Ra 226	1×10^{-7}
	Ra 228	3×10^{-7}
Rhenium (75)	Re 183	6×10^{-3}
	Re 186	9×10^{-4}
	Re 188	6×10^{-4}
Rhodium (45)	Rh 103m	1×10^{-1}
	Rh 105	1×10^{-3}
Rubidium (37)	Rb 86	7×10^{-4}
Ruthenium (44)	Ru 97	4×10^{-3}
	Ru 103	8×10^{-4}
	Ru 105	1×10^{-3}
	Ru 106	1×10^{-4}
Samarium (62)	Sm 153	8×10^{-4}
Scandium (21)	Sc 46	4×10^{-4}
	Sc 47	9×10^{-4}
	Sc 48	3×10^{-4}
Selenium (34)	Se 75	3×10^{-3}
Silicon (14)	Si 31	9×10^{-3}
Silver (47)	Ag 105	1×10^{-3}
	Ag 110m	3×10^{-4}
	Ag 111	4×10^{-4}
Sodium (11)	Na 24	2×10^{-3}
Strontium (38)	Sr 85	1×10^{-3}
	Sr 89	1×10^{-4}

	Sr 91		7×10^{-4}
	Sr 92		7×10^{-4}
Sulfur (16)	S 35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta 182		4×10^{-4}
Technetium (43)	Tc 96m		1×10^{-1}
	Tc 96		1×10^{-3}
Tellurium (52)	Te 125m		2×10^{-3}
	Te 127m		6×10^{-4}
	Te 127		3×10^{-3}
	Te 129m		3×10^{-4}
	Te 131m		6×10^{-4}
	Te 132		3×10^{-4}
Terbium (65)	Tb 160		4×10^{-4}
Thallium (81)	Tl 200		4×10^{-3}
	Tl 201		3×10^{-3}
	Tl 202		1×10^{-3}
	Tl 204		1×10^{-3}
Thulium (69)	Tm 170		5×10^{-4}
	Tm 171		5×10^{-3}
Tin (50)	Sn 113		9×10^{-4}
	Sn 125		2×10^{-4}
Tungsten(Wolfram) (74)	W 181		4×10^{-3}
	W 187		7×10^{-4}
Vanadium (23)	V 48		3×10^{-4}
Xenon (54)	Xe 131m	4×10^{-6}	
	Xe 133	3×10^{-6}	
	Xe 135	1×10^{-6}	
Ytterbium (70)	Yb 175		1×10^{-3}
Yttrium (39)	Y 90		2×10^{-4}
	Y 91m		3×10^{-2}
	Y 91		3×10^{-4}
	Y 92		6×10^{-4}
	Y 93		3×10^{-4}
Zinc (30)	Zn 65		1×10^{-3}
	Zn 69m		7×10^{-4}
	Zn 69		2×10^{-2}
Zirconium (40)	Zr 95		6×10^{-4}
	Zr 97		2×10^{-4}
Beta and/or gamma emitting radioactive material not listed above with half-life less than 3 years		1×10^{-10}	1×10^{-6}

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

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

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

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

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} \text{ less than or equal to } 1$$

*History Note: Authority G.S. 104E-7; 104E-10; 104E-20;
Eff. February 1, 1980;
Amended Eff. May 1, 1993; June 1, 1989.*

.0304 EXEMPT QUANTITIES: OTHER THAN SOURCE MATERIAL

(a) Any person who possesses radioactive material received or acquired under the general license formerly provided in Rule .0303(b) of this Section is exempt from the requirements for a license set forth in this Section to the extent that such person possesses, uses, transfers or owns such radioactive material.

(b) This Rule does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(c) No person shall, for the purposes of commercial distribution, transfer individual quantities of radioactive materials to persons exempt from regulation in Paragraph (a) of this Rule except in accordance with a specific license issued by:

- (1) the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 for source and byproduct material;
- (2) the agency pursuant to Rule .0326 for radioactive material other than source, byproduct and special nuclear material; or
- (3) any agreement state pursuant to equivalent regulation for radioactive material other than source, byproduct and special nuclear material.

(d) Licensees for commercial distribution shall not transfer the quantities of radioactive material to persons exempt under Paragraph (e) of this Rule if the licensee knows or has reason to believe that the recipient will redistribute the quantities to persons exempt under Paragraph (e) of this Rule.

(e) Except as provided in Paragraphs (b) and (c) of this Rule, any person is exempt from the rules of this Chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in the following table:

EXEMPT QUANTITIES

Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10

Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100
Europium-152 (Eu 152) 9.2h	100
Europium-152 (Eu 152) 13 yr	1
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10
Fluorine-18 (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10
Germanium-71 (Ge 71)	100
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100

Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m(In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.1
Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100
Mercury-203 (Hg 203)	10
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100
Nickel-63(Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1

Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100
Promethium -147 (Pm 147)	10
Promethium-149 (Pm 149)	10
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulfur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100

Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha emitting radioactive material	0.1

*History Note: Authority G.S. 104E-7; 104E-10(b); 104E-20;
Eff. February 1, 1980;
Amended Eff. May 1, 1993.*

.0305 EXEMPT ITEM CONTAINING OTHER THAN SOURCE MATERIAL

(a) Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from the rules of this Chapter may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(b) Certain items containing radioactive material are exempt as provided in this Paragraph.

- (1) Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from the rules of this Chapter to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:
 - (A) timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:
 - (i) 25 millicuries of tritium per timepiece;
 - (ii) five millicuries of tritium per hand;
 - (iii) 15 millicuries of tritium per dial (bezels when used shall be considered as part of the

- dial);
 - (iv) 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per any other timepiece;
 - (v) 20 microcuries of promethium-147 per watch hand or 40 microcuries of promethium-147 per other timepiece hand;
 - (vi) 60 microcuries of promethium-147 per watch dial or 120 microcuries of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);
 - (vii) the levels of radiation from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:
 - (I) for wrist watches, 0.1 millirad per hour at ten centimeters from any surface;
 - (II) for pocket watches, 0.1 millirad per hour at one centimeter from any surface;
 - (III) for any other timepiece, 0.2 millirad per hour at ten centimeters from any surface.
 - (B) lock illuminators containing not more than 15 millicuries of tritium or not more than two millicuries of promethium-147 installed in automobile locks (the levels of radiation from each lock illuminator containing promethium-147 shall not exceed one millirad per hour at one centimeter from any surface when measured through 50 milligrams per square centimeter of absorber);
 - (C) balances of precision containing not more than one millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part;
 - (D) automobile shift quadrants containing not more than 25 millicuries of tritium;
 - (E) marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas;
 - (F) thermostat dials and pointers containing not more than 25 millicuries of tritium per thermostat;
 - (G) electron tubes, provided that each tube does not contain more than one of the following specified quantities of radioactive material:
 - (i) 150 millicuries of tritium per microwave receiver protector tube or ten millicuries of tritium per any other electron tube;
 - (ii) one microcurie of cobalt-60;
 - (iii) five microcuries of nickel-63;
 - (iv) 30 microcuries of krypton-85;
 - (v) five microcuries of cesium-137;
 - (vi) 30 microcuries of promethium-147; and provided further, that the levels of radiation from each electron tube containing radioactive material does not exceed one millirad per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber (for purposes of this Subparagraph, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents);
 - (H) ionizing radiation measuring instruments containing for purposes of internal calibration or standardization, sources of radioactive material each not exceeding the applicable quantity set forth in Rule .0304(e) of this Section.
 - (I) spark gap irradiation containing not more than one microcurie of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least three gallons (11.4 liters) per hour.
- (2) For purposes of Part (b)(1)(H) of this Rule, where there is involved a combination of radionuclides, the limit for the combination shall be derived as follows:

- (A) Determine for each radionuclide in an ionizing radiation measuring instrument the ratio between the quantity present in the instrument and the exempt quantity established in Rule .0304(e) of this Section for the specific radionuclide when not in combination;
 - (B) No ratio shall exceed one and the sum of such ratios shall not exceed ten.
 - (C) For the purpose of Part (b)(1)(H) 0.05 microcurie of americium-241 is considered an exempt quantity under Rule .0304 of this Section.
- (c) Self-luminous products are exempt as provided in this Paragraph.
- (1) Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from the rules of this Chapter to the extent that any person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements.
 - (2) The exemption in Subparagraph (c)(1) of this Rule does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.
- (d) Gas and aerosol detectors are exempt as provided in this Paragraph.
- (1) Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, any person is exempt from the rules of this Chapter to the extent that any person receives, possesses, uses, transfers, owns or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall be manufactured, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or any agreement state, pursuant to Section 32.26 of 10 CFR 32, or equivalent, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.
 - (2) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an agreement state shall be considered exempt under Subparagraph (d)(1) of this Rule, provided that the devices are labeled in accordance with the specific license authorizing distribution of the general licensed device, and providing further that the devices meet the requirements of Rule .0327.
- (e) Resins containing scandium-46 are exempt as provided in this Paragraph.
- (1) Any person is exempt from these Rules to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. These resins shall be manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall be manufactured in accordance with the specifications contained in a specific license issued by the agency or any agreement state to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Sections 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.
 - (2) This exemption does not authorize the manufacture of any resins containing scandium-46.
- (f) Capsules containing Carbon-14 urea for "in-vivo" diagnostic use for humans are exempt as provided in this Paragraph:
- (1) Except as provided in Subparagraphs (2) and (3) of this Paragraph, any person is exempt from the requirements for a license set forth in this Section provided that such person receives, possesses, uses, transfers, owns or acquires capsules containing approximately one microcurie (37kBq) Carbon-14 urea each for "in-vivo" diagnostic use for humans.
 - (2) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license from the agency.
 - (3) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license

- from the U.S. Nuclear Regulatory Commission.
- (4) Nothing in this Rule relieves persons from complying with applicable FDA and other federal regulations, and North Carolina requirements governing the receipt, administration, and use of drugs.

*History Note: Authority G.S. 104E-7; 104E-10(b); 104E-20;
Eff. February 1, 1980;
Amended Eff. April 1, 1999; June 1, 1993; October 1, 1982; September 1, 1981.*

.0306 TYPES OF LICENSES: GENERAL AND SPECIFIC

(a) General licenses provided in this Section are effective without the filing of applications with the agency or the issuance of licensing documents to the general licensee, although registration with the agency may be required by the particular general license. The general license is subject to all other applicable rules in this Chapter and any limitations contained in the general license.

(b) Specific licenses require the submission of an application to the agency and the issuance of a licensing document by the agency. The licensee is subject to all applicable rules of this Chapter as well as any limitations and requirements specified in the licensing document.

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

.0307 GENERAL LICENSES: SOURCE MATERIAL

(a) A general license shall be issued authorizing use and transfer of not more than 15 pounds of source material at any one time by persons in the following categories:

- (1) pharmacists using the source material solely for the compounding of medicinals;
- (2) physicians using the source material for medicinal purposes;
- (3) persons receiving possession of source material from pharmacists and physicians in the form of medicinals or drugs;
- (4) commercial and industrial firms, and research, educational, and medical institutions, and state and local governmental agencies for research, development, educational, commercial or operational purposes.

(b) Pursuant to this general license no person shall receive more than a total of 150 pounds of source material in any one calendar year.

(c) Persons who receive, possess, use, or transfer source material pursuant to the general license issued in Paragraph (a) of this Rule are exempt from the provisions of Sections .1000 and .1600 of this Chapter to the extent that the receipt, possession, use, or transfer is within the terms of the general license, provided that this exemption shall not be deemed to apply to any person who is also in possession of source material under a specific license issued pursuant to the rules in this Section.

(d) A general license shall be issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.

(e) A general license shall be issued to receive, acquire, possess, use, or transfer in accordance with the provisions of Subparagraphs (e)(2), (3), (4) and (5) of this Rule, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

- (1) The general license in Paragraph (e) of this Rule applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to Rule .0336 of this Section or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes manufacture of the products or devices for distribution

- to persons generally licensed by the U.S. Nuclear Regulatory Commission or an agreement state.
- (2) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by Paragraph (e) of this Rule shall file with the agency appropriate form(s) provided by the agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on appropriate form(s) provided by the agency the following information and such other information as may be required by that form:
 - (A) name and address of the registrant;
 - (B) a statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in Paragraph (e) of this Rule and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and
 - (C) name, title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in Part (e)(2)(B) of this Rule.
 - (3) The registrant possessing or using depleted uranium under the general license established by Paragraph (e) of this Rule shall report in writing to the agency any changes in information furnished by him on the appropriate form(s) provided by the agency. The report shall be submitted within 30 days after the effective date of such change.
 - (4) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by Paragraph (e) of this Rule shall:
 - (A) not introduce such depleted uranium, in any form, into a chemical, physical or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;
 - (B) not abandon such depleted uranium;
 - (C) transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of Rule .0343 of this Section;
 - (i) In the case where the transferee receives the depleted uranium pursuant to the general license established by Paragraph (e) of this Rule, the transferor shall furnish the transferee a copy of this Rule and a copy of the appropriate agency form described in Subparagraph (e)(2) of this Rule;
 - (ii) In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission or agreement state regulations equivalent to Paragraph (e) of this Rule, the transferor shall furnish the transferee a copy of this Rule and a copy of the appropriate agency form accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or agreement state under requirements substantially the same as those in this Rule;
 - (D) within 30 days of any transfer, report in writing to the agency the name and address of the person receiving the depleted uranium pursuant to such transfer;
 - (E) not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.
 - (5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by Paragraph (e) of this Rule is exempt from the requirements of Sections .1000 and .1600 of this Chapter with respect to the depleted uranium covered by that general license.

*History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. January 1, 1994; May 1, 1992.*

.0308 GENERAL LICENSES: OTHER THAN SOURCE MATERIAL

(a) A general license shall be issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31:

- (1) static elimination devices designed for use as static eliminators which contain as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device;
- (2) ion generating tube designed for ionization of air and containing, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device or a total of not more than 50 millicuries of hydrogen-3 (tritium) per device.

(b) The general license in Paragraph (a) of this Rule is subject to the provisions of Rules .0107 to .0111, .0303(a), .0337, .0342, .0343 and .0345 of this Chapter and to labeling requirements in Section .1600 of this Chapter.

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

.0309 GENERAL LICENSES: MEASURING GAUGING: CONTROLLING DEVICES

(a) A general license shall be issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and federal, state, or local government agencies to acquire, receive, possess, use, or transfer in accordance with Paragraphs (b), (c), and (d) of this Rule, radioactive material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(b) The general license in Paragraph (a) of this Rule applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued pursuant to Rule .0328 of this Section or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes distribution of the devices to persons generally licensed pursuant to equivalent regulations.

(c) Any person who acquires, receives, possesses, uses or transfers radioactive material in a device pursuant to the general license issued under Paragraph (a) of this Rule:

- (1) shall assure that all labels, affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by the labels;
- (2) shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label, except as follows:
 - (A) Devices containing only krypton need not be tested for leakage of radioactive material;
 - (B) Devices containing only tritium or not more than 100 microcuries of other beta, gamma, or beta and gamma emitting material or ten microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;
- (3) shall assure that the tests required by Subparagraph (c)(2) of this Rule and other testing, installation, servicing and removal from installation involving the radioactive materials, its shielding or containment are performed:

- (A) in accordance with the instructions provided on labels affixed to the device, except that tests for leakage or contamination may be performed by the general licensee using leak test kits provided and analyzed by a specific licensee who is authorized to provide leak test kit services; or
 - (B) by a person holding a specific license or registration which authorizes the providing of services required by this Rule and which is issued pursuant to Rules .0205 and .0306 of this Chapter or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state.
- (4) shall maintain records, showing compliance with the requirements in Subparagraphs (c)(2) and (3) of this Rule, to include:
- (A) the name of the person(s) performing the test(s) and the date(s) of the test(s);
 - (B) the name of the person(s) performing installation, servicing and removal of any radioactive material, shielding or containment;
 - (C) retention of leakage or contamination, on-off mechanism and on-off indicator test records for one year after the next required test is performed or until the sealed source is disposed of or transferred, whichever is shorter;
 - (D) retention of other records of tests required in Subparagraph (c)(3) of this Rule for two years from the date of the recorded test or until the device is disposed of or transferred.
- (5) upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie or more removable radioactive material, shall immediately suspend operation of the device until it has been:
- (A) repaired by the manufacturer or other person authorized to repair the device(s) by a specific license issued by the agency, the U.S. Nuclear Regulatory Commission, or an agreement state; or
 - (B) disposed of by transfer to a person authorized by a specific license to receive the radioactive material contained in the device; and within 30 days, furnish to the agency at the address in Rule .0111 of this Chapter a report containing a brief description of the event and the remedial action taken;
- (6) shall not abandon the device containing radioactive material;
- (7) except as provided in Subparagraph (c)(8) of this Rule, shall transfer or dispose of the device containing radioactive material only by transfer to a person holding a specific license authorizing receipt of the device; and, within 30 days after transfer of a device to a specific licensee, shall furnish to the agency at the address in Rule .0111 of this Chapter, identification of the device by manufacturer's name and model number and the name and address of the person receiving the device, except no report is required if the device is transferred to the specifically licensed manufacturer or distributor in order to obtain a replacement device;
- (8) shall transfer the device to another general licensee only where the device:
- (A) remains in use at a particular location.
 - (i) In this case the transferor shall give the transferee a copy of this Section and any safety documents identified in the label of the device;
 - (ii) The transferor shall, within 30 days of the transfer, report to the agency at the address in Rule .0111 of this Chapter, the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and position of an individual who may constitute a point of contact between the Commission and the transferee.
 - (B) is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee.
- (9) shall comply with the provisions of Sections .0100 and .1600 of this Chapter for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other

requirements of Section .1600 of this Chapter.

(d) The general license in Paragraph (a) of this Rule does not authorize the manufacture or distribution of devices containing radioactive material.

(e) The general license in Paragraph (a) of this Rule is subject to the provisions of Rules .0107 to .0111, .0303(a), .0337, .0342, .0343 and .0345 of this Chapter and to labeling requirements in Section .1600 of this Chapter.

*History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. January 1, 1994; June 1, 1989.*

.0310 GENERAL LICENSES: INSTALL GENERALLY LICENSED DEVICES

Any person who is authorized to manufacture, install or service a device described in Rule .0309 of this Section pursuant to a specific license issued by the agency, the U.S. Nuclear Regulatory Commission or an agreement state is hereby granted a general license to install and service the device described in Rule .0309, provided the following requirements are met:

- (1) The person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each report shall identify each general licensee, to whom the device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;
- (2) The device is manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to the person by the U.S. Nuclear Regulatory Commission or an agreement state;
- (3) The person shall assure that any labels satisfy the requirements in Rule .0309 of this Section and shall furnish to each general licensee, to whom he transfers a device or on whose premises he installs a device, a copy of the general license contained in Rule .0309 of this Section.

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

.0311 GENERAL LICENSES: LUMINOUS SAFETY DEVICES

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

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

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

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

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

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

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

.0312 GENERAL LICENSES: CALIBRATION AND REFERENCE

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

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

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

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

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

- (1) shall not possess at any one time, at any one location of storage or use, more than five microcuries of americium-241 and five microcuries of plutonium in the calibration and reference sources;
- (2) shall not receive, possess, use, or transfer a calibration or reference source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement:
The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

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

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

(Name of manufacturer or importer)

- (3) shall not transfer, abandon, or dispose of a calibration or reference source except by transfer to a person authorized by a license issued by the agency, the U.S. Nuclear Regulatory

- Commission, or an agreement state and authorizing receipt of the source;
- (4) shall store each source, except when being used, in a closed container adequately designed and constructed to contain americium-241 or plutonium which might otherwise escape during storage; and
 - (5) shall not use a calibration or reference source for any purpose other than the calibration of radiation detectors or the standardization of other sources.
- (e) The general licenses in Paragraphs (a) and (b) of this Rule do not authorize the manufacture or calibration of reference sources containing americium-241 or plutonium.

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

.0313 OWNERSHIP OF RADIOACTIVE MATERIAL

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

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

.0314 GENERAL LICENSES: IN VITRO CLINICAL OR LABORATORY TESTING

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

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

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

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

(c) A person who receives, acquires, possesses or uses radioactive material pursuant to the general

license established in Paragraph (a) of this Rule:

- (1) shall not possess at any one time, pursuant to the general license in Paragraph (a) of this Rule at any one location of storage or use a total amount of iodine-125, iodine-131, and iron-59 in excess of 200 microcuries;
 - (2) shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection;
 - (3) shall use the radioactive material only for the uses authorized in Paragraph (a) of this Rule;
 - (4) shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the agency, the U.S. Nuclear Regulatory Commission, or an agreement state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier; and
 - (5) shall dispose of the mock iodine-125 reference or calibration sources described in Subparagraph (a)(8) of this Rule as required by Rule .1628 of this Chapter.
- (d) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to Paragraph (a) of this Rule:
- (1) except as prepackaged units which are labeled in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, or an agreement state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, mock iodine-125 (of iodine-129 and americium-241), or iron-59 for distribution to persons generally licensed under Paragraph (a) of this Rule or its equivalent; and
 - (2) unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:
 - (A) This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories, or hospitals and only for IN VITRO clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals.
 - (B) Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the United States Nuclear Regulatory Commission, or, of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. (Name of Manufacturer).
- (e) The physician, clinical laboratory or hospital possessing or using radioactive material under the general license in Paragraph (a) of this Rule shall report in writing to the agency, any changes in the information furnished in the "Certificate IN VITRO Testing with Radioactive Material Under General License" agency form within 30 days after the effective date of the changes.
- (f) Any person using radioactive material pursuant to the general license in Paragraph (a) of this Rule is exempt from the requirements of Sections .1000 and .1600 of these Rules with respect to radioactive material covered by the general license. The new drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

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

.0315 GENERAL LICENSES: ICE DETECTION DEVICES

(a) A general license shall be issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries of strontium-90 and each device has been manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or in accordance with the specifications contained in a specific

license issued by the agency or an agreement state to the manufacturer of the device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.

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

- (1) shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an agreement state authorizing manufacture or servicing of the devices; or shall dispose of the device pursuant to the provisions of Rule .1628 of this Chapter;
- (2) shall assure that all labels affixed to the device at the time of receipt, and bearing a statement which prohibits removal of the labels, are maintained thereon; and
- (3) are exempt from the requirements of Sections .1000 and .1600 of this Chapter except that such persons shall comply with the provisions of Rules .1628, .1645 and .1646 of this Chapter.

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

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

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

.0316 GENERAL LICENSES: TRANSPORTATION

(a) Except for persons exempt from these Rules, a general license is hereby issued to any common, contract or other carrier to transport and store radioactive material in the regular course of their carriage for another or storage incident thereto; provided the transportation and storage is in accordance with the applicable requirements of the regulations appropriate to the mode of transport of the U.S. Department of Transportation in 49 CFR Part 170-189 and the U.S. Postal Service in the Postal Service Manual, (Domestic Mail Manual), Section 124.3; insofar as, such regulations relate to the packaging of radioactive material, marking and labeling of the package, loading and storage of packages, placarding of the transportation vehicle, monitoring requirements and accident reporting. Any common, contract or other carrier transporting nuclear waste or spent nuclear fuel under this general license shall comply with the provisions in Paragraph (c) of this Rule. Persons who transport and store radioactive material pursuant to the general license in this Paragraph are exempt from the requirements of Sections .1000 and .1600 of this Chapter.

(b) Except for persons exempt from these Rules, a general license is hereby issued to any private carrier to transport radioactive material; provided, the transportation is in accordance with the applicable requirements of the regulations, appropriate to the mode of transport of the U.S. Department of Transportation in 49 CFR Part 170-189 and the U.S. Postal Service in the Postal Service Manual, (Domestic Mail Manual), Section 124.3; insofar as, such regulations relate to the packaging, loading and storage of packages, placarding of the transportation vehicle, monitoring requirements and accident reporting. The following exemptions and requirements shall apply to transportation of radioactive material under this general license:

- (1) Persons who transport radioactive material pursuant to the license in Paragraph (b) of this Rule are exempt from the requirements in Sections .1000 and .1600 of this Chapter to the extent that they transport radioactive material. Any notification of incidents referred to in those requirements shall be filed with, or made to, the agency.
- (2) Physicians, as defined in Rule .0104 of this Chapter, are exempt from the requirements in Paragraph (b) of this Rule to the extent that they transport in their private vehicle radioactive

material for use in the practice of medicine.

- (3) Any person who transports nuclear waste within or through this state under this general license shall comply with the provisions in Paragraph (c) of this Rule.

(c) No carrier shall transport within or through this state any nuclear waste or spent nuclear fuel unless the shipper has notified the "governor's designee" in accordance with the requirements of 10 CFR Part 71.97 for nuclear waste and 10 CFR 73.37(f) for spent nuclear fuel. The governor's designee and contact information is as follows:

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

(d) As used in Paragraphs (a) through (c) of this Rule:

- (1) "Shipment" means any single vehicle carrying one or more containers of nuclear waste.
- (2) "Nuclear Waste" means:
 - (A) any quantity of radioactive material required by 10 CFR Part 71 to be in Type B packaging or subject to advance notification requirements of 10 CFR §§ 71.97 while transported within or through this state to a disposal site, or to a collection point for transport to a disposal site; or
 - (B) any quantity of irradiated fuel required by 10 CFR Part 71 to be in Type B packaging while transported within or through this state irrespective of destination if the quantity of irradiated fuel is less than that subject to advance notification requirements of 10 CFR Part 73.
- (3) "Spent Nuclear Fuel" means a quantity of irradiated reactor fuel in excess of 100 grams in net weight of irradiated fuel exclusive of cladding or other structural or packaging material which has a total external radiation dose rate in excess of 100 rems per hour at a distance of three feet from any accessible surface without intervening shielding.

*History Note: Authority G.S. 20-167.1; 104E-7; 104E-10(b); 104E-15(a); 150B-21.6;
Eff. February 1, 1980;
Amended Eff. January 1, 1994; May 1, 1992; October 1, 1982.*

.0317 SPECIFIC LICENSES: FILING APPLICATION AND GENERAL REQUIREMENT

(a) Applications for specific licenses shall be filed on an agency form. Completed applications shall include the following information and other information required by the agency form:

- (1) name, address and use location of the applicant;
- (2) training and experience of radioactive material users and of the person responsible for radiation protection;
- (3) types, quantities and uses of radioactive materials;
- (4) description of facilities, equipment and safety program;
- (5) procedures for disposal of radioactive material; and
- (6) how facility design and procedures for operation will minimize, to the extent practical, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practical, the generation of radioactive waste.

(b) The agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act on his behalf.

(d) An application for a license may include a request for a license authorizing one or more activities.

(e) Applications and documents submitted to the agency may be made available for public inspection except as may be determined otherwise by the agency pursuant to the provisions of G.S. 104E-9(4).

- (f) A license application shall be approved if the agency determines that:
- (1) the applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these Rules in such a manner as to minimize danger to public health and safety or property;
 - (2) the applicant's proposed equipment, facilities, and procedures are adequate to protect public health from radiation hazards and minimize radiological danger to life or property;
 - (3) the issuance of the license will not be inimical to the health and safety of the public; and
 - (4) the applicant satisfies any applicable special requirements in Rules .0318 to .0336 of this Section.

(g) As provided by Rule .0353 of this Section, certain applications for specific licenses filed under this Section must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning. In the case of renewal applications submitted before the effective date of this Rule, this submittal may follow the renewal application but must be submitted on or before the effective date of this Rule.

*History Note: Authority G.S. 104E-7; 104E-10(b); 104E-12; 104E-18;
Eff. February 1, 1980;
Amended Eff. April 1, 1999; May 1, 1992; November 1, 1989.*

.0318 SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE

- (a) License required:
- (1) A person shall not manufacture, produce, acquire, receive, possess, use or transfer radioactive material for medical use except in accordance with a specific license issued by the agency or as allowed pursuant to Subparagraphs (a)(2) and (a)(3) of this Rule.
 - (2) An individual may receive, possess, use, or transfer radioactive material in accordance with the rules of this Section under the supervision of an authorized user as provided in this Section unless prohibited by license condition.
 - (3) An individual may prepare unsealed radioactive material for medical use in accordance with the rules of this Section under the supervision of a pharmacist who is an authorized user or physician who is an authorized user as provided in this Section unless prohibited by license condition.
- (b) A license application for human use of radioactive material shall be approved if the agency determines that:
- (1) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these Rules;
 - (2) The applicant's proposed equipment, facilities, and procedures are adequate to protect public health from radiation hazards and minimize radiological danger to life or property;
 - (3) The issuance of the license will not be inimical to the health and safety of the public;
 - (4) The following training and supervisory relationship are adhered to:
 - (A) the user of radioisotopes applied to humans for diagnostic, therapeutic, or investigational purposes shall be a physician authorized by a condition of a specific license, including a specific license of broad scope.
 - (B) An authorized physician may delegate only to persons who are physicians under the supervision of the authorized physician, the following:
 - (i) the approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radioisotope sources;
 - (ii) the prescription of the radiopharmaceutical or source of radiation and the dose or exposure to be administered;
 - (iii) the determination of the route of administration;

- (iv) the interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered;
- (C) The authorized physician shall review the work of the supervised individual as it pertains to the delegated work in Subparagraph (b)(4) of this Rule and the records kept reflecting that work.
- (5) the applicant satisfies any applicable special requirements in Rules .0319 to .0322 of this Section.
- (c) Subject to the provisions of Subparagraph (b)(4) and Paragraphs (d) to (g) of this Rule, an authorized physician may permit technicians and other paramedic personnel to perform the following activities:
 - (1) preparation and quality control testing of radiopharmaceuticals and sources of radiation;
 - (2) measurement of radiopharmaceutical doses prior to administration;
 - (3) use of appropriate instrumentation for the collection of data to be used by the physician;
 - (4) administration of radiopharmaceuticals and radiation from radioisotope sources to patients.
- (d) Authorized physicians who permit activities to be performed by technicians and other paramedical personnel pursuant to Paragraph (c) of this Rule shall:
 - (1) prior to giving permission, determine that the technicians and other paramedical personnel have been properly trained to perform their duties with specific training in the following subjects, as applicable to the duties assigned:
 - (A) general characteristics of radiation and radioactive materials;
 - (B) physical, chemical, and pharmaceutical characteristics of each radiopharmaceutical to be used;
 - (C) mathematics and calculations basic to the use and measurement of radioactivity, including units of radiation dose and radiation exposure;
 - (D) use of radiation instrumentation for measurements and monitoring including operating procedures, calibration of instruments, and limitations of instruments;
 - (E) principles and practices of radiation protection;
 - (F) additional training in the above subjects, as appropriate, when new duties are added.
 - (2) assure that the technicians and other paramedical personnel receive appropriate retraining in the subjects listed in Subparagraph (d)(1) of this Rule to maintain proficiency and to keep abreast of developments in the field of nuclear medical technology;
 - (3) keep records showing the bases for the determinations of proper training;
 - (4) retain responsibility as licensee or authorized user for the satisfactory performance of the activities; and
 - (5) review the work of the supervised individual and the records kept reflecting that work.
- (e) Certification in nuclear medicine technology by the American Registry of Radiologic Technologists or in nuclear medical technology by the Registry of Medical Technologists of the American Society of Clinical Pathologists or the Society of Nuclear Medicine shall be deemed to satisfy the training requirements in Subparagraphs (d)(1) and (2) of this Rule.
- (f) An applicant for a license or for amendment or renewal of a license shall state whether he desires to permit technicians or other paramedical personnel to perform activities pursuant to Paragraph (c) of this Rule and, if so, shall include in his application for license, license amendment, or license renewal a statement of the activities to be so performed and a description of an adequate program for training the personnel, including retraining as required to keep abreast of developments in technology, or for otherwise determining that the personnel are properly trained to perform their duties.
- (g) Whenever a technician or other paramedical person administers a radiopharmaceutical to a patient by injection, a physician shall be immediately accessible, but not necessarily a physician authorized by the agency to be a user of radioisotopes.
- (h) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized pharmacist as allowed by Subparagraph (a)(3) of this Rule shall:

- (1) instruct the supervised individual in the preparation of radioactive material for medical use and the principles of and procedures for radiation safety and in the licensee's written quality management program, as appropriate to that individual's use of radioactive material;
 - (2) require the supervised individual to follow the instructions given pursuant to Subparagraph (h)(1) of this Rule and to comply with the rules of this Chapter and license conditions; and
 - (3) require the supervising authorized pharmacist to periodically review the work of the supervised individual as it pertains to preparing radioactive material for medical use and the records kept to reflect that work.
- (i) A licensee shall appoint a Radiation Safety Officer (RSO) responsible for implementing the radiation safety program. The licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.
- (j) A licensee shall establish in writing the authority, duties and responsibilities of the Radiation Safety Officer.
- (k) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, and management prerogative to:
- (1) identify radiation safety problems;
 - (2) investigate radiation safety problems such as overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations, and other deviations from approved radiation safety practice and implement corrective actions as necessary;
 - (3) initiate, recommend or provide corrective actions for radiation safety problems;
 - (4) verify implementation of corrective actions; and
 - (5) retain records of items listed in Subparagraphs (k)(1) through (4) of this Rule.
- (l) For each individual receiving radiopharmaceutical therapy and hospitalized for compliance with Rule .0358 of this Section, a licensee shall:
- (1) provide a private room with a private sanitary facility;
 - (2) post the individual's door with a "Radioactive Materials" sign and note on the door or the individual's chart, where and how long visitors may stay in the individual's room;
 - (3) promptly, after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with Section .1600 of this Chapter; and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who performed the survey;
 - (4) either monitor material and items removed from the individual's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste; and
 - (5) Notify the Radiation Safety Officer and authorized user as soon as feasible if the individual has a medical emergency and immediately if the patient dies.

*History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. April 1, 1999; May 1, 1993; November 1, 1989.*

.0319 SPECIFIC LICENSES: HUMAN USE IN HOSPITALS

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

approved if:

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

*History Note: Authority G.S. 104E-7(2);
Eff. February 1, 1980;
Amended Eff. October 1, 1984.*

.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.

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

Eff. February 1, 1980;
Amended Eff. November 1, 1989.

.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 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, 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. April 1, 1999; May 1, 1993.*

.0322 SPECIFIC LICENSES: HUMAN USE OF SEALED SOURCES

(a) In addition to the requirements set forth in Rule .0318 or .0319 of this Section, a specific license for human use of sealed sources will be issued only if the applicant, or if the application is made by an institution, the individual user:

- (1) has specialized training in the diagnostic or therapeutic use or the experience equivalent to such training, and
 - (2) is a physician.
- (b) The licensee shall comply with the provisions of Section .0700 of this Chapter.

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

.0323 SPECIFIC LICENSES: SEALED SOURCES IN INDUSTRIAL RADIOGRAPHY

In addition to the requirements set forth in Rule .0317 of this Section, a specific license for use of sealed sources in industrial radiography shall be issued if:

- (1) The applicant has a program for training radiographers and radiographers' assistants to meet the requirements of this Rule and Rule .0510 of this Chapter and submits to the agency a schedule or description of such program which specifies the:
 - (a) initial training;
 - (b) periodic training;
 - (c) on-the-job training;
 - (d) means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with agency regulations and licensing requirements, and the operating and emergency procedures of the applicant; and
 - (e) means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant;
- (2) The applicant has established and submits to the agency satisfactory written operating and emergency procedures described in Rule .0513 of this Chapter;
- (3) The applicant has established and submits to the agency a description of its inspection program which is adequate to ensure that each radiographer and radiographer assistant follows the rules in this Chapter and the applicant's operating and emergency procedures.
- (4) The inspection program described in the applicant's procedures shall include:
 - (a) observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation at the intervals not to exceed six months; provided that, if a radiographer or a radiographer's assistant has not participated in a radiographic operation for more than six months since the last inspection, that individual's performance must be observed and recorded by a practical examination before the individual participates in a radiographic operation;
 - (b) in those operations where a single individual serves as both radiographer and Radiation Safety Officer, and performs all radiography operations, an inspection program is not required; and
 - (c) the retention of inspection records on the performance of radiographers or radiographers' assistants for three years;
- (5) The applicant submits to the agency a description of his overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program;
- (6) The applicant who desires to conduct his own leak tests has established procedures to be followed in leak testing sealed sources for possible leakage and contamination sufficient to detect 0.005 microcuries of removable contamination on the source, and submits to the agency a description of the procedures, including:
 - (a) instrumentation to be used;
 - (b) method of performing tests, e.g., points on equipment to be tested and method of taking tests; and
 - (c) pertinent experience of the person who will perform the test; and
- (7) The licensee conducts a program for inspection and maintenance of radiographic exposure devices and storage containers to assure proper functioning of components important to safety.

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

*Eff. February 1, 1980;
Amended Eff. April 1, 1999; June 1, 1989.*

.0324 SPECIFIC LICENSES: BROAD SCOPE

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

- (1) the applicant has engaged in a wide variety of activities involving the use of many different types of radioactive material in a variety of physical and chemical forms; and
- (2) the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:
 - (A) the establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;
 - (B) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety measures; and
 - (C) the establishment of appropriate administrative procedures to assure:
 - (i) control of procurement and use of radioactive material;
 - (ii) completion of safety evaluations of proposed uses of radioactive material which takes into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and
 - (iii) review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with Part (a)(2)(C) of this Rule prior to use of the radioactive material.
- (3) Unless specifically authorized pursuant to other rules of this Section, persons licensed under this Rule shall not:
 - (A) conduct tracer studies in the environment involving direct release of radioactive material;
 - (B) receive, acquire, own, possess, use, or transfer devices containing 100,000 curies or more of byproduct material in sealed sources used for irradiation of materials;
 - (C) conduct activities for which a specific license issued by the agency under the rules of this Section is required; or
 - (D) add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.
- (4) Each specific license of broad scope issued under this Rule shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

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

- (1) the applicant has appointed a radiation safety committee as required in Part (a)(2)(A) of this Rule, except that this committee shall evaluate all proposals for research, diagnostic and therapeutic use of radioactive material within the medical facility;
- (2) membership of the committee consists of physicians specializing in nuclear medicine, diagnostic radiology, clinical pathology, and a pharmacist specializing in radiopharmacy, someone competent in radiation safety and a representative of the hospital management; and
- (3) the applicant for a medical radioactive materials license of broad scope has an ongoing teaching program with interns and residents associated with a four-year medical school.

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

Amended Eff. June 1, 1993.

.0325 SPECIFIC LICENSES: PRODUCTS WITH EXEMPT CONCENTRATIONS

(a) In addition to the requirements set forth in Rule .0317 of this Section, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under Rule .0303(b) of this Section will be issued if:

- (1) the applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and
- (2) the applicant provides a detailed analysis which demonstrates that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being, use of lower concentration is not feasible and that the concentrations of radioactive material at the time of transfer, or that reconcentration of the radioactive material, will not exceed the concentrations listed in the table in Rule .0303(b) of this Section.
 - (A) Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in the table in Rule .0303(b) of this Section, the activity stated is that of the parent isotope and takes into account the daughters.
 - (B) Values are given in Column I of the table in Rule .0303(b) of this Section, only for those materials normally used as gases.
 - (C) For purposes of this Rule where there is involved a combination of isotopes, the limit for the combination shall be derived as follows:
 - (i) Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in the table in Rule .0303(b) of this Section for the specific isotope when not in combination.
 - (ii) The sum of these ratios shall not exceed unity.

Example:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} \text{ less than or equal to } 1$$

(b) Each person licensed under Paragraph (a) of this Rule shall file with the agency an annual report which shall identify:

- (1) the type and quantity of each product or material into which radioactive material has been introduced during the reporting period;
- (2) name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction;
- (3) the type and quantity of radionuclide introduced into each such product or material; and
- (4) the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee.

If no transfers of radioactive material have been made pursuant to Paragraph (a) of this Rule during the reporting period, the report shall so indicate. The report shall cover the 12-month period ending June

30, and shall be filed within 30 days thereafter.

*History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. June 1, 1993.*

.0326 SPECIFIC LICENSES: EXEMPT DISTRIBUTION

(a) An application for a specific license to distribute radioactive material other than source, byproduct or special nuclear material to persons exempt from these Rules pursuant to Rule .0304(e) of this Section will be approved if:

- (1) The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;
- (2) The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and
- (3) The applicant submits copies of prototype labels and brochures and the agency approves their labels and brochures.

(b) The license issued pursuant to this Rule is subject to the following conditions:

- (1) No more than ten exempt quantities shall be sold or transferred in any single transaction. An exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fraction shall not exceed unity.
- (2) Each exempt quantity shall be separately and individually packaged. No more than ten packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to Rule .0304(e) of this Section. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.
- (3) The immediate container of each quantity of separately packaged fractional quantity of radioactive material shall bear the words "Radioactive Material".
- (4) In addition to the labeling information required by Subparagraph (b)(3) of this Rule, the label affixed to the immediate container, or an accompanying brochure, shall:
 - (A) state that the contents are exempt from U.S. Nuclear Regulatory Commission or agreement state requirements;
 - (B) contain the following statements:
 - (i) Radioactive material;
 - (ii) Not for human use;
 - (iii) Introduction into foods, beverages, cosmetics, drugs, or medicinals, or into products manufactured for commercial distribution is prohibited;
 - (iv) Exempt quantities should not be combined.
 - (C) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

(c) Each person licensed under Paragraph (a) of this Rule shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under Rule .0304(e) of this Section or the equivalent regulations of an agreement state, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the agency. Each report shall cover the 12 month period ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to this Rule during the reporting period, the report shall so indicate.

(d) Authority to transfer possession or control by the manufacturer, processor, or producer of any

equipment, device, commodity, or other product containing source or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

*History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. May 1, 1993.*

.0327 SPECIFIC LICENSES: EXEMPT GAS AND AEROSOL DETECTORS

An application for a specific license authorizing the incorporation of radioactive material other than source material into gas and aerosol detectors to be distributed to persons exempt under Rule .0305(d) of this Section will be approved if the application satisfies requirements contained in Section 32.26 of 10 CFR Part 32 for source and byproduct material.

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

.0328 SPECIFIC LICENSES: MANUFACTURE DEVICES TO PERSONS LICENSED

(a) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under Rule .0309 of this Section or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state will be approved if:

- (1) the applicant satisfies the general requirements of Rule .0317 of this Section;
- (2) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:
 - (A) the device can be safely operated by persons not having training in radiological protection;
 - (B) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar quarter a dose in excess of ten percent of the limits specified in the table of Rule .1604 of this Chapter;
 - (C) under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:
 - (i) whole body, head and trunk, active blood-forming organs, gonads, or lens of eye: 15 rems;
 - (ii) hands and forearms, feet and ankles, localized areas of skin averaged over areas no larger than one square centimeter: 200 rems;
 - (iii) other organs: 50 rems.
- (3) each device bears a durable, legible, clearly visible label or labels approved by the agency, which contain in a clearly identified and separate statement:
 - (A) instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);
 - (B) the requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of

- determination of the quantity; and
- (C) the information called for in the following statement in the same or substantially similar form: "The receipt, possession, use, and transfer of this device Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an agreement state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited."

CAUTION - RADIOACTIVE MATERIAL

(name of manufacturer or distributor)

- (4) the model, serial number, and name of manufacturer or distributor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.
- (b) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the agency will consider information which includes, but is not limited to:
- (1) primary containment (source capsule);
 - (2) protection of primary containment;
 - (3) method of sealing containment;
 - (4) containment construction materials;
 - (5) form of contained radioactive material;
 - (6) maximum temperature withstood during prototype test;
 - (7) maximum pressure withstood during prototype tests;
 - (8) maximum quantity of contained radioactive material;
 - (9) radiotoxicity of contained radioactive material; and
 - (10) operating experience with identical devices or similarly designed and constructed devices.
- (c) In the event the applicant desires that the general licensee under Rule .0309 of this Section, or under equivalent regulations of the U.S. Nuclear Regulatory Commission, or an agreement state, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, he shall include in his application:
- (1) Written instructions to be followed by the general licensee;
 - (2) Estimated calendar quarter doses associated with such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage and use of devices under the general license; and
 - (3) information to demonstrate that performance of such activity(ies) is unlikely to cause that individual to receive a calendar quarter dose in excess of ten percent of the limits specified in Rule .1604 of this Chapter.
- (d) Each person licensed under this Rule to distribute devices shall furnish a copy of the general license contained in Section 31.5 of 10 CFR Part 31 to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in Rule .0309 of this Section, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state. The copy of Section 31.5 of 10 CFR Part 31 shall be accompanied by a note explaining that the use of the device is regulated by agreement states under requirements substantially the same as those in Section 31.5 of 10 CFR Part 31. Alternatively, when transferring the devices to persons in a specific agreement state, a copy of that agreement state's equivalent regulations shall be furnished.

(e) Each person, licensed under this Rule to distribute devices, shall report to the agencies specified in Subparagraphs (e)(1), (2) and (3) of this Rule all transfers of the devices to persons generally licensed under the rules of those agencies. Such reports shall identify each general licensee by name and address, an individual by name or position who may constitute a contact with the general licensee, the type and model number of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the reports shall include identification of each intermediate person by name, address, contact and relationship to the intended user. If no transfers have been made to generally licensed persons during the reporting period, the reports shall so indicate. The reports shall cover each calendar quarter and shall be filed within 30 days thereafter. The reports shall be submitted to:

- (1) the agency for devices transferred to persons generally licensed under Rule .0309 of this Section;
- (2) each agreement state for devices transferred to persons generally licensed under rules equivalent to Rule .0309 of this Section; and
- (3) the U.S. Nuclear Regulatory Commission for devices transferred to persons generally licensed under Section 31.5 of 10 CFR Part 31.

(f) Each person, licensed under this Rule to distribute devices, shall maintain for agency inspection either copies of all reports required in Paragraph (e) of this Rule or a record containing substantially the same information. Such copies or records of transfer shall be maintained for at least five years after the date of each transfer of a device to a generally licensed person.

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

.0329 SPECIFIC LICENSES: LUMINOUS SAFETY DEVICES IN AIRCRAFT

An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under Rule .0311 of this Section will be approved subject to the following conditions:

- (1) the applicant satisfies the general requirements specified in Rule .0317 of this Section; and
- (2) the applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.56, and 32.101 of 10 CFR Part 32 or their equivalent.

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

.0330 SPECIFIC LICENSES: MANUFACTURE OF CALIBRATION SOURCES

An application for a specific license to manufacture calibration sources containing americium-241 and plutonium for distribution to persons generally licensed under Rule .0312 of this Section will be approved subject to the following conditions:

- (1) the applicant satisfies the general requirements of Rule .0317 of this Section; and
- (2) the applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, 32.60 and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.

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

.0331 SPECIFIC LICENSES-MANUFACTURE OF IN VITRO TEST KITS

An application for a specific license to manufacture or distribute radioactive material for use under the

general license in Rule .0314 of this Section will be approved if the following requirements are satisfied:

- (1) The applicant satisfies the general requirements specified in Rule .0317 of this Section.
- (2) The radioactive material is to be prepared for distribution in prepackaged units of:
 - (a) iodine-125 in units not exceeding ten microcuries each;
 - (b) iodine-131 in units not exceeding ten microcuries each;
 - (c) carbon-14 in units not exceeding ten microcuries each;
 - (d) hydrogen-3 (tritium) in units not exceeding 50 microcuries each;
 - (e) iron-59 in units not to exceed 20 microcuries each;
 - (f) cobalt-57 in units not to exceed ten microcuries each;
 - (g) selenium-75 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.
- (3) Each prepackaged unit bears a durable, clearly visible label:
 - (a) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed the appropriate limit in Item (2) of this Rule, and
 - (b) displaying the radiation caution symbol described in Rule .1623 of this Chapter and the words, "CAUTION, RADIOACTIVE MATERIAL", and "NOT FOR INTERNAL OR EXTERNAL USE IN HUMANS OR ANIMALS".
- (4) The following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories or hospitals and only for IN VITRO clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or a state with which the Commission has entered into an agreement for the exercise of regulatory authority. (Name of Manufacturer)
- (5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in Rule .1628 of this Chapter.

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

.0332 SPECIFIC LICENSES: MANUFACTURE OF ICE DETECTOR DEVICES

An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under Rule .0315 of this Section will be approved subject to the following conditions:

- (1) the applicant satisfies the general requirements of Rule .0317 of this Section, and
- (2) the applicant satisfies the requirements of Sections 32.61, 32.62, 32.63 and 32.103 of 10 CFR Part 32 or their equivalent.

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

.0333 SPECIFIC LICENSES: MANUFACTURE OF RADIOPHARMACEUTICALS

An application for a specific license to manufacture and distribute radiopharmaceuticals containing

radioactive material for use by persons licensed pursuant to Rule .0321 of this Section for the radiopharmaceuticals and associated uses in Groups I, II or IV will be approved subject to the following conditions:

- (1) the applicant satisfies the general requirements of Rule .0317 of this Section, and
- (2) the applicant satisfies the applicable requirements in Section 32.72 of 10 CFR Part 32 or their equivalent.

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

.0334 SPECIFIC LICENSES: GENERATORS AND REAGENT KITS

An application for a specific license to manufacture and distribute generators and reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to Rule .0321 of this Section for the generators, reagent kits and associated uses in Group III will be approved subject to the following conditions:

- (1) the applicant satisfies the general requirements of Rule .0317 of this Section, and
- (2) the applicant satisfies the applicable requirements in Section 32.73 of 10 CFR Part 32 or their equivalent.

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

.0335 SPECIFIC LICENSES: PRODUCTS CONTAINING DEPLETED URANIUM

(a) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to Rule .0307(e) of this Section or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state will be approved if:

- (1) the applicant satisfies the general requirements specified in Rule .0317 of this Section;
- (2) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of ten percent of the limits specified in Rule .1604 of this Chapter; and
- (3) the applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(b) In the case of an industrial product or device whose unique benefits are questionable, the agency will approve an application for a specific license under this Rule only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(c) The agency may deny any application for a specific license under this Rule if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(d) Each person licensed pursuant to Paragraph (a) of this Rule shall:

- (1) maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;
- (2) label or mark each unit to:
 - (A) identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or

- device; and
- (B) state that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of an agreement state.
- (3) assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";
- (e) Each person, licensed under this Rule to distribute devices, shall furnish a copy of the general license contained in Section 40.25 of 10 CFR Part 40 to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in Rule .0307(e) of this Section, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state. The copy of Section 40.25 of 10 CFR Part 40 shall be accompanied by a note explaining that the use of the device is regulated by agreement states under requirements substantially the same as those in Section 40.25 of 10 CFR Part 40. Alternatively, when transferring the devices to persons in a specific agreement state, a copy of that agreement state equivalent regulations shall be furnished.
- (f) Each person, licensed under this Rule to distribute devices, shall report to the agencies specified in Subparagraphs (f)(1),(2) and (3) of this Rule all transfers of the devices to persons generally licensed under the rules of those agencies. Such reports shall identify each general licensee by name and address, an individual by name or position who may constitute a contact with the general licensee, the type and model number of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the reports shall include identification of each intermediate person by name, address, contact and relationship to the intended user. If no transfers have been made to generally licensed persons during the reporting period, the reports shall so indicate. The reports shall cover each calendar quarter and shall be filed within 30 days thereafter. The reports shall be submitted to:
- (1) the agency for devices transferred to persons generally licensed under Rule .0307(e) of this Section;
 - (2) each agreement state for devices transferred to persons generally licensed under rules equivalent to Rule .0307(e) of this Section; and
 - (3) the U.S. Nuclear Regulatory Commission for devices transferred to persons generally licensed under Section 40.25 of 10 CFR Part 40.
- (g) Each person, licensed under this Rule to distribute devices, shall maintain for agency inspection either copies of all reports required in Paragraph (f) of this Rule or a record containing substantially the same information. Such copies or records of transfer shall be maintained for at least five years after the date of each transfer of a device to a generally licensed person.

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

.0336 COPIES OF APPLICABLE FEDERAL REGULATIONS

*History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Repealed Eff. May 1, 1993.*

.0337 ISSUANCE OF SPECIFIC LICENSES

- (a) Upon a determination that an application meets the requirements of the Act and the rules of this

Section, the agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(b) The agency may amend any license, when not in conflict with any law, to waive any requirement in these Rules or to impose additional requirements in accordance with 46 FR 7540, with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to the rules in this Chapter as it deems appropriate or necessary in order to:

- (1) minimize danger to public health and safety or property;
- (2) require such reports and the keeping of such records, and provide for such inspections of activities under the license as may be appropriate or necessary; and
- (3) prevent loss or theft of radioactive material subject to this Section.

*History Note: Authority G.S. 104E-7; 104E-10(b); 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540;
Eff. February 1, 1980;
Amended Eff. June 1, 1993.*

.0338 SPECIFIC TERMS AND CONDITIONS OF LICENSES

(a) Each license issued pursuant to the rules in this Section shall be subject to all the provisions of the Act, now or hereafter in effect, to all rules adopted pursuant to provisions of the Act and to orders of the agency.

(b) No license issued or granted pursuant to this Section and no right to possess or utilize radioactive material granted by any license issued pursuant to this Section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the agency, after securing full information, finds that the transfer is in accordance with the provisions of the Act, and gives its consent in writing.

(c) Each person licensed by the agency pursuant to this Section shall confine his use and possession of the radioactive material licensed to the locations and purposes authorized in the license.

(d) Each licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

- (1) licensee;
- (2) an entity [as that term is defined in 11 U.S.C. 101(14)] controlling the licensee or listing the license or licensee as property of the estate; or
- (3) an affiliate [as that term is defined in 11 U.S.C. 101(2)] of the licensee.

(e) The notification in Paragraph (d) of this Rule shall indicate:

- (1) the bankruptcy court in which the petition for bankruptcy was filed; and
- (2) the date of the filing of the petition.

(f) Licensees required to submit emergency plans pursuant to Rule .0352 of this Section shall follow the emergency plan approved by the agency. The licensees may change the approved plan without agency approval only if the licensee believes the changes do not decrease the effectiveness of the plan and are submitted to the agency no later than 20 calendar days after the changes are made. The licensee shall furnish the change to affected off-site response organizations within six months after the change is made. Proposed changes that the licensee believes are likely to decrease, or may potentially decrease, the effectiveness of the approved emergency plan shall not be implemented without prior application to and prior approval by the agency.

*History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. May 1, 1993; May 1, 1992; June 1, 1989.*

.0339 EXPIRATION AND TERMINATION OF LICENSES & DECOMMISSIONING

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

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

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

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

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

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

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

- (1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this Rule becomes effective.
- (2) Following agency approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the agency.

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

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

- (1) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;
- (2) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;
- (3) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or
- (4) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation. For the purpose of Subparagraphs (g)(2)-(4) of this Rule, significantly higher or significantly greater is defined as an increase likely to result in either an increase in radiation exposure to workers or the public in excess of one percent of their respective annual radiation exposure limit.

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

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

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

- (1) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;
- (2) A description of planned decommissioning activities;
- (3) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;
- (4) A description of the planned final radiation survey;
- (5) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning; and
- (6) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in Paragraph (m) of this Rule.

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

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

(m) The agency may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the agency determines that the alternative is warranted by consideration of the following:

- (1) Whether it is technically feasible to complete decommissioning within the allotted 24 month period;
- (2) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24 month period;
- (3) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;
- (4) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and
- (5) Other site-specific factors which the agency may consider appropriate on a case-by-case basis,

such as:

- (A) regulatory requirements of other government agencies;
 - (B) lawsuits;
 - (C) ground-water treatment activities;
 - (D) monitored natural ground-water restoration;
 - (E) actions that could result in more environmental harm than deferred cleanup; and
 - (F) other factors beyond the control of the licensee.
- (n) As the final step in decommissioning, the licensee shall:
- (1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed "Certificate of Disposition"; and
 - (2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner. The licensee shall, as appropriate:
 - (A) Report levels of gamma radiation in units of microrem (millisieverts) per hour at one meter from surfaces;
 - (B) Report levels of radioactivity, including alpha and beta, in units of microcuries per 100 square centimeters (or disintegrations per minute), removable and fixed, for surfaces; microcuries per milliliter for water; and picocuries per gram for solids such as soils or concrete; and
 - (C) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.
- (o) Specific licenses shall be terminated by written notice to the licensee when the agency determines that:
- (1) radioactive material has been properly disposed;
 - (2) reasonable effort has been made to eliminate residual radioactive contamination, if present; and
 - (3) a radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the requirements for decommissioning described in Rule .1653 of this Chapter, or other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the requirements for decommissioning described in Rule .1653 of this Chapter.

*History Note: Authority G.S. 104E-7; 104E-10(b); 104E-18;
Eff. February 1, 1980;
Amended Eff. April 1, 1999; August 1, 1998; May 1, 1992.*

.0340 RENEWAL OF LICENSES

Applications for renewal of specific licenses shall be filed in accordance with Rule .0317 of this Section.

*History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. August 1, 1998.*

.0341 AMENDMENT OF LICENSES AT REQUEST OF LICENSEE

Applications for amendment of a license shall be filed in accordance with Rule .0317 of this Section and shall specify the respects in which the licensee desires his license to be amended and the grounds for such amendment. The applicant shall submit such other supporting information as required by the agency.

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

.0342 AGENCY ACTION ON APPLICATIONS TO RENEW OR AMEND

In considering an application by a licensee to renew or amend his license, the agency shall apply the criteria set forth in the applicable rules of this Section.

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

.0343 TRANSFER OF MATERIAL

- (a) No licensee shall transfer radioactive material except as authorized pursuant to this Section.
- (b) Except as otherwise provided in his license and subject to the provisions of Paragraphs (c), (d) and (e) of this Rule any licensee may transfer radioactive material to:
 - (1) the agency;
 - (2) the U.S. Department of Energy;
 - (3) any person exempt from the rules in this Section to the extent permitted under the exemption;
 - (4) any person authorized to receive the radioactive material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the agency, the U.S. Nuclear Regulatory Commission, or an agreement state, or any person otherwise authorized to receive the radioactive material by the federal government or any agency thereof, the agency, or an agreement state; or
 - (5) as otherwise authorized by the agency in writing.
- (c) A licensee may transfer material to the agency only after receiving prior approval from the agency.
- (d) Before transferring radioactive material to a specific licensee of the agency, the U.S. Nuclear Regulatory Commission, or an agreement state, or to a general licensee who is required to register with the agency, the U.S. Nuclear Regulatory Commission, or an agreement state prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.
- (e) The following methods for the verification required by Paragraph (d) of this Rule are acceptable:
 - (1) The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;
 - (2) The transferor may have in his possession a written certificate by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;
 - (3) For emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided the oral certification is confirmed in writing within 10 days after the date of the oral certification;
 - (4) The transferor may obtain other sources of information compiled by a reporting service from official records of the agency, the U.S. Nuclear Regulatory Commission, or the licensing agency of an agreement state as to the identity of licensees and the scope and expiration dates of licenses and registration; or
 - (5) When none of the methods of verification described in this Rule are readily available or when a transferor desires to verify that information received by one of the methods is correct or updated, the transferor may obtain and record confirmation from the agency, the U.S. Nuclear Regulatory Commission, or the licensing agency of an agreement state that the transferee is licensed to receive the radioactive material.

(f) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of Rule .0346 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-10(b);
Eff. February 1, 1980;
Amended Eff. May 1, 1995; May 1, 1993; June 1, 1989.

.0344 MODIFICATION: REVOCATION: AND TERMINATION OF LICENSES

(a) The terms and conditions of all licenses are subject to amendment, revision or modification and all licenses are subject to suspension or revocation by reason of:

- (1) amendments to the Act,
- (2) rules adopted pursuant to provisions of the Act, or
- (3) orders issued by the agency pursuant to provisions of the Act and rules adopted pursuant to provisions of the Act.

(b) Any license may be revoked, suspended, or modified, in whole or in part:

- (1) for any material false statement in the application or in any statement of fact required by provisions of this Section;
- (2) because of conditions which would warrant the agency to refuse to grant a license or an original application revealed by:
 - (A) the application;
 - (B) any statement of fact;
 - (C) any report, record, inspection or other means; or
- (3) for violation of, or failure to observe any of the terms and conditions of the Act, the license, the rules of this Chapter, or order of the agency.

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, prior to the institution of proceedings for modification, revocation, or suspension of a license, the agency shall:

- (1) call to the attention of the licensee in writing the facts or conduct which may warrant these actions, and
- (2) provide an opportunity for the licensee to demonstrate or achieve compliance with all lawful requirements.

(d) The agency may terminate a specific license upon request submitted by the licensee to the agency in writing.

History Note: Authority G.S. 104E-7; 104E-10(b); 104E-13;
Eff. February 1, 1980;
Amended Eff. June 1, 1993.

.0345 RECIPROCAL RECOGNITION OF LICENSES

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

- (1) The licensing document does not limit the activity authorized by such document to specified installations or locations;
- (2) The out-of-state licensee notifies the agency in writing at least three days prior to engaging in

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

- (3) The out-of-state licensee complies with all applicable rules of the agency and with all the terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the agency;
- (4) The out-of-state licensee supplies such other information as the agency may request; and
- (5) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this Rule except by transfer to a person:
 - (A) specifically licensed by the agency or by the U.S. Nuclear Regulatory Commission to receive the material, or
 - (B) exempt from the requirements for a license for the material under Rule .0303 of this Section.

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

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

*History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. June 1, 1993.*

.0346 PREPARATION OF RADIOACTIVE MATERIAL FOR TRANSPORT

(a) No licensee shall deliver any radioactive material to a carrier for transport, unless:

- (1) The licensee complies with the applicable requirements of the regulations, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such regulations relate to the packing of radioactive material, and to the monitoring, marking and labeling of those packages;
- (2) The licensee has established procedures for opening and closing packages in which radioactive material is transported to provide safety and to assure that, prior to the delivery to a carrier for transport, each package is properly closed for transport; and
- (3) Prior to delivery of a package to a carrier for transport, the licensee shall assure that any special instructions needed to safely open the package are sent to, or have been available to the consignee.

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

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

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

information:

- (1) the name, address, and telephone number of the shipper, carrier and receiver of the shipment;
- (2) a description of the nuclear waste contained in the shipment as required by the regulations of the U.S. Department of Transportation in 49 CFR 172.202 and 172.203(d);
- (3) the point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;
- (4) the seven-day period during which arrival of the shipment at state boundaries is estimated to occur;
- (5) the destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and
- (6) a point of contact with a telephone number for current shipment information.

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

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

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

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

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

*History Note: Authority G.S. 104E-7; 104E-10(b); 104E-15(a);
Eff. February 1, 1980;
Amended Eff. May 1, 1993; November 1, 1989; October 1, 1982.*

.0347 SECURITY REQUIREMENTS

*History Note: Authority G.S. 104E-18;
Eff. February 1, 1980;
Repealed Eff. May 1, 1992.*

.0348 SPECIFIC LICENSES: CERTAIN INCINERATOR FACILITIES

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

- (1) description of the applicant:

- (A) the company or corporate structure with the names, addresses and titles of officers;
 - (B) present products and activities;
 - (C) prior experience in the use, processing and disposal of radioactive material;
 - (D) financial and technical ability to construct, operate and decommission the proposed radioactive waste processing facility;
- (2) description of the site:
- (A) physical location and general description to include nearest buildings, residences, schools, hospitals, etc.;
 - (B) populations and land use in the general area to include nearest buildings, residences, schools, hospitals, etc.;
 - (C) geological and hydrological characterization of the site to include soil type, topography, past and projected seismic activity, groundwater, aquifers and surface waters;
 - (D) meteorology to include climate, distribution of wind speed and direction, atmospheric stability and dispersion characteristics, and data on precipitation, floods, hurricanes and tornados;
 - (E) background radiation and radioactivity;
 - (F) transportation routes;
- (3) incinerator design:
- (A) general description;
 - (B) manufacturer, basis for selecting the proposed incinerator design and identification of operating incinerators of the same or similar design;
 - (C) maximum capacity, minimum chamber temperatures, minimum chamber residence times, residual ash collection and effluent controls (e.g., scrubber filters and stack);
 - (D) decontamination, maintenance and anticipated operating life;
 - (E) waste handling, storage and injection systems;
 - (F) instrumentation and controls;
 - (G) minimum performance specifications for the incinerator and effluent control systems, and preoperational testing/certification program;
- (4) facility design:
- (A) compartmentalization/zoning, waste storage and handling areas, waste flow, ventilation and contamination control/containment;
 - (B) sanitary sewer, drains, holdup systems, showers and other liquid handling systems;
- (5) management and staffing:
- (A) structure of facility organization showing line configuration of the radiation safety officer;
 - (B) qualifications of management, supervisory and safety personnel;
 - (C) staff training program;
- (6) description of waste:
- (A) general chemical, physical and radiological properties;
 - (B) maximum quantity of each radionuclide to be incinerated per year;
 - (C) maximum quantity of each radionuclide to be stored on-site at any one time;
 - (D) maximum quantity of each toxic or hazardous constituent of the waste to be incinerated per year;
 - (E) maximum quantity of each toxic or hazardous constituent of the waste to be stored on-site at any one time;
 - (F) acceptance and rejection criteria for waste to be received for incineration;
- (7) treatment of waste to be shipped off-site:
- (A) classification;
 - (B) immobilization;
 - (C) packaging;
 - (D) storage;

- (E) shipment;
- (F) disposal;
- (G) processing and disposal of ash;
- (8) preclicensing and operational public information program:
 - (A) state and local government;
 - (B) media and public;
- (9) plan for maintaining radiation exposures and releases of radioactivity as low as reasonably achievable (ALARA):
 - (A) procedures, systems and criteria to maintain whole body, thyroid, and other organ radiation doses of the off-site public as low as reasonably achievable below the limits stated in Section .1600 of this Chapter;
 - (B) procedures, systems and criteria to maintain whole body, thyroid, and other organ radiation doses of on-site personnel as low as reasonably achievable below the limits established in Section .1600 of this Chapter;
- (10) off-site impact assessment for routine operation:
 - (A) maximum quantity and concentration of each radionuclide and toxic or hazardous constituent of the waste released annually to the air, to the water and to the soil;
 - (B) maximum radiation doses to off-site populations to include dose to the nearest resident, a description of computational models, sample computations and a summary of any previous experience;
 - (C) maximum off-site radionuclide concentrations in air, soil, water and food;
- (11) monitoring programs and systems:
 - (A) analytical and portable monitoring equipment for radiological and chemical measurements;
 - (B) inspection, monitoring and analysis of waste containers and waste prior to incineration;
 - (C) alarms, area monitors, stack/effluent monitors and facility shutdown mechanisms to include action levels, reset and restart procedures and criteria;
 - (D) personnel monitoring and bioassay;
 - (E) preoperational environmental monitoring;
 - (F) operational environmental monitoring, to include, if available, a copy of the last environmental monitoring report filed with the U.S. Nuclear Regulatory Commission or agreement state program;
- (12) other rules, standards and permits:
 - (A) federal, state and local regulations and standards which will apply to the proposed facility or would apply to the facility in the absence of the radioactive content of the waste;
 - (B) other permits which are required to include the current status of applications for and issuance of such permits;
- (13) accident analysis:
 - (A) identification of accident modes;
 - (B) major credible accidents and projected potential off-site impacts;
 - (C) mitigation of accidents and protection of the public;
- (14) emergency response plan:
 - (A) on-site response;
 - (B) local and county;
 - (C) state and regional;
 - (D) training and public information;
 - (E) if available, copies of most current emergency response plans submitted to the U.S. Nuclear Regulatory Commission or an agreement state;
- (15) decontamination and decommissioning:
 - (A) schedule;

- (B) procedure;
- (C) radioactive waste disposal plan.

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

*History Note: Authority G.S. 104E-7(2); 104E-7(a)(8); 104E-10(b);
Eff. October 1, 1984;
Amended Eff. January 1, 1994.*

.0349 EXEMPTIONS: WASTE MANAGEMENT BY GENERATORS

(a) Subject to the limitations in Paragraphs (b) and (c) of this Rule, any licensee is exempt from the provisions of G.S. 104E-6.1, G.S. 104E-10.1, G.S. 104E-20(b), G.S. 104E-25, and G.S. 104E-26 with respect to the following waste management practices:

- (1) storage of waste incidental to transfer to a licensed low-level radioactive waste facility authorized to receive such waste;
- (2) storage of waste to allow for total decay of contained radioactive material prior to disposal as nonradioactive waste;
- (3) storage of waste to allow for partial decay of contained radioactive material prior to disposal, incineration or other treatment; or
- (4) compaction, incineration, treatment, packaging or disposal of waste as provided in the rules in Section .1600 of this Chapter.

(b) Except as provided in Paragraph (c) of this Rule, the exemptions in Paragraph (a) of this Rule shall apply only to a licensee:

- (1) who possesses and uses radioactive material pursuant to specific licenses issued by the agency and only to management by the licensee of waste generated incidental to such possession and use;
- (2) who is determined by the agency to be using sound waste management practices;
- (3) who is determined by the agency to be managing such low volumes or activity of waste that such exemptions will not endanger the public health or safety or the environment; and
- (4) whose combined waste management activities do not cause a radiation dose to the off-site public in excess of the limits stated in Rule .1223 of this Chapter.

(c) The exemptions in Paragraph (a) of this Rule shall also apply to on-site disposal of waste by persons who generate waste pursuant to a license issued by the U.S. Nuclear Regulatory Commission, provided that:

- (1) the U.S. Nuclear Regulatory Commission determines that such on-site disposal is subject to regulation by the agency;
- (2) such persons satisfy the requirements in Subparagraphs (b)(2) and (b)(3) of this Rule;
- (3) such persons do not receive waste, generated by others or generated at other sites for the purpose of disposal;
- (4) such persons shall limit off-site dose to the public, resulting from all activities authorized by the agency and the U.S. Nuclear Regulatory Commission, to the limits stated in Rule .1223 of this Chapter or as prescribed by the U.S. Nuclear Regulatory Commission, 10 CFR Part 50 for U.S. Nuclear Regulatory Commission regulated activities, whichever is more restrictive;
- (5) such persons apply for and receive a specific radioactive material license, issued by the agency pursuant to the rules in this Section, which authorizes such disposal pursuant to Rule .1628 of this Chapter; and
- (6) such persons provide notification to the agency prior to each disposal made pursuant to any radioactive material license described in Subparagraph (c)(5) of this Rule.

History Note: Filed as a Temporary Amendment Eff. November 22, 1995, For a Period of 180 Days or

*Until the Permanent Rule Becomes Effective, Whichever is Sooner;
Authority G.S. 104E-7(a)(10);
Eff. June 1, 1989;
Amended Eff. May 1, 1996; January 1, 1994.*

.0350 RECORDS AND REPORTS OF MISADMINISTRATION

- (a) As defined in this Rule, "patient" means the patient or the patient's responsible relative or guardian.
- (b) For a misadministration as defined in Rule .0104 of this Chapter:
- (1) The licensee shall notify the agency by telephone no later than the next business day after discovery of the misadministration.
 - (2) Within 15 days after the discovery of the misadministration, the licensee shall submit a written report to the agency. The written report shall include:
 - (A) the licensee's name;
 - (B) the name of the authorized user that issued the written directive;
 - (C) a brief description of the event recorded on the agency misadministration form;
 - (D) the licensee's evaluation of why the event occurred;
 - (E) any anticipated short and long term effects on the patient;
 - (F) the licensee's evaluation of improvements needed to prevent recurrence;
 - (G) documentation of the actions taken by the licensee to prevent recurrence; and
 - (H) whether or not the licensee notified the patient; and
 - (i) if the patient was not notified, the reason why not; or
 - (ii) if the patient was notified, what information was provided.
 - (3) The report required in Subparagraph (b)(2) of this Rule shall not include the patient's name or other information that could lead to the identification of the patient.
 - (4) The licensee shall notify the referring physician and the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the patient or that, based on medical judgment, telling the patient would be harmful. The licensee is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the licensee shall notify the patient as soon as possible thereafter. The licensee shall not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification.
 - (5) If the patient was notified, the licensee, shall also furnish, within 15 days after discovery of the misadministration a written report to the patient by sending either:
 - (A) A copy of the report that was submitted to the agency; or
 - (B) A brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the agency can be obtained from the licensee.
- (c) Each licensee shall retain a record of each misadministration for five years. The record shall contain:
- (1) the names of all individuals involved including the authorized user, allied health personnel, the patient, and the patient's referring physician;
 - (2) the patient's social security number or identification number if one has been assigned; and
 - (3) the information required in Parts (b)(2)(C)-(G) of this Rule.
- (d) Aside from the notification requirements, nothing in this Rule shall affect the rights or duties of licensees, and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.

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. June 1, 1989;
Amended Eff. May 1, 1995; May 1, 1992.*

.0351 SPECIFIC LICENSES: MOBILE NUCLEAR MEDICINE SERVICES

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

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

(b) The mobile nuclear medicine service licensee shall:

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

*History Note: Filed as a Temporary Amendment Eff. August 20, 1994, For a Period of 180 Days or Until the Permanent Rule Becomes Effective, Whichever is Sooner;
Authority G.S. 104E-7(a)(2); 104E-10(b);
Eff. June 1, 1989;
Amended Eff. May 1, 1995.*

.0352 EMERGENCY PLANS

(a) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or

sealed in glass in excess of the quantities in the table in Subparagraph (e)(1) of this Rule must contain either:

- (1) an evaluation showing that the maximum dose to a person off-site due to a release of radioactive materials would not exceed one rem effective dose equivalent or five rems to the thyroid; or
 - (2) an emergency plan for responding to a release of radioactive material.
- (b) One or more of the following factors may be used to support an evaluation submitted under Subparagraph (a)(1) of this Rule:
- (1) the radioactive material is physically separated so that only a portion could be involved in an accident;
 - (2) all or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;
 - (3) the release fraction in the respirable size range would be lower than the release fraction shown in Subparagraph (e)(1) of this Rule due to the chemical or physical form of the material;
 - (4) the solubility of the radioactive material would reduce the dose received;
 - (5) facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Subparagraph (e)(1) of this Rule;
 - (6) operating restrictions or procedures would prevent a release fraction as large as that shown in Subparagraph (e)(1) of this Rule; or
 - (7) other factors appropriate for the specific facility.
- (c) An emergency plan for responding to a release of radioactive material submitted under Subparagraph (a)(2) of this Rule must include the following information:
- (1) brief description of the licensee's facility and area near the site;
 - (2) identification of each type of radioactive materials accident for which protective actions may be needed;
 - (3) classification system for classifying accidents as alerts or site area emergencies;
 - (4) identification of the means of detecting each type of accident in a timely manner;
 - (5) brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on-site, and a description of the program for maintaining the equipment;
 - (6) brief description of the methods and equipment to assess releases of radioactive materials;
 - (7) brief description of the responsibilities of licensee personnel, should an accident occur, including identification of personnel responsible for promptly notifying off-site response organizations and the agency, and responsibilities for developing, maintaining, and updating the plan;
 - (8) brief description of notification and coordination, to include a commitment to and a brief description of the means to promptly notify off-site response organizations and request off-site assistance, including medical assistance for the treatment of contaminated injured on-site workers when appropriate, provided that:
 - (A) a control point shall be established;
 - (B) the notification and coordination shall be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination;
 - (C) the licensee shall also commit to notify the agency immediately after notification of the appropriate off-site response organizations, not to exceed one hour after the licensee declares an emergency; and
 - (D) the reporting requirements in Subparagraph (c)(8) of this Rule do not substitute for or relieve the licensee from responsibility for complying with the requirements in the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499 or other state or federal reporting requirements;

- (9) brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to off-site response organizations and to the agency;
- (10) brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency, including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel, where such training shall:
 - (A) familiarize personnel with site-specific emergency procedures; and
 - (B) thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios;
- (11) brief description of the means of restoring the facility to a safe condition after an accident;
- (12) brief description of provisions for conducting quarterly communications checks with off-site response organizations and biennial on-site exercises to test response to simulated emergencies where such provisions shall meet the following specific requirements:
 - (A) quarterly communications checks with off-site response organizations shall include the check and update of all necessary telephone numbers;
 - (B) while participation of off-site response organizations in biennial exercises is encouraged but not required, the licensee shall invite off-site response organizations to participate in the biennial exercises;
 - (C) accident scenarios for biennial exercises shall not be known to most exercise participants;
 - (D) the licensee shall critique each exercise using individuals who do not have direct implementation responsibility for the plan; and
 - (E) critiques of exercises shall evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response; and
 - (F) deficiencies found by the critiques in Part (c)(12)(E) of this Rule shall be corrected;
- (13) certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

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

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

(1) TABLE

RADIOACTIVE MATERIAL	RELEASE FRACTION	QUANTITY (CURIES)
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000

Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9 (20 mg)
Carbon-14 (NON CO)	.01	50,000
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166 m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114 m	.01	1,000
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Ruthenium-106	.01	200
Samarium-151	.01	4,000

Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110 m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99 m	.01	400,000
Tellurium-127 m	.01	5,000
Tellurium-129 m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha	.0001	20

- (2) For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in the table in Subparagraph (e)(1) of this Rule exceeds one.
- (3) Waste packaged in Type B containers, as defined in 10 CFR Part 71.4, does not require an emergency plan.

*History Note: Authority G.S. 104E-7; 104E-18;
Eff. May 1, 1992;
Amended Eff. May 1, 1993; October 1, 1992.*

.0353 FINANCIAL ASSURANCE AND RECORD-KEEPING FOR DECOMMISSIONING

(a) Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities such that R divided by 10^5 is greater than one (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in the table in Appendix C to 10 CFR §§ 20.1001 - 20.2401 shall submit a decommissioning funding plan as described in Paragraph (g) of this Rule.

(b) Each holder of a specific license issued before the effective date of this Rule, and of a type described in Paragraph (a) of this Rule shall submit, no later than 60 days after the effective date of this Rule, a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount of at least seven hundred and fifty thousand dollars (\$750,000) in accordance with the criteria set forth in this Rule. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

(c) Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in Paragraph (f) of this Rule shall either:

- (1) submit a decommissioning funding plan as described in Paragraph (g) of this Rule; or
- (2) submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by Paragraph (f) of this Rule using one of the methods described in Rule .0354 of this Section. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material. As part of the certification, the applicant shall submit to this agency, a copy of the financial instrument obtained to satisfy the requirements of Paragraph (g) of this Rule.

(d) Each holder of a specific license issued before the effective date of this Rule, and of a type described in Paragraph (c) of this Rule shall submit, no later than 60 days after the effective date of this Rule, a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in this Rule.

(e) Each holder of a specific license issued on or after the effective date of this Rule, which is of a type described in Paragraph (a) or (c) of this Rule, shall provide financial assurance for decommissioning in accordance with the criteria set forth in this Rule.

(f) Required amounts of financial assurance for decommissioning by quantity of radioactive material where R is defined as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix C to 10 CFR §§ 20.1001 - 20.2401 are as follows:

- (1) for unsealed form, if R divided by 10^5 is greater than one, then the minimum financial assurance amount is seven hundred and fifty thousand dollars (\$750,000) and shall be as stated in an approved decommissioning funding plan as described in Paragraph (g) of this Rule;
- (2) for unsealed form, if R divided by 10^4 is greater than one but R divided by 10^5 is less than or equal to one, then the financial assurance amount is seven hundred and fifty thousand dollars (\$750,000);
- (3) for unsealed form, if R divided by 10^3 is greater than one but R divided by 10^4 is less than or equal to one, then the financial assurance amount is one hundred and fifty thousand dollars (\$150,000);
- (4) for sealed sources or plated foils, if R , divided by 10^{10} is greater than one, then the financial assurance amount is seventy five thousand dollars (\$75,000).

(g) Each decommissioning funding plan shall contain a cost estimate for decommissioning and documentation of an approved method assuring funds for decommissioning as referenced in Rule .0354 of this Section, including means of adjusting cost estimates and associated funding levels periodically over the life of the facility.

(h) Each person licensed under this Section of this Chapter shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the agency. If records of relevant information are kept for other purposes,

reference to these records and their locations may be used. Information the agency considers important to decommissioning includes, but is not limited to:

- (1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site.
 - (A) These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete.
 - (B) These records shall include any known information on identification of involved nuclides, quantities, forms, and concentrations.
- (2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are being used or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination.
 - (A) If required drawings are referenced, each relevant document need not be indexed individually.
 - (B) If drawings are not available, the licensee shall substitute records of available information concerning these areas and locations.
- (3) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.
- (4) Except for areas containing only sealed sources (provided the sealed sources have not leaked or no contamination remains after cleanup of any leak) or radioactive materials having only half-lives of less than 65 days, or depleted uranium used only for shielding, licensees shall be required to establish and maintain a list, contained in a single document. The list shall be updated every two years, and include the following information:
 - (A) All areas designated and formerly designated as restricted areas as defined in Rule .0104 of this Chapter;
 - (B) All areas outside of restricted areas that require documentation under Paragraph (h) of this Rule;
 - (C) All areas outside of restricted areas where current and previous wastes have been buried as documented in Rule .1642 of this Chapter; and
 - (D) All areas outside of restricted areas which contain material that, if the license expired, the licensee would be required to decontaminate either the area to unrestricted release levels or to apply to the agency for approval for disposal as required in Rule .1629 of this Chapter.
 - (i) Prior to license termination, each licensee authorized to possess radioactive material in an unsealed form, shall forward to the agency the records required in Paragraph (h) of this Rule.
 - (j) Before licensed activities are transferred, licensees shall transfer all records required in Paragraph (h) of this Rule. In this case, the new licensee shall maintain the records until the license is terminated.

*History Note: Authority G.S. 104E-7; 104E-18;
Eff. May 1, 1992;
Amended Eff. April 1, 1999; August 1, 1998; January 1, 1994.*

.0354 METHODS OF FINANCIAL ASSURANCE FOR DECOMMISSIONING

- (a) Financial assurance for decommissioning as required by Rule .0353 of this Section must be provided by one or more of the following methods:
 - (1) prepayment, where:
 - (A) Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets

- such that the amount of funds would be sufficient to pay decommissioning costs; and
- (B) Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.
- (2) a surety method, insurance, or other guarantee method, where:
- (A) These methods guarantee that decommissioning costs will be paid should the licensee default;
 - (B) A surety method may be in the form of a surety bond, letter of credit, or line of credit;
 - (C) A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the parent company and guarantee meet the criteria contained in Rule .0355 of this Section;
 - (D) A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this Section; and
 - (E) Any surety method or insurance used to provide financial assurance for decommissioning shall contain the following conditions:
 - (i) The surety method or insurance shall be open-ended or, if written for a specified term, such as five years, shall be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the agency, the beneficiary, and the licensee of its intention not to renew;
 - (ii) The surety method or insurance shall provide that the full face amount be paid to the beneficiary automatically prior to the expiration date without proof of forfeiture if the licensee fails to provide a replacement acceptable to the agency within 30 days after receipt of notification of cancellation;
 - (iii) The surety method or insurance shall be payable to a trust established for decommissioning costs. The trustee and trust shall be acceptable to the agency. An acceptable trust includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency;
 - (iv) The surety method or insurance shall remain in effect until the agency has terminated the license.
- (3) an external sinking fund where:
- (A) Deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund;
 - (B) An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected;
 - (C) An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit or deposits of government securities; and
 - (D) The surety or insurance provisions shall be as stated in Subparagraph (a)(2) of this Rule.
- (4) in the case of federal, state or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the provisions of Rule .0353 of this Section, and indicating that funds for decommissioning shall be obtained when required by the agency.

*History Note: Authority G.S. 104E-7; 104E-18;
Eff. May 1, 1992.*

.0355 FIN. TESTS- PARENT CO. GUARANTEES: DECOMMISSIONING FUNDING

(a) An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for

decommissioning costs and on a demonstration that the parent company passes a financial test. This Rule establishes criteria for passing the financial test and for obtaining the parent company guarantee.

(b) To pass the financial test, the parent company shall meet the criteria of either Subparagraph (b)(1) or (b)(2) of this Rule as follows:

(1) The parent company shall have:

- (A) two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and
- (B) net working capital and tangible net worth each at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used); and
- (C) tangible net worth of at least ten million dollars (\$10,000,000); and
- (D) assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used).

(2) The parent company shall have:

- (A) a current rating for its most recent bond issuance of AAA, AA, A or BBB as issued by Standard and Poor's or Aaa, Aa, A or Baa as issued by Moody's; and
- (B) tangible net worth at least six times the current decommissioning cost estimate (or prescribed amount if a certification is used); and
- (C) tangible net worth of at least ten million (\$10,000,000); and
- (D) assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if certification is used).

(c) The parent company's independent certified public accountant shall have compared the data used by the parent company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform the agency within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(d) After the initial financial test, the parent company shall repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(e) If the parent company no longer meets the requirements of Paragraph (b) of this Rule, the licensee shall send notice to the agency of intent to establish alternate financial assurance as specified in this Section. The notice shall be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee shall provide alternate financial assurance within 120 days after the end of such fiscal year.

(f) The terms of a parent company guarantee which an applicant or licensee obtains shall provide that:

- (1) the parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the agency. Cancellation shall not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the agency, as evidenced by the return receipts.
- (2) if the licensee fails to provide alternate financial assurance as specified in this Section within 90 days after receipt by the licensee and the agency of a notice of cancellation of the parent company guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

(g) The parent company guarantee and financial test provisions shall remain in effect until the agency has terminated the license.

(h) If a trust is established for decommissioning costs, the trustee and trust shall be acceptable to the

agency. An acceptable trustee includes an appropriate state or federal agency or an entity to act as a trustee whose trust operations are regulated and examined by a federal or state agency.

*History Note: Authority G.S. 104E-7; 104E-18;
Eff. May 1, 1992.*

.0356 QUALITY MANAGEMENT PROGRAM

(a) Each applicant or licensee for medical use under this Section shall establish and maintain a written quality management program to provide high confidence that radioactive material or radiation from licensed sources will be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:

- (1) that, prior to administration, a written directive is prepared for any:
 - (A) diagnostic administration of a radiopharmaceutical;
 - (B) therapeutic administration of a radiopharmaceutical;
 - (C) brachytherapy radiation dose;
 - (D) teletherapy or accelerator radiation dose; or
 - (E) gamma stereotactic radiosurgery radiation dose;
- (2) that, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive;
- (3) that final plans of treatment and related calculations for brachytherapy, teletherapy, accelerator treatment and gamma stereotactic radiosurgery are in accordance with written directives;
- (4) that each administration is in accordance with the written directive; and
- (5) that any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(b) Notwithstanding the requirements of Subparagraph (a)(1) of this Rule for diagnostic administration of a radiopharmaceutical, if an authorized user determines that deviation from the diagnostic clinical procedures manual is necessary for reasons other than the emergent nature of the patient's condition, an authorized user may issue an oral revision to a written directive that shall be documented in writing within 48 hours after the oral directive.

(c) Notwithstanding the requirements of Subparagraph (a)(1) this Rule;

- (1) if, due to the patient's condition, a delay in the execution of an existing written directive in order to obtain a written revision to the existing written directive would jeopardize the patient's health, an oral revision by an authorized user to an existing written directive shall be acceptable, provided that:
 - (A) the oral revision is documented immediately in the patient's record; and
 - (B) a revised written directive is signed by an authorized user within 48 hours of the oral revision;
- (2) a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy or accelerator radiation dose, or the next teletherapy or accelerator radiation fractional dose;
- (3) if, because of the emergent nature of the patient's condition, a delay in order to acquire a written directive by an authorized user would jeopardize the patient's health, an oral directive by an authorized user shall be acceptable, provided that:
 - (A) the information contained in the oral directive is documented immediately in the patient's record; and
 - (B) a written directive is prepared and signed by an authorized user within 48 hours of the oral directive.

(d) The medical use licensee shall:

- (1) develop procedures for and conduct a review of the quality management program at intervals not to exceed 12 months to verify compliance, since the last review, with all aspects of the quality management program including an evaluation of:
 - (A) a representative sample of therapeutic administrations and those diagnostic administrations of greater than 30 microcuries of sodium iodide I-125 or I-131 patient administrations;
 - (B) all recordable events; and
 - (C) all misadministrations;
 - (2) evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of Paragraph (a) of this Rule; and
 - (3) retain records of each review in an auditable form, including the evaluations and findings of the review for three years.
- (e) The medical use licensee shall evaluate and respond, within 30 days after discovery of a recordable event as defined in Rule .0104 of this Chapter, to each recordable event by:
- (1) assembling the relevant facts including the cause of the event;
 - (2) identifying any corrective action required to prevent recurrence; and
 - (3) retaining a record, in an auditable form, for three years, of the information required in Subparagraphs (1) and (2) of this Paragraph.
- (f) The medical use licensee shall retain:
- (1) each written directive;
 - (2) a record of each administered radiation dose or radiopharmaceutical dosage; and
 - (3) retaining a record, in an auditable form, for three years, of the information required in Subparagraphs (1) and (2) of this Paragraph.
- (g) The medical use licensee is authorized to make modifications to the quality management program, without prior approval by the agency, that do not degrade the program's ability to maintain exposures as low as reasonably achievable. Changes to the quality management program shall be submitted to the agency for review within 30 days of the change.
- (h) Each applicant for a new medical use license shall submit to the agency a quality management program as part of the application for a license and implement the program upon issuance of the license.
- (i) Each existing medical use licensee shall submit to the agency by May 1, 1995 a written certification that the quality management program has been implemented along with a copy of the program.

History Note: Filed as a Temporary Adoption 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-10(b); Eff. May 1, 1995.

.0357 REPORTING REQUIREMENTS

- (a) Immediate report. Each licensee shall notify the agency as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to sources of radiation that could exceed regulatory limits or releases of licensed radioactive material that could exceed regulatory limits. These events include but are not limited to fires, explosions and toxic gas releases.
- (b) Twenty-four hour report. Each licensee shall notify the agency within 24 hours after the discovery of any of the following events involving licensed radioactive material:
- (1) an unplanned contamination event that:
 - (A) requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

- (B) involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B to 10 CFR §§ 20.1001-20.2401 for the material; and
- (C) causes the licensee to restrict access to the area for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination;
- (2) an event in which equipment is disabled or fails to function as designed when:
 - (A) the equipment is required by rule or license condition to:
 - (i) prevent releases exceeding regulatory limits;
 - (ii) prevent exposures to sources of radiation exceeding regulatory limits; or
 - (iii) to mitigate the consequences of an accident;
 - (B) the equipment is required to be available and operable at the time that it is disabled or fails to function; and
 - (C) no redundant equipment is available and operable to perform the required safety function;
- (3) an event that requires unplanned medical treatment at a medical facility of an individual with removable radioactive contamination on the individual's clothing or body; or
- (4) an unplanned fire or explosion damaging any licensed material or any device, container or equipment containing licensed radioactive material when:
 - (A) the quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B to 10 CFR §§ 20.1001-20.2401 for the material; and
 - (B) the damage affects the integrity of the licensed radioactive material or its container.
- (c) Preparation and submission of reports. Reports made by licensees in response to the requirements of this Rule shall be made as follows:
 - (1) Licensees shall make reports required by Paragraphs (a) and (b) of this Rule by telephone as specified in Rule .0111(b) of this Chapter. To the extent that the information is available at the time of notification, the information provided in these reports shall include:
 - (A) the caller's name and call back telephone number;
 - (B) a description of the event, including date and time;
 - (C) the exact location of the event;
 - (D) the isotopes, quantities, and chemical and physical form of the licensed radioactive material involved; and
 - (E) any personnel radiation exposure data available.
 - (2) Each licensee who makes a report required by Paragraph (a) or (b) of this Rule shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other rules may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports shall be submitted to the agency as specified in Rule .0111(a) of this Chapter. The reports shall include the following:
 - (A) a description of the event, including the probable cause and the manufacturer and model number, if applicable, of any equipment that failed or malfunctioned;
 - (B) the exact location of the event;
 - (C) the isotopes, quantities and chemical and physical form of the licensed material involved;
 - (D) the date and time of the event;
 - (E) the corrective actions taken or planned and the result of any evaluations or assessments; and
 - (F) the extent of exposure of individuals to sources of radiation without identification of individuals by name.

History Note: Filed as a Temporary Adoption Eff. August 20, 1994, for a Period of 180 Days or Until the Permanent Rule Becomes Effective, Whichever is Sooner; Authority G.S. 104E-7(a)(2); 104E-10(b); Eff. May 1, 1995.

.0358 RELEASE OF PATIENTS CONTAINING RADIOPHARMACEUTICALS OR PERMANENT IMPLANTS

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

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

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

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

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

(d) The licensee shall maintain a record, for three years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 500 millirem (5 mSv).

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

.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 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.*

.0360 SURVEYS OF RADIOPHARMACEUTICAL AREAS FOR CONTAMINATION & RADIATION EXPOSURE RATE

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

(b) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

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

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

(e) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

(f) A licensee shall conduct the surveys required by Paragraph (e) of this Rule so as to be able to detect contamination on each wipe sample of 2,000 disintegrations per minute.

(g) A licensee shall establish removable contamination trigger levels for the surveys required by Paragraph (e) of this Rule. A licensee shall require the individual performing the survey to promptly notify the Radiation Safety Officer if contamination levels exceed the trigger level.

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

- (1) the date of the survey;
- (2) a plan of each area surveyed;
- (3) the trigger level established for each area;
- (4) the detected dose rate at several points in each area surveyed;
- (5) the detected dose rate at several points in each area expressed in millirem (or microsievert) per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters;
- (6) the instrument used to make the survey or analyze the samples; and

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

*History Note: Authority G.S. 104E-7; 104E-10(b); 104E-12;
Eff. April 1, 1999.*

.0361 MEDICAL USE OF UNSEALED RADIOACTIVE MATERIAL

- (a) A licensee may use for diagnostic or therapeutic administration any unsealed radioactive material prepared for medical use that is either:
- (1) obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent agreement state requirements; or
 - (2) prepared by a pharmacist who is an authorized user, a physician who is an authorized user or an individual under the supervision of either.
- (b) A licensee shall not administer to humans a radiopharmaceutical containing more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m.
- (c) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate or extract.
- (d) A licensee that must measure molybdenum concentration shall retain a record of each measurement for three years. The record shall include for each elution or extraction of technetium-99m:
- (1) the measured activity of the technetium expressed in millicuries;
 - (2) the measured activity of the molybdenum expressed in microcuries;
 - (3) the time and date of the measurement; and
 - (4) the initials of the individual who made the measurement.
- (e) A licensee that administers radioactive aerosols or gases shall:
- (1) do so in a room with a system that will keep airborne concentrations low enough so as not to exceed the limits prescribed by Rules .1604 and .1605 of this Chapter;
 - (2) before receiving, using or storing a radioactive gas, calculate the amount of time needed after a

- spill to reduce the concentration in the room low enough so as to not exceed the limits prescribed by Rules .1604 and .1605 of this Chapter;
- (3) post the calculated time and safety measures to be instituted in the case of a spill at the area of use;
 - (4) store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container; and
 - (5) store multi-dose containers in a fume hood or other enclosure vented directly to the atmosphere after drawing the first dosage from the container.

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

.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, 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,*

SECTION .0400 - STANDARDS FOR PROTECTION AGAINST RADIATION

This Section .0400, Chapter 11 of Title 15A of the North Carolina Administrative Code (T15A.11 .0400); STANDARDS FOR PROTECTION AGAINST RADIATION; has been transferred and recodified from Section .2500, Subchapter 3G of Title 10 of the North Carolina Administrative Code (T10.03G .2500), effective January 4, 1990. The recodification was pursuant to G.S. 143B-279.3.

.0401 PURPOSE AND SCOPE

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Repealed Eff. August 1, 1998.*

.0402 RADIATION DOSE TO INDIVIDUALS IN RESTRICTED AREAS

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. May 1, 1992;
Repealed Eff. August 1, 1998.*

.0403 DETERMINATION OF PRIOR DOSE

*History Note: Authority G.S. 104E-7; 104E-12(a)(2);
Eff. February 1, 1980;
Amended Eff. May 1, 1992; October 1, 1980;
Repealed Eff. August 1, 1998.*

.0404 CONCENTRATIONS IN A RESTRICTED AREA

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Repealed Eff. August 1, 1998.*

.0405 EXPOSURE OF MINORS

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Repealed Eff. August 1, 1998.*

.0406 PERMISSIBLE LEVELS IN UNRESTRICTED AREAS

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Repealed Eff. August 1, 1998.*

.0407 CONCENTRATION IN EFFLUENTS TO UNRESTRICTED AREAS

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;*

Repealed Eff. August 1, 1998.

.0408 BIOASSAY SERVICES

*History Note: Authority G.S. 104E-7; 104E-12(a)(2);
Eff. February 1, 1980;
Repealed Eff. August 1, 1998.*

.0409 SURVEYS

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Repealed Eff. August 1, 1998.*

.0410 PERSONNEL MONITORING

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Repealed Eff. August 1, 1998.*

.0411 CAUTION SIGNS: LABELS: AND SIGNALS

*History Note: Authority G.S. 104E-7; 104E-12(a)(1);
Eff. February 1, 1980;
Amended Eff. May 1, 1992; September 1, 1981; October 1, 1980;
Repealed Eff. August 1, 1998.*

.0412 EXCEPTIONS FROM POSTING AND LABELING

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Repealed Eff. August 1, 1998.*

.0413 INSTRUCTION OF PERSONNEL

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Repealed Eff. August 1, 1998.*

.0414 STORAGE OF SOURCES OF RADIATION

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Repealed Eff. August 1, 1998.*

.0415 PICKING UP: RECEIVING: AND OPENING PACKAGES

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;*

Amended Eff. June 1, 1989;
Repealed Eff. August 1, 1998.

.0416 WASTE DISPOSAL

History Note: Authority G.S. 104E-7(2), (5);
Eff. February 1, 1980;
Amended Eff. June 1, 1989; October 1, 1984; September 1, 1981;
Repealed Eff. August 1, 1998.

.0417 RECORDS

History Note: Authority G.S. 104E-7(2); 104E-12(a);
Eff. February 1, 1980;
Amended Eff. May 1, 1992; October 1, 1984;
Repealed Eff. August 1, 1998.

.0418 REPORTS OF THEFT OR LOSS

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Repealed Eff. August 1, 1998.

.0419 NOTIFICATION OF INCIDENTS

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Repealed Eff. August 1, 1998.

.0420 OVEREXPOSURES AND EXCESSIVE LEVELS AND CONCENTRATIONS

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. May 1, 1992;
Repealed Eff. August 1, 1998.

.0421 VACATING PREMISES

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Repealed Eff. August 1, 1998.

.0422 NOTIFICATION AND REPORTS TO INDIVIDUALS

History Note: Authority G.S. 104E-7; 104E-12(b);
Eff. February 1, 1980;
Repealed Eff. August 1, 1998.

.0423 REFERENCE CONCENTRATIONS IN AIR AND WATER

*History Note: Authority G.S. 104E-7(2);
Eff. February 1, 1980;
Amended Eff. October 1, 1984;
Repealed Eff. August 1, 1998.*

.0424 REFERENCE FOR LABELING AND DISPOSAL REQUIREMENTS

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Repealed Eff. August 1, 1998.*

.0425 CLASSIFICATION/RADIOACTIVE WASTE FOR NEAR-SURFACE DISPOSAL

*History Note: Authority G.S. 104E-7(2);
Eff. October 1, 1984;
Amended Eff. June 1, 1989;
Repealed Eff. August 1, 1998.*

.0426 RADIOACTIVE WASTE CHARACTERISTICS

*History Note: Authority G.S. 104E-7(2);
Eff. October 1, 1984;
Repealed Eff. August 1, 1998.*

.0427 LABELING

*History Note: Authority G.S. 104E-7(2);
Eff. October 1, 1984;
Repealed Eff. August 1, 1998.*

.0428 TRANSFER OF RADIOACTIVE WASTE FOR DISPOSAL AND MANIFESTS

*History Note: Authority G.S. 104E-7(2), (3); 104E-12(a);
Eff. October 1, 1984;
Amended Eff. June 1, 1989;
Repealed Eff. August 1, 1998.*

SECTION .0500
SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHY OPERATIONS

This Section .0500, Chapter 11 of Title 15A of the North Carolina Administrative Code (T15A.11 .0500); SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHY OPERATIONS; has been transferred and recodified from Section .2600, Subchapter 3G of Title 10 of the North Carolina Administrative Code (T10.03G .2600), effective January 4, 1990. The recodification was pursuant to G.S. 143B-279.3.

.0501 PURPOSE AND SCOPE

(a) The rules in this Section establish radiation safety requirements for persons utilizing sources of radiation for industrial radiography. The requirements of this Section are in addition to and not in substitution for the other requirements of this Chapter.

(b) The rules in this Section apply to all licensees or registrants who use sources of radiation for industrial radiography; provided, however that nothing in this Section shall apply to the use of sources of radiation in the healing arts.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. May 1, 1993.*

.0502 DEFINITIONS

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

- (1) "Annual refresher safety training" means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and shall also provide opportunities for employees to ask safety questions.
- (2) "Associated equipment" means equipment used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides or comes in contact with the sealed source or radiation machines (e.g. guide tube, control tube, control (guide) tube, removable source stop, "J" tube and collimator when it is used as an exposure head).
- (3) "Cabinet radiography using radiation machines" means industrial radiography using radiation machines, which is conducted in an enclosed, interlocked cabinet, such that the radiation machine will not operate unless all openings are securely closed, and which cabinet is so shielded that every location on the exterior meets conditions for an unrestricted area as specified in Rule .1611 of this Chapter.
- (4) "Certifying entity" means an independent certifying organization meeting the requirements in Rule .0525 of this Section.
- (5) "Collimator" means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to limit the size, shape, and direction of the primary radiation when the sealed source is cranked into position, to make a radiographic exposure.
- (6) "Control device", commonly called a crank-out, means the control cable, the protective sheath and control drive mechanism used to move the sealed source from the shielded position in the radiographic device or camera to an unshielded position outside the device for the purpose of making a radiographic exposure.
- (7) "Control drive mechanism" means a device that enables the source assembly to be moved to and from the exposure device.
- (8) "Control tube" means a protective sheath for guiding the control cable. The control tube connects the control device mechanism to the radiographic exposure device.
- (9) "Exposure head", commonly called a source stop, means a device that locates the gamma

- radiography sealed source in the selected working position.
- (10) "Field examination" means a practical examination.
 - (11) "Field station" means a facility where licensed material or registered equipment may be stored or used and from which licensed material or registered equipment is dispatched.
 - (12) "Guide tube" (Projection sheath) means a flexible or rigid tube (i.e., "J" tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.
 - (13) "Hands-on experience" means experience in all of those areas considered to be directly involved in the radiography process.
 - (14) "Independent certifying organization" means an independent organization that meets all of the requirements of Rule .0525 of this Section.
 - (15) "Industrial radiography" means the examination of the structure of materials by nondestructive methods utilizing ionizing radiation to make radiographic images.
 - (16) "Lay-barge radiography" means industrial radiography performed on any water vessel used for laying pipe.
 - (17) "Off-shore platform radiography" means industrial radiography conducted from a platform over a body of water.
 - (18) "Periodic training" means a periodic review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of radiography. The review shall include the results of internal inspections, new procedures or equipment, accidents or errors that have been observed, and opportunities for employees to ask safety questions.
 - (19) "Permanent radiographic installation" means an enclosed shielded room, cell, or vault not located at a temporary job-site in which radiography is performed.
 - (20) "Projection sheath", means a guide tube.
 - (21) "Practical examination" means a demonstration through practical application of the safety rules and principles in industrial radiography including the use of all appropriate equipment and procedures.
 - (22) "Radiation safety officer" means an individual named by the licensee or registrant who has knowledge of and responsibility for the overall radiation safety program on behalf of the licensee or registrant and who meets the requirements of Rule .0510(h) of this Section.
 - (23) "Radiographer" means any individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of these Rules and all license or registration conditions.
 - (24) "Radiographer certification" means written approval received from a certifying organization stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.
 - (25) "Radiographer's assistant" means any individual who, under the direct supervision of a radiographer, uses radiographic exposure devices, sources of radiation, related handling tools, or survey instruments in industrial radiography.
 - (26) "Radiographic exposure device", commonly called a camera or projector, means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.
 - (27) "Radiographic operations" means all activities associated with the presence of radioactive sources in a radiographic exposure device during use of the device or transport (except when being transported by a common or contract transport), to include surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

- (28) "S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.
 - (29) "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.
 - (30) "Shielded position" means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement. This position incorporates maximum shielding for the sealed source.
 - (31) "Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly also includes the stop ball if one is used to secure the sealed source in the shielded position. The connector attaches to the control cable.
 - (32) "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those also used for transporting and storage of sealed sources.
 - (33) "Storage area" means any location, facility or vehicle which is used to store or secure a radiographic exposure device, a storage container or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with or unauthorized removal of the device, storage container or sealed source.
 - (34) "Storage container" means a device in which sealed sources are secured and stored.
 - (35) "Temporary jobsite" means a location, where radiographic operations are conducted and where licensed material may be stored other than those location(s) of use authorized on the license.
 - (36) "Underwater radiography" means industrial radiography performed when the radiographic exposure device or related equipment are beneath the surface of the water.
- (b) Other definitions applicable to this Section may be found in Rule .0104 of this Chapter.

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Eff. February 1, 1980;
Amended Eff. April 1, 1999; May 1, 1995; January 1, 1994; June 1, 1989.

.0503 EQUIPMENT RADIATION LEVEL LIMITS

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

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.0504 RADIOGRAPHIC EXPOSURE DEVICES AND STORAGE CONTAINERS

(a) Each radiographic exposure device shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device or its container shall be kept locked when not under the direct surveillance of a radiographer or a radiographer's assistant or as otherwise may be authorized in Rule .0515 of this Section. If the exposure device or container is secured with a keyed lock, the key shall be removed at all times when the device or container is not being used. In addition, during radiographic operations, the sealed source assembly

shall be manually secured in the shielded position each time the sealed source is returned to that position in those devices manufactured prior to the effective date of this Rule.

(b) Each sealed source storage container and source changer shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers shall be kept locked when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

(c) Prior to moving a radiographic exposure device, source changer or storage container from one temporary jobsite to another, the licensee shall:

- (1) perform a survey to ensure that the sealed source is in the shielded position;
- (2) disassemble the radiographic exposure device, source changer or storage container from associated equipment;
- (3) apply safety plugs or covers;
- (4) lock the radiographic exposure device, source changer or storage container; and
- (5) physically secure the radiographic exposure device, source changer or storage container to prevent accidental loss, tampering or removal of sealed sources.

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.0505 STORAGE, LABELS AND TRANSPORTATION PRECAUTIONS

(a) Security precautions during storage or transportation:

- (1) Locked radiographic exposure devices and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store sealed sources in a manner which will minimize danger from explosion or fire.
- (2) The licensee shall lock and physically secure the transport package containing sealed sources in the transporting vehicle to prevent accidental loss, tampering or unauthorized removal of the sealed sources from the vehicle.

(b) Labels:

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

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

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

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.0506 SURVEY INSTRUMENTS

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

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

- (1) at intervals not to exceed six months and after each instrument servicing except for battery change;
- (2) at the following points for each instrument, as applicable:
 - (A) linear scale instruments shall be calibrated at two points located approximately 1/3 and 2/3 of full-scale on each scale;
 - (B) logarithmic scale instruments shall be calibrated at the midrange of each decade and at two points in the same decade for at least one decade; and
 - (C) digital instruments shall be calibrated in accordance with procedures that include the following calibration points:
 - (i) 2 mR/hr or 0.02 mSv/hr;
 - (ii) 5 mR/hr or 0.05 mSv/hr;
 - (iii) 50 mR/hr or 0.5 mSv/hr;
 - (iv) 500 mR/hr or 5 mSv/hr; and
 - (v) 1 R/hr or 0.01 Sv/hr;
- (3) so that an accuracy within plus or minus 20 percent of the calibration standard can be demonstrated on each scale.

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

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

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

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

.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 0.005uCi (185 Bq) of radioactive material on the test sample and shall be performed by persons licensed or registered by the agency to perform such a service.

(e) Any test conducted pursuant to Paragraphs (c) and (d) of this Rule which reveals the presence of

0.005 microcurie (185 Bq) or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of, in accordance with these Rules. A report describing the equipment involved, the test results, and the corrective action taken shall be submitted in writing to the agency at the address in Rule .0111 of this Chapter within five days after the test.

(f) The licensee shall maintain records of the leak test results in accordance with Rule .0523 of this Section.

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.0508 QUARTERLY INVENTORY

(a) Each licensee shall conduct a quarterly physical inventory to account for all sealed sources and devices containing depleted uranium received and possessed under the license.

(b) The licensee shall maintain records of the quarterly inventory in accordance with Rule .0523 of this Section.

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Amended Eff. April 1, 1999; May 1, 1995.

.0509 UTILIZATION LOGS

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

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Authority G.S. 104E-7; 104E-12(a)(1);
Eff. February 1, 1980;
Amended Eff. April 1, 1999; May 1, 1995.

.0510 LIMITATIONS

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

- (1) has been instructed in the subjects outlined in Rule .0519 of this Section and has demonstrated understanding thereof by successful completion of a written test. Within two years after the effective date of this Rule, the person shall also have a minimum of two months of on-the-job training, and be certified through a radiography certification program by a certifying entity in accordance with the requirements of Rule .0525 of this Section;
- (2) has received copies of and instruction in the rules contained in this Section and in the applicable rules of Sections .0200, .0300, .0900 and .1600 of this Chapter, in applicable U.S. Department of Transportation regulations referenced in Rule .0117 of this Chapter, and the licensee's or registrant's operating and emergency procedures, and has demonstrated understanding thereof by successful completion of a written test;

- (3) has received training in the use of the licensee or registrant's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments;
 - (4) has demonstrated competence to use the radiographic exposure devices, sealed sources, related handling tools, radiation machines and survey instruments which will be employed in his assignment by successful completion of a practical examination covering this material; and
 - (5) has demonstrated understanding of the instructions in Paragraph (a) of this Rule by successful completion of a written test on the subjects covered.
- (b) The licensee or registrant shall not permit any person to act as a radiographer's assistant until the person:
- (1) has received copies of and instructions in the licensee's or registrant's operating and emergency procedures, and has demonstrated understanding thereof by successful completion of a written or oral test and practical examination on the subjects covered;
 - (2) has demonstrated competence to use under the personal supervision of the radiographer, the radiographic exposure devices, sealed sources, related handling tools, radiation machines and radiation survey instruments which will be employed in his assignment; and
 - (3) has demonstrated understanding of the instructions in Paragraph (b) of this Rule by successfully completing a written or oral test and a field examination on the subjects covered.
- (c) Records of the training including copies of written tests and dates of oral tests and field examinations shall be maintained in accordance with Rule .0523 of this Section.
- (d) Each licensee or registrant shall conduct an internal audit program to ensure that the agency's radioactive material license, registration conditions and the licensee's or registrant's operating and emergency procedures are followed by each radiographer and radiographer's assistant. These internal audits shall be performed and records maintained by the licensee or registrant as specified in Items (3) and (4) of Rule .0323 of this Chapter.
- (e) The licensee or registrant shall provide periodic training for radiographers and radiographer's assistants at least once during every 12 months.
- (f) Whenever radiography is performed outside of a permanent radiographic installation, the radiographer shall be accompanied by another radiographer or an individual with, at least, the qualifications of a radiographer's assistant. This person's responsibilities shall include but not be limited to observing the operations and being capable and prepared to provide immediate assistance to prevent unauthorized entry.
- (g) A licensee or registrant may conduct lay-barge, off-shore platform, or underwater radiography only if detailed procedures have been developed and submitted to the agency that ensure radiation exposure to the workers and the public are ALARA during the radiographic operation.
- (h) The radiation safety officer shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's or registrant's program.
- (1) The radiation safety officer's qualifications shall include:
 - (A) completion of the training and testing requirements of Paragraph (a) of this Rule; and
 - (B) Two thousand hours documented experience in industrial radiographic operations, with at least 40 hours of classroom training with respect to the establishment and maintenance of radiation protection programs; or
 - (C) an equivalent combination of education and experience.
 - (2) The specific duties and authorities of the radiation safety officer shall include, but are not limited to the following:
 - (A) to establish and oversee operating, emergency and ALARA procedures, and to review them regularly to assure that the procedures are current and conform with these Rules and to the license conditions;
 - (B) to oversee and approve all phases of the training of radiographic personnel so that

- appropriate and effective radiation protection practices are taught;
- (C) to ensure that required radiation surveys and leak tests are performed and documented in accordance with this Rule, including any corrective measures when levels of radiation exceed established limits;
 - (D) to ensure that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by Rule .1646 of this Chapter;
 - (E) to assure that operations are conducted safely and to assume control and have the authority to institute corrective actions including stopping of operations when necessary in emergency situations or unsafe conditions.

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.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 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.

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.0512 PERSONNEL MONITORING

(a) The licensee or registrant shall not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each such individual wears on the trunk of the body a direct reading pocket dosimeter, an operating alarm ratemeter, and either a film badge or a thermoluminescent dosimeter (TLD). At permanent radiography facilities where other alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required. Pocket dosimeters shall have a range from zero to 200 milliroentgens (2 millisieverts) and shall be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters. Each film badge and TLD shall be assigned to and worn by only one individual. Film badges shall be exchanged at least monthly and TLDs shall be exchanged at least once each three months. After exchange, each film badge or TLD shall be promptly processed.

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

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

(d) If an individual's pocket dosimeter is found to be off-scale, and the possibility of radiation exposure cannot be ruled out as the cause, their film badge or TLD shall be immediately sent for processing. In addition, the individual shall not work with sealed sources until a determination of his radiation exposure has been made by the radiation safety officer or his designee.

(e) If a film badge or TLD is lost or damaged, the worker shall cease work immediately until a replacement film badge or TLD is provided and exposure is calculated for the time period from issuance to loss or damage of the film badge or TLD.

(f) Each alarm ratemeter shall:

- (1) be checked to ensure that the alarm functions properly prior to use at the start of each shift;
- (2) be set to give an alarm signal at a preset rate not to exceed 500 mR/hr or 5 mSv/hr;
- (3) require special means to change the preset alarm function;
- (4) alarm within plus or minus 20 percent of the true radiation rate;
- (5) be calibrated at periods not to exceed one year for correct response to radiation.

(g) Records of daily dosimeter readings, determination of exposure as a result of a lost or damaged film badge or TLD, 12 month response checks on dosimeters and results from the film badge or TLD processor shall be maintained in accordance with Rule .0523 of this Section.

(h) Notwithstanding the requirements of Paragraph (a) of this Rule, the agency may approve a higher pocket dosimeter range upon written request by the licensee or registrant if the agency determines that the requested range will afford the protection required by the rules in this Chapter.

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Authority G.S. 104E-7; 104E-12(a)(2);
Eff. February 1, 1980;
Amended Eff. April 1, 1999; May 1, 1995.*

.0513 OPERATING AND EMERGENCY PROCEDURES

The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

- (1) the handling and use of licensed sealed sources of radiation and radiographic exposure devices

to be employed such that no individual is likely to be exposed to radiation doses in excess of the limits established in Rule .1604 of this Chapter;

- (2) methods and occasions for conducting radiation surveys;
- (3) methods for controlling access to radiographic areas;
- (4) methods and occasions for locking and securing radiographic exposure devices, transport and storage containers and sealed sources of radiation;
- (5) personnel monitoring and the use of personnel monitoring equipment;
- (6) transportation of sealed sources to field locations, including packing of radiographic exposure devices, and storage containers in the vehicles, placarding of vehicles, and control of sealed sources during transportation;
- (7) minimizing exposure of individuals in the event of an accident;
- (8) the procedure for notifying proper personnel in the event of an accident;
- (9) maintenance of records;
- (10) the inspection and maintenance and operability checks of radiographic exposure devices, radiation machines, survey instruments, transport containers, and storage containers;
- (11) steps that shall be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off scale or an alarm ratemeter alarms unexpectedly; and
- (12) sealed source recovery procedure if the licensee will perform sealed source recovery.

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Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. April 1, 1999; May 1, 1995; January 1, 1994.

.0514 SECURITY

During each radiographic operation the radiographer or radiographer's assistant shall maintain a continuous direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in Rule .0104 of this Chapter, except where the high radiation area:

- (1) is equipped with a control device or an alarm system as described in Rule .1615 of this Chapter, or
- (2) is locked to protect against unauthorized or accidental entry.

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Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. May 1, 1995; January 1, 1994.

.0515 RADIATION SURVEYS AND SURVEY RECORDS

(a) No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation as described in Rule .0506 of this Section is available and used at each site where radiography is performed, including sealed source exchange and at the storage area whenever a radiographic exposure device, a storage container or sealed source is being placed in storage.

(b) A survey with a radiation detection instrument shall be made after each radiographic exposure to determine that the sealed source has returned to its shielded position in the radiographic exposure device or the radiation machine is off. For sealed sources, the licensee shall conduct a survey of the guide tube as the radiographer or radiographer's assistant approaches the camera. The survey must determine that the sealed source has returned to its shielded position prior to exchanging films, repositioning the exposure head or dismantling the radiographic exposure device and associated

equipment.

(c) When the use of a radiographic exposure device or storage container is to be terminated at the end of a work period, a survey with a radiation detection instrument shall be made of the locked radiography device or storage container to determine that the sealed source is in its shielded position.

(d) A survey of the radiographic exposure device and source changer shall be performed with a radiation detection instrument any time the sealed source is exchanged and whenever a radiographic exposure device is placed in a storage area.

(e) An area survey of the perimeter of the restricted area with a radiation detection instrument shall be made with the sealed source exposed or the radiation machine on before or during the initial radiographic exposure on each shift and when the sealed source or the radiation machine target configuration for an exposure is different from that of the preceding exposure such that the radiation exposure rate at the perimeter of the restricted area is likely to increase by a measurable amount using a radiation detection instrument. These surveys are not required for radiography performed in a permanent radiographic installation.

(f) Records of surveys required by this Rule shall be maintained in accordance with the requirements of Rule .0523 of this Section.

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Authority G.S. 104E-7; 104E-12(a)(1);
Eff. February 1, 1980;
Amended Eff. April 1, 1999; May 1, 1995.

.0516 POSTING

Notwithstanding any provisions in Rule .1625 of this Chapter, areas in which radiography is being performed shall be conspicuously posted as required by Rule .1624 of this Chapter. The exception listed in Rule .1625 of this Chapter does not apply to industrial radiography.

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. April 1, 1999; January 1, 1994.

.0517 SUPERVISION OF RADIOGRAPHERS' ASSISTANTS

(a) Whenever a radiographer's assistant uses radiographic exposure devices or radiation machines, uses sealed sources or related source handling tools, or conducts radiation surveys required by Rule .0515(b) and (c) of this Section to determine that the exposure has been terminated and, if applicable, the sealed source has returned to the shielded position after an exposure, the assistant shall be under the personal supervision of a radiographer.

(b) The personal supervision shall include:

- (1) the radiographer's physical presence at the site where the sealed sources or radiation machines are being used;
- (2) the availability of the radiographer to give immediate assistance, if required; and
- (3) the radiographer's direct observation of the assistant's performance of the operations referred to in this Section.

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Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. April 1, 1999; May 1, 1995.

.0518 RADIATION MACHINES

The following are special requirements for radiography employing radiation machines:

- (1) Cabinet radiography using radiation machines shall be exempt from requirements of this Section except that no registrant shall permit any individual to operate a cabinet radiography unit until:
 - (a) the registrant has provided the individual a copy of, and instruction in, the operating procedures for the unit; and
 - (b) the individual has demonstrated, to the registrant, understanding of the operating procedures for the unit and competence in its use.
- (2) Other radiography using radiation machines are exempt from Rules .0503, .0504, .0505, .0507, .0508 and .0521 of this Section.

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Authority G.S. 104E-7; 104E-12(a)(1);
Eff. February 1, 1980;
Amended Eff. May 1, 1995; June 1, 1993.*

.0519 SUBJECTS TO BE COVERED DURING INSTRUCTION OF RADIOGRAPHERS

The following subjects shall be covered in the instructions of radiographers:

- (1) fundamentals of radiation safety:
 - (a) characteristics of gamma and x-radiation;
 - (b) units of radiation dose (mrem, sievert) and quantity of radioactivity (curie, becquerel);
 - (c) hazards of exposure of radiation;
 - (d) levels of radiation from sources of radiation;
 - (e) methods of controlling radiation dose:
 - (i) working time,
 - (ii) working distances,
 - (iii) shielding,
- (2) radiation detection instrumentation to be used:
 - (a) use of radiation survey instruments:
 - (i) operation,
 - (ii) calibration,
 - (iii) limitations,
 - (b) survey techniques;
 - (c) use of personnel monitoring equipment;
 - (i) film badges,
 - (ii) pocket dosimeters,
 - (iii) pocket chambers,
- (3) radiographic equipment to be used:
 - (a) remote handling equipment;
 - (b) radiographic exposure devices, radiation machines and sealed sources;
 - (c) storage containers;
 - (d) operation and control of radiography equipment;
 - (e) storage, control and disposal of sealed sources;
- (4) the requirements of pertinent federal and state regulations;
- (5) the licensee's or registrant's written operating and emergency procedures;
- (6) inspection and maintenance performed by radiographers;
- (7) case histories of radiography accidents;

- (8) the conditions of the license or registration issued by the agency.

History Note: Filed as a Temporary Amendment Eff. August 20, 1994, for a Period of 180 Days or Until the Permanent Rule Becomes Effective, Whichever is Sooner;
Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. May 1, 1995.

.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 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.

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Authority G.S. 104E-7; 104E-12(a)(1);
Eff. October 1, 1980;
Amended Eff. April 1, 1999; May 1, 1995; January 1, 1994.

.0521 PERFORMANCE REQUIREMENTS FOR RADIOGRAPHY EQUIPMENT

Equipment used in industrial radiographic operations shall meet the following minimum criteria:

- (1) Each radiographic exposure device, source assembly or sealed source, and all associated equipment shall meet the requirements specified in American National Standard N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography". This publication is incorporated by reference in Rule .0117 of this Chapter.
- (2) Engineering analysis may be submitted to the agency to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review by the agency, this may be an acceptable alternative to actual testing of the component pursuant to the above referenced standard.
- (3) In addition to the requirements specified in Item (1) of this Rule, the following requirements apply to radiographic exposure devices, source changers, source assemblies, and sealed sources:
 - (a) Each radiographic exposure device shall have attached to it by the user a durable, legible, clearly visible label bearing the following:

- (i) Chemical symbol and mass number of the radionuclide in the device;
 - (ii) Activity and the date on which this activity was last measured;
 - (iii) Model number (or product code) and serial number of the sealed source;
 - (iv) Manufacturer's identity of the sealed source; and
 - (v) Licensee's name, address, and telephone number.
- (b) Radiographic exposure devices intended for use as Type B transport containers shall meet the applicable requirements of 10 CFR Part 71.
- (c) Modification of radiographic exposure devices, source chargers and source assemblies and associated equipment is prohibited, unless the design of any replacement component, including sealed source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.
- (4) In addition to the requirements specified in Items (1) and (3) of this Rule, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the sealed source to be moved out of the device for radiographic operations or to source changers.
- (a) The coupling between the source assembly and the control cable shall be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling shall be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.
 - (b) The device shall automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system shall be designed to only allow release of the sealed source by means of a deliberate operation on the exposure device.
 - (c) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device shall be equipped with safety plugs or covers which shall be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.
 - (d) Each sealed source or source assembly shall have attached to it or engraved in it, a durable, legible, visible label with the words: "DANGER--RADIOACTIVE." The label shall not interfere with the safe operation of the exposure device or associated equipment.
 - (e) The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.
 - (f) Guide tubes shall be used when moving the sealed source out of the device.
 - (g) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube shall be attached to the outermost end of the guide tube during radiographic operations.
 - (h) The guide tube exposure head connection shall be able to withstand the tensile test for control units specified in ANSI N432.
 - (i) Source changers shall provide a system for assuring that the sealed source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.
- (5) All associated equipment acquired after January 10, 1996 shall be labeled to identify that the components have met the requirements of this Rule.

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 Authority G.S. 104E-7;
 Eff. May 1, 1995;*

Amended Eff. April 1, 1999.

.0522 REPORTING REQUIREMENTS

(a) In addition to the reporting requirements specified in other rules of this Chapter, each licensee or registrant shall provide a written report to the agency at the address specified in Rule .0111 of this Chapter within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

- (1) unintentional disconnection of the source assembly from the control cable;
- (2) inability to retract the source assembly to its fully shielded position and secure it in this position;
or
- (3) failure of any component critical to safe operation of the device to properly perform its intended function.

(b) The licensee or registrant shall include the following information in each report required by Paragraph (a) of this Rule, and in each report of overexposure submitted pursuant to Section .1600 which involves failure of safety components of radiography equipment:

- (1) a description of the equipment problem;
- (2) cause of each incident, if known;
- (3) manufacturer and model number of equipment involved in the incident;
- (4) place, time and date of the incident;
- (5) actions taken to establish normal operations;
- (6) corrective actions taken or planned to prevent recurrence; and
- (7) qualifications of personnel involved in the incident.

(c) Any licensee or registrant conducting radiographic operations or storing radioactive material at any location not listed on the license for a period in excess of 180 days in a calendar year, shall notify the agency prior to exceeding the 180 days.

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Authority G.S. 104E-7;
Eff. May 1, 1995;
Amended Eff. April 1, 1999.*

.0523 RECORDS OF INDUSTRIAL RADIOGRAPHY

(a) Each licensee or registrant shall maintain, for a period of three years after the record is made, the following records for inspection by the agency:

- (1) copies of the following documents:
 - (A) radioactive materials license or registration issued by the agency;
 - (B) the complete application submitted for the license or registration that includes all amendments; and
 - (C) current operating and emergency procedures;
- (2) records showing the receipt and transfer of all sealed sources and devices using depleted uranium (DU) for shielding that include:
 - (A) date;
 - (B) individual making the record;
 - (C) radionuclide;
 - (D) activity in curies or becquerel or mass for depleted uranium; and
 - (E) make, model and serial number of each sealed source and device;
- (3) records of the calibrations of radiation detection instrumentation;
- (4) records of leak tests for sealed sources and devices containing depleted uranium in units of microcuries or becquerel;

- (5) records of quarterly inventories that include:
 - (A) radionuclide;
 - (B) activity in curies or becquerel;
 - (C) specific information on each sealed source and the radiographic exposure device, storage container or source changer which contains the sealed source to include:
 - (i) model numbers;
 - (ii) serial numbers; and
 - (iii) manufacturers names;
 - (D) location of sealed sources;
 - (E) name of the individual conducting the inventory; and
 - (F) the date of the inventory;
- (6) records of utilization logs showing the following information:
 - (A) a description of each radiographic exposure device, radiation machine or transport or storage container in which the sealed source is located that includes:
 - (i) make;
 - (ii) model number; and
 - (iii) serial number;
 - (B) the identity and signature of the radiographer to whom assigned; and
 - (C) the plant or site where used; and
 - (D) dates of use that includes the dates removed and returned to storage;
- (7) records of inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers and radiation machines. The record shall include:
 - (A) date of the check;
 - (B) name of the individual performing the check;
 - (C) equipment involved;
 - (D) any problems found in daily checks and quarterly inspections; and
 - (E) any repairs or maintenance made and name of individual or company performing the repair;
- (8) records of alarm system tests for permanent radiographic installations;
- (9) records of the training and certification of each radiographer and radiographer's assistant as follows:
 - (A) radiographer certification documents and verification of certification status;
 - (B) for initial training, copies of written tests, dates and results of oral tests and field examinations; and names of individuals conducting and receiving the oral test or field examination;
 - (C) for periodic training and semi-annual inspections of job performance, list of topics discussed, date(s) of the review, names of the instructors and the attendees; and
 - (D) for inspections of job performance, the records shall also include a list showing the items checked and any noncompliance observed by the Radiation Safety Officer.
- (10) records for pocket dosimeters to include daily exposure readings and yearly operability checks;
- (11) records of reports received from the film badge or TLD processor. These records shall be maintained until the agency terminates the license or registration or until authorized by the agency;
- (12) records of exposure device surveys performed at the end of the work day and prior to placing the device in storage;
- (13) records of area surveys required by Rule .0515 of this Section;
- (14) copy of current operating and emergency procedures until the agency terminates the license or registration and copies of superseded material shall be retained for three years after the change is made; and

- (15) evidence of the latest calibrations of alarm ratemeters and operability checks of pocket dosimeters or electronic personal dosimeters.
- (b) Each licensee or registrant conducting operations at temporary jobsites shall maintain copies of the following documents and records at the temporary jobsite until the radiographic operation is completed:
- (1) operating and emergency procedures required by Rule .0513 of this Section;
 - (2) radioactive materials license or registration;
 - (3) evidence of training of the radiographers and radiographer's assistants. The individuals shall either be listed on the radioactive materials license or registration and offer identification or shall have certification of his training and offer identification;
 - (4) evidence of the latest calibration of the radiation detection instrumentation in use at the site as required by Rule .0506 of this Section;
 - (5) evidence of the latest leak test of the sealed source required by Rule .0507 of this Section;
 - (6) records of the latest surveys required by Rule .0515 of this Section;
 - (7) records of current direct reading dosimeters such as pocket dosimeter or electronic personal dosimeter readings;
 - (8) shipping papers for the transportation of radioactive materials required by 10 CFR Part 71.5;
 - (9) records of area surveys required by Rule .0515 of this Section;
 - (10) a copy of Section .0500 of this Chapter;
 - (11) utilization records for each radiographic exposure device dispatched from that location as required by Subparagraph (a) of Rule .0523 of this Section;
 - (12) records of equipment problems identified in daily checks of equipment; and
 - (13) when operating under reciprocity, a copy of the Nuclear Regulatory Commission or agreement state license authorizing the use of radioactive material.
- (c) Each record required by this Rule shall be legible throughout the specified retention period. The record may be an original, a reproduced copy or microform provided that the copy or microform is authenticated by the licensee and the microform is capable of reproducing a clear copy throughout the required record retention period. The record may also be stored in electronic media with the capability for producing legible, accurate and complete records during the required record retention period. Records, such as letters, drawings and specifications shall include all pertinent information, such as stamps, initials and signatures. The licensee or registrant shall maintain safeguards against tampering with and loss of records.

*History Note: Filed as a Temporary Adoption 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. May 1, 1995;
Amended Eff. April 1, 1999.*

.0524 SPECIFIC LICENSE FOR INDUSTRIAL RADIOGRAPHY

An application for a specific license for the use of licensed material in industrial radiography shall be approved if the applicant meets the following requirements:

- (1) the applicant satisfies the general requirements specified in Rules .0317 and .0323 of this Chapter for radioactive material, as appropriate, and any special requirements contained in this Section;
- (2) the applicant submits a program for training radiographers and radiographers' assistants, that meets the requirements of Rule .0323 of this Chapter and Rule .0510 of this Section.
- (3) the applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid;
- (4) the applicant submits written operating and emergency procedures as described in Rule .0323

- of this Chapter and Rule .0513 of this Section;
- (5) the applicant submits a description of a program for inspections of the job performance of each radiographer and radiographers' assistant at intervals not to exceed six months as described in Rule .0323 of this Chapter;
 - (6) the applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility;
 - (7) the applicant identifies and lists the qualifications of the individual(s) designated as the radiation safety officer and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with the requirements of this Chapter;
 - (8) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium shielding, the applicant shall describe the procedures for performing and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application shall include a description of the procedures to be followed. The description shall include the:
 - (a) instruments to be used;
 - (b) methods of performing the analysis; and
 - (c) pertinent experience of the person who will analyze the wipe samples;
 - (9) If the applicant intends to perform "in-house" calibrations of survey instruments, the applicant shall describe methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations shall be performed according to the procedures described and at the intervals prescribed in Rule .0506 of this Section;
 - (10) The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations; and
 - (11) The applicant identifies the locations where all records required by this Section and other Sections of this Chapter will be maintained.

*History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. April 1, 1999.*

.0525 RADIOGRAPHER CERTIFICATION

- (a) An independent certifying organization shall:
 - (1) be an organization such as the American Society of Nondestructive Testing (ASNT) or other society or association, whose members participate in, or have an interest in, the field of industrial radiography;
 - (2) make its membership available to the general public nationwide that is not restricted because of race, color, religion, sex, age, national origin or disability;
 - (3) have a certification open to nonmembers, as well as members;
 - (4) be an incorporated, nationally recognized organization, such as ASNT, that is involved in setting national standards of practice within its field of expertise;
 - (5) have staff, a viable system for financing its operations, and policy and decision-making review board;
 - (6) have a set of written organizational by-laws and policies that provide assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;
 - (7) have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;
 - (8) have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;

- (9) have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program;
 - (10) have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;
 - (11) have procedures for proctoring examinations, including qualifications for proctors;
 - (12) ensure that the procedures in Subparagraph (a)(11) of this Paragraph require that the individuals proctoring each examination are not employed by the same company or corporations (or a wholly-owned subsidiary of such company or corporation) as any of the examinees;
 - (13) exchange information about certified individuals with the agency and other independent certifying organizations or the U.S. Nuclear Regulatory Commission and other agreement states, and allow periodic review of its certification program and related records; and
 - (14) provide a description to the agency of its procedures for choosing examination sites and for providing an environment suitable for examination.
- (b) All certification programs shall:
- (1) require applicants for certification to receive training in the topics set forth in Rule .0519 of this Section and satisfactorily complete a written examination covering the topics in Rule .0519 of this Section;
 - (2) require applicants for certification to provide documentation that demonstrates that the applicant has:
 - (A) received training in the topics set forth in Rule .0519 of this Section; or
 - (B) satisfactorily completed a minimum period of on-the-job training; and
 - (C) received verification by an agreement state or a Nuclear Regulatory Commission licensee that the applicant has demonstrated the capability of independently working as a radiographer;
 - (3) include procedures to ensure that all examination questions are protected for disclosure;
 - (4) include procedures for denying an application, and for revoking, suspending, and reinstating a certification;
 - (5) provide a certification period of not less than three years and not more than five years;
 - (6) include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training; and
 - (7) provide a timely response to inquiries by telephone or letter, from members of the public, about an individual's certification status.
- (c) All examinations shall be:
- (1) designed to test an individual's knowledge and understanding of the topics set forth in Rule .0519 of this Section;
 - (2) written in a multiple-choice format; and
 - (3) have test items drawn from a question list based on the material contained in Rule .0519 of this Section.

History Note: Authority G.S. 104E-7; 104E-10(b); 10 C.F.R. 34.43; 10 C.F.R. 34, Appendix A; Eff. April 1, 1999.

SECTION .0600 - X-RAYS IN THE HEALING ARTS

This Section .0600, Chapter 11 of Title 15A of the North Carolina Administrative Code (T15A.11 .0600); X-RAYS IN THE HEALING ARTS; has been transferred and recodified from Section .2700, Subchapter 3G of Title 10 of the North Carolina Administrative Code (T10.03G .2700), effective January 4, 1990. The recodification was pursuant to G.S. 143B-279.3.

.0601 PURPOSE AND SCOPE

This Section establishes requirements for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of this Section are in addition to, and not in substitution for, the provisions of Sections .0100, .0200, .0900, .1000, and .1600 of this Chapter.

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

.0602 DEFINITIONS

- (a) As used in this Section, the following definitions shall apply:
- (1) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.
 - (2) "Added filter" means the filter added to the inherent filtration.
 - (3) "Aluminum equivalent" means the thickness of aluminum, type 1100 alloy, affording the same attenuation, under specified conditions, as the material in question. The nominal composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum and 0.12 percent copper.
 - (4) "Attenuation block" means a block or stack, having dimensions 20 cm by 20 cm by 3.8 cm, of type 1100 aluminum alloy or other materials having equivalent attenuation.
 - (5) "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain, at a preselected location(s), a required quantity of radiation. Phototimer is described separately.
 - (6) "Beam axis" means a line from the source of x-rays through the centers of the x-ray fields.
 - (7) "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.
 - (8) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.
 - (9) "Changeable filters" means any added filter which can be removed from the useful x-ray beam through any electronic, mechanical or physical process.
 - (10) "Contact therapy system" means that the x-ray tube target is put within five centimeters of the surface being treated.
 - (11) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for manually setting the technique factors.
 - (12) "Cooling curve" means the graphical relationship between heat units stored and cooling time.
 - (13) "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.
 - (14) "Diagnostic source assembly" means the tube housing assembly with a device attached.
 - (15) "Diagnostic-type protective tube housing" means a tube housing so constructed that the leakage radiation measured at a distance of one meter from the source does not exceed 100 mR in one hour when the tube is operated at its leakage technique factors.
 - (16) "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

- (17) "Direct scattered radiation" means that radiation which has been deviated in direction by materials irradiated by the useful beam. (See also scattered radiation).
- (18) "Entrance exposure rate" means the roentgens per unit time at the point where the center of the useful beam enters the patient.
- (19) "Exposure" means the quotient of dQ by dm where " dQ " is the absolute value of the total charge of the ions of one sign produced in air when all the electrons, negatrons and positrons, liberated by photons in a volume element of air having mass " dm " are completely stopped in air. The special unit of exposure is the roentgen.
- (20) "Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.
- (21) "Filter" means material placed in the useful beam to preferentially attenuate selected radiations.
- (22) "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks and structural material providing linkage between the image receptor and the diagnostic source assembly.
- (23) "General purpose radiographic x-ray system" means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.
- (24) "Gonad shield" means a protective barrier used to reduce exposure to the testes or ovaries.
- (25) "Half-value layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.
- (26) "Healing arts mass screening" means the examination of human beings using x-rays for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts who is legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment. It does not include the use of x-ray tests as a requirement for hospital admission or as a condition of employment.
- (27) "Image intensifier" means a device, including housing, which converts an x-ray pattern into a corresponding light image of higher energy density.
- (28) "Image receptor" means any device, such as fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.
- (29) "Inherent filtration" means the filtration permanently in the useful beam; it includes the window of the x-ray tube and any permanent tube or source enclosure.
- (30) "Installation" means the act of physical movement of a radiographic system from one location to another in conjunction with a change of ownership.
- (31) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.
- (32) "Leakage radiation" means radiation emanating from a diagnostic or therapeutic source assembly except for:
- (A) the useful beam and
 - (B) radiation produced when the exposure switch or timer is not activated.
- (33) "Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly (i.e., tube housing and beam limiting device) which are used in measuring leakage radiation. They are defined as follows:
- (A) for diagnostic source assemblies intended for capacitor energy storage equipment, the maximum rated peak tube potential and the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (mC) or the minimum obtainable from the unit, whichever is larger;

- (B) for diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum rated peak tube potential and the maximum rated number of x-ray pulses in an hour for operation at the maximum rated peak tube potential; and
 - (C) for all other diagnostic or therapeutic source assemblies, the maximum rated peak tube potential and the maximum rated continuous tube current for the maximum rated peak tube potential.
- (34) "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.
 - (35) "Maximum line current" means the rms (root-mean-square) current in the supply line of an x-ray machine operating at its maximum rating.
 - (36) "Mobile equipment" (see x-ray equipment).
 - (37) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.
 - (38) "Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (see also "Automatic exposure control").
 - (39) "Portable equipment" (see x-ray equipment).
 - (40) "Position indicating device (PID)" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-skin distance. It may or may not incorporate or serve as a beam-limiting device.
 - (41) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for radiation protection purposes, to reduce the radiation exposure.
 - (42) "Protective apron" means an apron made of radiation attenuating materials used to reduce radiation exposure.
 - (43) "Protective barrier" means a barrier of radiation attenuating material(s) used to reduce radiation exposure. Types of protective barriers are defined in other items of this Rule.
 - (44) "Protective glove" means a glove made of radiation attenuating materials used to reduce radiation exposure.
 - (45) "Qualified expert" means an individual who is registered pursuant to Rule .0205 of this Chapter.
 - (46) "Radiograph" means an image receptor on which the image has been created directly or indirectly by an x-ray pattern and results in a permanent record.
 - (47) "Radiographic imaging system" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.
 - (48) "Rating" means the operating limits as specified by the component manufacturer.
 - (49) "Recording" means producing a permanent form of an image resulting from x-ray photons such as film and video tape.
 - (50) "Registrant", as used in this Section, means any person who owns or possesses and administratively controls an x-ray system which is used to deliberately expose humans or animals to the useful beam of the system and is required by the provisions contained in Sections .0100 and .0200 of this Chapter to register with the agency.
 - (51) "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state mid-scale reading.
 - (52) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction. (See also "direct scattered radiation".)
 - (53) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

- (54) "SID" means source-image receptor distance.
- (55) "Source" means the focal spot of the x-ray tube.
- (56) "Source-image receptor distance (SID)" means the distance from the source to the center of the input surface of the image receptor.
- (57) "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.
- (58) "Stationary equipment" (see x-ray equipment).
- (59) "Stray radiation" means the sum of leakage and scattered radiation.
- (60) "Technique factors" means the conditions of operation. They are specified as follows:
 - (A) for capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
 - (B) for field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses; and
 - (C) for all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.
- (61) "Therapeutic-type protective tube housing" means the tube housing with tube installed, and it includes high voltage and filament transformers and other appropriate elements when they are contained within that housing.
- (62) "Transportation equipment" means x-ray equipment which is installed in a vehicle or trailer.
- (63) "Tube" means an x-ray tube, unless otherwise specified.
- (64) "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and filament transformers and other appropriate elements when they are contained within the tube housing.
- (65) "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.
- (66) "Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.
- (67) "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at the given SID.
- (68) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons produce a visible image.
- (69) "X-ray control" means a device which controls input power to the x-ray high-voltage generator or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers and similar devices which control the technique factors of an x-ray exposure.
- (70) "X-ray equipment" means an x-ray system, subsystem or component thereof.
 - (A) "Mobile equipment" means x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.
 - (B) "Portable equipment" means x-ray equipment designed to be hand-carried.
 - (C) "Stationary equipment" means x-ray equipment which is installed in a fixed location.
- (71) "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.
- (72) "X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices and other appropriate elements.
- (73) "X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device and the necessary supporting structures. Additional components which

function with the system are considered integral parts of the system.

(74) "X-ray subsystem" means any combination of two or more components of an x-ray system for which there are requirements specified in this Section.

(75) "X-ray tube" means an electron tube which is designed for the conversion of electrical energy into x-ray energy.

(b) Other definitions applicable to this Section may be found in Sections .0100 and .0200 of this Chapter.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. June 1, 1993; May 1, 1992; October 1, 1980.*

.0603 GENERAL REQUIREMENTS

(a) Administrative controls

(1) The registrant shall be responsible for directing the operation of the x-ray machines which he has registered with the agency. He or his agent shall assure that the following provisions are met in the operation of the x-ray machine(s):

(A) An x-ray machine which does not meet the provisions of these Rules shall not be operated for diagnostic or therapeutic purposes, if so ordered by the agency in accordance with Rules .0109 and .0110 of this Chapter.

(B) Individuals who will be operating the x-ray equipment shall be instructed in the safe operating procedures and use of the equipment and demonstrate an understanding thereof to the registrant.

(C) In the vicinity of each diagnostic x-ray system's control panel, a chart shall be provided, which specifies for all usual examinations and associated projections which are performed by that system, a listing of information including patient's anatomical size versus technique factors to be utilized at a given source to image receptor distance. The chart shall also provide:

- (i) type and size of the film or film-screen combination to be used,
- (ii) type and ratio of grid to be used, if any, and focal spot to film distance,
- (iii) type and placement of gonad shielding to be used.

(D) Written safety procedures and rules shall be established and made available to each individual operating x-ray equipment under his control. The operator shall be familiar with these rules.

(E) Only the professional staff and ancillary personnel required for the medical procedure or for training shall be in the room during the radiographic exposure. Other than the patient being examined:

- (i) All individuals shall be positioned such that no part of the body including the extremities which is not protected by 0.5 mm lead equivalent will be exposed to the useful beam.
- (ii) Professional staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead equivalent.
- (iii) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 mm lead equivalent or shall be so positioned that the nearest portion of the body is at least six feet from both the tube head and the nearest edge of the image receptor.
- (iv) When a portion of the body of a non- occupationally exposed professional staff or ancillary personnel is potentially subjected to stray radiation which would result in that individual receiving one-fourth of the maximum permissible dose as defined in

- Rule .1604 of this Chapter, additional protective measures shall be employed.
- (v) Upon written application to the agency, the agency may waive the requirements in Subparts (a)(1)(E)(ii) and (a)(1)(E)(iii) of this Rule if the registrant demonstrates that such waiver is necessary for best management of patients and will not result in violation of the public and occupational dose limits established in the rules in this Chapter.
 - (F) Gonad shielding of not less than 0.5 mm lead equivalent shall be used for potentially procreative patients during radiographic procedures in which the gonads are in the direct, or useful beam, except for cases in which this would interfere with the diagnostic procedures.
 - (G) Individuals shall not be exposed to the useful beam except for healing arts purposes. Such exposures shall have been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other nonhealing arts purposes.
 - (H) When a patient or film must be provided with auxiliary support during a radiographic exposure:
 - (i) Mechanical holding devices shall be used whenever medical circumstances permit. Written safety procedures, as required in Part (a)(1)(D) of this Rule shall indicate the requirements for selecting a holder;
 - (ii) If a human holder is required, written safety procedures as required in Part (a)(1)(D) of this Rule, shall indicate the instructions provided to the holder;
 - (iii) The human holder shall be protected as required in Part (a)(1)(E) of this Rule;
 - (iv) No individual shall be used routinely to hold patients or film.
 - (I) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. This includes, but is not limited to, the following requirements:
 - (i) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.
 - (ii) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.
 - (iii) Portable or mobile equipment shall be used only for examinations where it is impractical for medical reasons to transfer the patient to a stationary radiographic installation.
 - (J) All persons who are associated with the operation of an x-ray system are subject to the occupational exposure limits as defined in Rules .1604 and .1638 of this Chapter, and personnel monitoring procedures in Rule .1614 of this Chapter. In addition, when protective clothing or equipment is worn on portions of the body and a monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:
 - (i) When an apron is worn the monitoring device shall be worn at the collar outside the apron.
 - (ii) The dose to the whole body shall be recorded in the reports required in Rule .1640 of this Chapter. If more than one device is used, each dose shall be identified with the area where the device was worn on the body.
- (2) The registrant shall maintain at least the following information for each x-ray machine:
- (A) current registration information and other correspondence with the agency regarding that machine;
 - (B) records of surveys and calibrations;
 - (C) records of maintenance or modifications which affect the useful beam after the effective date of these Rules, along with the names of persons who performed the service.
- (b) Plans Review. Prior to construction or structural modification, the floor plans and equipment

arrangement of all installations utilizing x-rays for diagnostic or therapeutic purposes shall be reviewed by a qualified expert. The registrant shall submit recommendations of the expert to the agency.

(c) Radiation Survey

- (1) For installations of x-ray equipment after the effective date of this Rule, an area radiation survey shall be performed within 30 days following initial operation of each radiation machine to show compliance with Rule .0604(b) of this Section. This survey shall include:
 - (A) a drawing of the room in which a stationary x-ray system is located and radiation levels in adjacent areas; and
 - (B) the name of the person approved by the agency performing the survey and the date the survey was performed.
- (2) Any modification to the x-ray room or adjacent areas which could increase the radiation dosage to any individual ~~shall require a new survey.~~
- (3) Records of this survey shall be maintained in accordance with Subparagraph (a)(2) of this Rule.

*History Note: Authority G.S. 104E-7; 104E-12(a);
 Eff. February 1, 1980;
 Amended Eff. January 1, 1994; October 1, 1980.*

.0604 GENERAL REQUIREMENTS FOR ALL DIAGNOSTIC SYSTEMS

(a) In addition to other requirements of this Section, all diagnostic x-ray systems shall meet the following requirements:

- (1) The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operation instructions are observed."
- (2) Equivalent wording may be used on battery-powered generators; visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.
- (3) The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 100 millirem in one hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- (4) The radiation emitted by a component other than the diagnostic source assembly shall not exceed two millirem in one hour at five centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- (5) Beam Quality
 - (A) Half-Value Layer
 - (i) The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the appropriate value shown in the following table. "Specified Dental System" is any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980. "Other X-Ray Systems" shall be all other x-ray systems subject to this Section.

X-Ray Tube Voltage	(kilovolt peak) (millimeters of Aluminum)	Minimum HVL (millimeters of Aluminum)	Minimum HVL
Measured	Specified	Other	

Designed operating range	Operating Potential	Dental Systems	X-ray Systems
Below 50-----	30	1.5	0.3
40	1.5	0.4	
49	1.5		0.5
50 to 70-----	50	1.5	1.2
60	1.5	1.2	
70	1.5	1.5	
Above 70-----	71	2.1	2.1
80	2.3	2.3	
90	2.5	2.5	
100	2.7	2.7	
110	3.0	3.0	
120	3.2	3.2	
130	3.5	3.5	
140	3.8	3.8	
150	4.1	4.1	

If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in the table, linear interpolation or extrapolation may be made. Positive means shall be provided to insure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure.

- (ii) The requirements of Subpart (a)(5)(A)(i) of this Rule shall be considered to be met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in the following table:

Filtration Required versus Operating Voltage

Operating Voltage (kVp)	Minimum total filtration (inherent plus added) (millimeters aluminum equivalent)
Below 50	0.5 millimeters
50 - 70	1.5 millimeters
Above 70	2.5 millimeters

- (iii) Notwithstanding the requirements of Subpart (a)(5)(A)(ii) of this Rule, all intraoral dental systems manufactured after December 1, 1980, shall have a minimum of 1.5 mm aluminum equivalent filtration permanently installed in the useful beam.
- (iv) Beryllium window tubes shall have a minimum of 0.5 mm aluminum equivalent filtration permanently mounted in the useful beam.
- (v) For capacitor energy storage equipment, compliance shall be determined with the maximum quantity of charge per exposure.
- (vi) The required minimum aluminum equivalent filtration shall include the filtration

contributed by all materials which are always present between the focal spot of the tube and the patient, such as a tabletop when the tube is mounted under the table and inherent filtration of the tube.

- (B) For new x-ray systems installed after the effective date of these Rules and which have variable kVp and selectable filtration for the useful beam, a device shall link the kVp selector with the filter(s), so that the minimum filtration is always present for the kVp selected.
- (6) Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected and their location shall be clearly indicated on the master control panel prior to initiation of the exposure.
- (7) The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a design function of the x-ray system.
- (8) The location of the focal spot may be indicated on a readily visible area of the x-ray source housing in the plane parallel to the image receptor when the image receptor is perpendicular to the beam axis.
- (9) Technique Indicators
 - (A) The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated.
 - (B) Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.
 - (C) On equipment having fixed technique factors, the recommendation in Part (a)(9)(A) of this Rule may be met by permanent markings.
- (b) Structural Shielding
 - (1) For stationary diagnostic systems, except for intraoral dental systems which shall meet the requirements of Rule .0607(j) of this Section, structural shielding shall be provided to assure compliance with Rules .1604 and .1611 of this Chapter. The following shall be provided:
 - (A) All wall, floor and ceiling areas exposed to the useful beam shall have primary barriers. Primary barriers in walls shall extend to a minimum height of 84 inches above the floor;
 - (B) Secondary barriers in the wall, floor and ceiling areas not having a primary barrier or where the primary barrier requirements are lower than the secondary barrier requirements; and
 - (C) A window of lead-equivalent glass equal to that required by the adjacent barrier or a mirror system shall be provided large enough and so placed that the operator can see the patient without having to leave the protected area during exposures.
 - (2) When a mobile system is used routinely in one location, the structural shielding in that location shall meet the requirements for stationary diagnostic systems in Subparagraph (b)(1) of this Rule.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. January 1, 1994; October 1, 1980.*

.0605 FLUOROSCOPIC X-RAY SYSTEMS

All fluoroscopic x-ray systems shall meet the following requirements:

- (1) Limitation of useful beam
 - (a) The fluoroscopic tube shall not produce x-rays unless the primary protective barrier is in position to intercept the entire useful beam at all times.
 - (b) The entire cross section of the useful beam shall be intercepted by the primary protective

- barrier of the fluoroscopic image assembly at any SID.
- (c) Limitation to the Imaging Surface
 - (i) The x-ray field produced by fluoroscopic equipment without image intensification shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size during both fluoroscopic procedures and spot-filming procedures.
 - (ii) Image-intensified fluoroscopy and spot-filming shall comply with the following:
 - (A) During fluoroscopic or spot-filming procedures, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed the visible area of the image receptor by more than three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID.
 - (B) Compliance shall be determined with the beam axis perpendicular to the image receptor. For rectangular x-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.
 - (iii) In addition to other requirements of this Rule, equipment manufactured after the effective date of these Rules shall comply with the following:
 - (A) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. This adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film.
 - (B) It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID, shall be equal to or less than five centimeters by five centimeters.
 - (C) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent of the SID.
 - (2) X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.
 - (3) Entrance exposure rates shall be limited as required in the following:
 - (a) Fluoroscopic equipment shall not be operated at any combination of tube potential and current which will result in an exposure rate in excess of ten roentgens per minute at the point where the center of the useful beam enters the patient, except:
 - (i) during recording of fluoroscopic images; or
 - (ii) when provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of five roentgens per minute at the point where the center of the beam enters the patient unless the high level control is activated. Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.
 - (b) In addition to the other requirements of this Rule equipment manufactured after August, 1974, which does not incorporate an automatic exposure control (e.g., automatic brightness control or ionization chamber control) shall not be operated at any combination

of tube potential and current which will result in an exposure rate in excess of five roentgens per minute at the point where the center of the useful beam enters the patient except during the recording of fluoroscopic images or when provided with an optional high level control.

- (c) Compliance with the provisions of Item (3) of this Rule shall be determined as follows:
 - (i) Movable grids and compression devices shall be removed from the useful beam during the measurement.
 - (ii) If the source is below the table, the exposure rate shall be measured one centimeter above the tabletop or cradle.
 - (iii) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
 - (iv) In a C-arm type fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.
- (d) Periodic measurement of entrance exposure rate limits shall comply with the following:
 - (i) Such measurements shall be made every two years or after any maintenance of the system which might affect the exposure rate.
 - (ii) Results of these measurements shall be available or posted where any fluoroscopist may have ready access to them and shall be in the record required in Rule .0603(a)(2)(B) of this Section. Results of the measurements shall include the exposure rate, as well as the physical factors used to determine all data; the name of the person approved by the agency performing the measurements and the date the measurements were performed.
 - (iii) Entrance exposure rate shall be determined with the attenuation block in Rule .0602(a) in the primary beam.
- (4) Radiation transmitted through the primary protective barrier of the fluoroscopic imaging assembly shall comply with the following requirements:
 - (a) The exposure rate resulting from transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed two milliroentgens per hour at ten centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.
 - (b) Measurements to determine compliance with Sub-item (4)(a) of this Rule shall be in accordance with the following:
 - (i) The exposure rate resulting from transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters;
 - (ii) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly, positioned 30 centimeters above the tabletop.
 - (iii) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters;
 - (iv) Movable grids and compression devices shall be removed from the useful beam during the measurement;
 - (v) The attenuation block shall be positioned in the useful beam ten centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.
- (5) During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously

- indicated.
- (6) The source-skin distance shall not be less than:
 - (a) 38 centimeters on stationary fluoroscopes,
 - (b) 30 centimeters on all mobile fluoroscopes, or
 - (c) 20 centimeters for image intensified fluoroscopes during surgical application.
 - (7) Fluoroscopic timers shall meet the following requirements:
 - (a) Means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.
 - (b) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.
 - (8) Mobile fluoroscopes, in addition to the other requirements of this Rule, shall provide image intensification.
 - (9) Scattered radiation shall be controlled in accordance with the following requirements:
 - (a) A shielding device of at least 0.25 mm lead equivalent for covering the Bucky slot during fluoroscopy shall be provided.
 - (b) A shield of at least 0.25 mm lead equivalent, such as overlapping protective drapes or hinged or sliding panels, shall be provided to intercept scattered radiation which would otherwise reach the fluoroscopist and others near the machine.
 - (c) Upon application to the agency with adequate justification, exceptions from Sub-items (9)(a) or (9)(b) of this Rule may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers or where the protective barriers would interfere with the procedures.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. May 1, 1993; May 1, 1992; October 1, 1980.*

.0606 SYSTEMS OTHER THAN FLUOROSCOPIC AND DENTAL INTRAORAL

(a) Unless specifically provided otherwise by the rules in this Chapter, the requirements in this Rule shall apply to all x-ray systems, except for fluoroscopic and dental intraoral x-ray systems. The useful beam of x-ray systems subject to provisions of this Rule shall be limited to the area of clinical interest or the image receptor, whichever is smaller.

- (1) General purpose stationary and mobile x-ray systems shall meet the following special requirements:
 - (A) There shall be provided a means for stepless adjustment of the size of the x-ray field. The minimum field size at a SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters.
 - (B) Means shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.
 - (C) Notwithstanding Parts (a)(1)(A) and (B) of this Rule, equipment manufactured before August 1, 1974 may employ fixed cones and diaphragms or variable collimators without beam defining lights.
- (2) In addition to the requirements of Subparagraph (a)(1) of this Rule, all stationary x-ray systems, except equipment originally manufactured before the effective date of this Rule, shall meet the following requirements:

- (A) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within two percent of the SID, and to indicate the SID to within two percent;
 - (B) The beam limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;
 - (C) Indication of field size dimensions and SID's shall be specified in inches or centimeters and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent of the SID when the beam axis is perpendicular to the plane of the image receptor.
- (3) Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor and to align the center of the x-ray field with the center of the image receptor to within two percent of the SID.
- (4) Special purpose x-ray systems shall meet the following requirements:
- (A) These systems shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
 - (B) Such systems shall also be provided with means to align the center of the x-ray field with the center of the image receptor to within two percent of the SID.
 - (C) The requirements in Parts (a)(4)(A) and (B) of this Rule may be met with a system that meets the requirements for a general purpose x-ray system as specified in Subparagraph (a)(1) of this Rule or, when alignment means are also provided, as follows:
 - (i) an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed, where each device has clear and permanent markings to indicate the image receptor size and SID for which it is designed; or
 - (ii) a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed, where the device has permanent, clearly legible, markings indicating image receptor size and SID for which the unit is designed, where the device has permanent, clearly legible, markings indicating image receptor size and SID for which each aperture is designated and indicating which aperture is in position for use.
- (b) Radiation exposure control devices shall meet the following requirements:
- (1) Means shall be provided to terminate the exposure after a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. In addition:
- (A) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero except during serial radiography, and
 - (B) It shall not be possible to make an exposure when the timer is set to a zero or "off" position if either position is provided.
- (2) Control over x-ray exposures shall be in accordance with the following requirements:
- (A) A control shall be incorporated into each x-ray system such that the operator can terminate an exposure at any time except for serial radiography where means may be provided to permit completion of any single exposure of the series in process.
 - (B) Each x-ray control shall be located in such a way as to meet the following criteria.
 - (i) For stationary x-ray systems, the control shall be permanently mounted in a protected area so that the operator is required to remain in that protected area

- during the entire exposure; and
- (ii) The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, except for equipment originally manufactured before the effective date of this Rule, a signal audible to the operator shall indicate that the exposure has terminated.
- (3) When an automatic exposure control (e.g., phototimer) is provided the following requirements shall be met, except equipment originally manufactured before the effective date of this Rule:
 - (A) Indication shall be made on the control panel when this mode of operation is selected;
 - (B) When the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;
 - (C) The minimum exposure time for all equipment other than that specified in Part (b)(3)(B) of this Rule shall be equal to or less than 1/60 second or a time interval required to deliver five mAs, whichever is greater;
 - (D) Either the product of peak x-ray tube potential, current and exposure time shall be limited to not more than 60 kW per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x-ray tube potential is less than 50 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and
 - (E) A visible signal shall indicate when an exposure has been terminated at the limits described in Part (b)(3)(D) of this Rule and manual resetting shall be required before further automatically timed exposures can be made.
 - (4) When four timer tests are performed at identical timer setting equal to 5.0 seconds or less, the average time period (T) shall be greater than five times the difference between the maximum period (T_{max}) and the minimum period (T_{min}) in accordance with the formula:

$$T > 5(T_{max} - T_{min})$$

(c) Source-skin or source-image receptor distance shall meet the following requirement:

All radiographic systems shall be provided with a durable, securely fastened means to limit the source-skin distance to at least 30 centimeters. This is considered to be met when the collimator or cone provides the required limits.

(d) The exposure produced shall be reproducible to within the following criteria:

When all technique factors are held constant, the coefficient of variation shall not exceed 0.10. This shall be deemed to be met if, when four exposures at identical technique factors are made, the value of the average exposure (E) is greater than five times the difference between the maximum exposure (E_{max}) and the minimum exposure (E_{min}) in accordance with the formula:

$$E > 5(E_{max} - E_{min})$$

(e) Standby radiation from capacitor energy storage equipment, when the exposure switch or timer is not activated, shall not exceed a rate of two milliroentgens per hour at five centimeters from any accessible surface of the diagnostic source assembly with the beam-limiting device fully open.

(f) Linearity

- (1) When the equipment allows a choice of x-ray tube current settings, the average ratios of exposure to the indicated milliamperere-seconds product, i.e., mR/mAs, obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum, i.e., $(x_1 - x_2) / \text{mean of } (x_1 + x_2) < 0.10$, where the mean of x_1 and x_2 are the average mR/mAs values obtained at each of two consecutive tube current settings.
- (2) Compliance shall be determined at the most commonly used mA stations by measuring

mR/mAs at those stations and at one adjacent station to each.

(g) Timer accuracy

- (1) For indicated values of 0.10 seconds and above, the measured value shall be within plus or minus 15 percent of the indicated values for equipment manufactured before August 1, 1974.
- (2) For equipment manufactured after August 1, 1974, the deviation of measured values from indicated values shall not exceed the limits specified for that system by its manufacturer.

History Note: Authority G.S. 104E-7;

Eff. February 1, 1980;

Amended Eff. May 1, 1993; November 1, 1989; October 1, 1980.

.0607 INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS

(a) In addition to the provisions of Rules .0603 and .0605 of this Section, the requirements of this Rule apply to x-ray equipment and associated facilities used for dental radiography. Criteria for extraoral dental radiographic systems are covered in Rule .0606 of this Section.

(b) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-skin distance to not less than:

- (1) 18 centimeters, if operated above 50 kilovolts peak; or
- (2) ten centimeters, if operated at or below 50 kilovolts peak.

(c) The size of the direct radiation beam shall be limited in accordance with the following rules:

- (1) Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:
 - (A) If the source-skin distance (SSD) is 18 centimeters or more, the x-ray field at the SSD shall be containable in a circle having a diameter of no more than seven centimeters; and
 - (B) If the SSD is less than 18 centimeters, the x-ray field at the SSD shall be containable in a circle having a diameter of no more than six centimeters.
- (2) Effective February 1, 1981, equipment manufactured prior to August 1974 shall be equipped with a lead line open position indicating device with at least 0.79 mm lead.

(d) The timing device shall comply with the following requirements:

- (1) Termination of the exposure after a preset interval;
- (2) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero;
- (3) It shall not be possible to make an exposure when the timer is set to a zero or "off" position if either position is provided; and
- (4) When four timer tests are performed at identical timer settings equal to five seconds or less, the average time period (T) shall be greater than five times the difference between the maximum period (T_{max}) and the minimum period (T_{min}) in accordance with the formula:

$$T > 5(T_{max} - T_{min})$$

- (5) Effective February 1, 1983, intraoral dental radiographic systems shall be equipped with an electronic timer.
- (6) Timer accuracy
 - (A) For indicated values of 0.10 seconds and above, the measured value shall be within plus or minus 15 percent of the indicated values for equipment manufactured before August 1, 1974.
 - (B) For equipment manufactured after August 1, 1974, the deviation of measured values from indicated values shall not exceed the limits specified for that system by its manufacturer.

(e) The exposure switch shall comply with the following requirements:

- (1) A control shall be incorporated into each x-ray system such that an exposure can be terminated at any time, except for exposures of one-half second or less.
- (2) Each x-ray control shall be located in such a way as to meet the following criteria:
 - (A) For stationary x-ray systems installed after the effective date of this Rule, the exposure switch shall be permanently mounted in a protected area (e.g., corridor outside the room) so that the operator is required to remain in that protected area during the entire exposure.
 - (B) For stationary x-ray systems without a protected area and installed before the effective date of this Rule, the exposure switch shall be such that the operator shall stand at least six feet away from the tube and out of the direct beam.
 - (C) For mobile and portable x-ray systems the switch shall meet the requirements of Part (e)(2)(B) of this Rule.
- (3) For equipment manufactured after August 1, 1974, the x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.
- (f) The exposure produced shall be reproducible to within the following criteria:

When all technique factors are held constant, the coefficient of variation shall not exceed 0.10. This shall be deemed to be met if, when four exposures at identical technique factors are made, the value of the average exposure (E) is greater than five times the difference between the maximum exposure (E_{max}) and the minimum exposure (E_{min}) in accordance with the formula:

$$E > 5(E_{max} - E_{min})$$
- (g) Patient and film holding devices shall be used when the techniques permit.
- (h) Neither the tube housing nor the position indicating device shall be hand-held during an exposure.
- (i) Dental fluoroscopy without image intensification shall not be used.
- (j) Structural shielding
 - (1) All wall, floor and ceiling areas shall have protective barriers sufficient to meet the requirements of Rules .1604 and .1611 of this Chapter.
 - (2) When intraoral x-ray systems are installed in adjacent rooms or areas, protective barriers as specified in Subparagraph (j)(1) of this Rule shall be provided between the rooms or areas.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. January 1, 1994; October 1, 1980.*

.0608 THERAPEUTIC X-RAY INSTALLATIONS: LESS THAN ONE MeV

- (a) Unless specifically provided otherwise by the rules in this Chapter, the requirements in this Rule shall apply only to therapeutic x-ray installations which are not capable of operating at or above one MeV. Therapeutic x-ray equipment subject to the provisions of this Rule shall comply with the following requirements:
- (1) When the tube is operated at its leakage technique factors, the leakage radiation in any direction shall not exceed the value specified at the distance specified for the classification of that x-ray system.
 - (A) For contact therapy systems, the leakage radiation shall not exceed 100 mR/hr at five centimeters from the tube housing.
 - (B) Systems operating from zero to 150 kVp which are manufactured or installed prior to the effective date of this Rule shall have a leakage radiation which does not exceed one R in

- one hour at one meter from the source.
- (C) Systems operating from zero to 150 kVp which are manufactured on or after the effective date of this Rule shall have a leakage radiation which does not exceed 100 mR in one hour at one meter from the source.
 - (D) Systems operating from 151 to 999 kVp shall have leakage radiation which does not exceed one R in one hour at one meter from the source, except systems which operate in excess of 500 kVp may have a leakage radiation in one hour at one meter from the source equivalent to 0.1 percent of the exposure in the useful beam in one hour at a distance of one meter from the source.
- (2) Permanent beam limiting devices used for collimating the useful beam shall provide the same or higher degree of protection as that required by the tube housing assembly.
 - (3) Adjustable or removable beam limiting devices shall transmit not more than five percent of the useful beam as determined at the maximum tube potential and maximum treatment filter.
 - (4) The filter system shall be so designed that:
 - (A) Filters cannot be accidentally displaced from the useful beam at any tube orientation;
 - (B) Each filter is marked as to its material of construction and its thickness or wedge angle for wedges;
 - (C) It shall be possible for the operator to determine the presence of and identify each filter and the orientation of each wedge filter in the useful beam when the operator is positioned at the control panel either by display at the control panel or by direct observation;
 - (D) The filters and filter insertion slot opening shall be so designed that the radiation at five centimeters from the filter insertion slot opening does not exceed 30 roentgens per hour under all operating conditions; and
 - (E) Each machine equipped with a beryllium or other low filtration window shall be clearly labeled as such upon the tube head housing and upon the control panel.
 - (5) The tube housing assembly shall be immobilized during stationary treatments.
 - (6) The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within five millimeters and such marking shall be readily accessible.
 - (7) Equipment of greater than 150 kVp installed after the effective date of this Rule shall be provided with a beam monitor system.
 - (8) The exposure timer shall meet the following requirements:
 - (A) A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and shall terminate irradiation when a preselected time has elapsed.
 - (B) The timer shall switch on and off with the radiation and retain its reading after irradiation is interrupted or terminated.
 - (9) The control panel shall have:
 - (A) an indication of whether electrical power is present and activation of the x-ray tube is possible;
 - (B) an indication of whether x-rays are being produced;
 - (C) the means for indicating kVp and x-ray tube current;
 - (D) the means for terminating an exposure at any time;
 - (E) a locking device which will prevent unauthorized use of the x-ray system and, for systems not having a lock at the control panel, an alternate method of preventing unauthorized use, shall be provided;
 - (F) for equipment manufactured after the effective date of this Rule, a positive display of specific filter(s) in the beam.
 - (10) When a control panel may energize more than one x-ray tube:
 - (A) It shall be possible to activate only one x-ray tube during any one time interval;

- (B) There shall be an indication at the control panel identifying which x-ray tube can be energized; and
- (C) There shall be an indication at the x-ray tube if that tubehead can be energized.
- (11) There shall be means of determining the target to patient distance to within one centimeter.
- (12) If exposures are controlled by a timer, that timer:
 - (A) shall permit the setting of exposure times at least as short as one second, and
 - (B) shall not permit an exposure if set at zero or "off".
- (13) Unless it is possible to bring the x-ray exposure rate to its prescribed value within five seconds of actuating the x-ray "on" control, the tube housing shall be fitted with a shutter operable only from the control panel, and of lead equivalent not less than that of the tube housing. In addition:
 - (A) The status of the shutter "Beam On", "Beam Off" or "Shutter Open", "Shutter Closed" or equivalent description, shall be indicated at the control panel.
 - (B) It shall not be possible to initiate an exposure sequence unless the shutter has first been placed in the "Beam Off" or "Shutter Closed" position.
 - (C) The shutter shall automatically go to the "Beam Off" or "Shutter Closed" position if the exposure is terminated by:
 - (i) the operation of the timer,
 - (ii) the dose monitoring system, if provided,
 - (iii) the operation of a safety interlock, or
 - (iv) a power failure.
- (b) In addition to shielding adequate to meet requirements of Section .1600 of this Chapter, the following treatment room design requirements shall be met:
 - (1) Treatment room entrances shall be provided with warning lights in a readily observable position, which will indicate when the useful beam is "on".
 - (2) Provision shall be made for two-way communication with the patient from the control room.
 - (3) A system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may see the patient and the control panel from the same position.
 - (4) Facilities which contain an x-ray system which may be operated above 150 kVp shall:
 - (A) have all necessary shielding, except for any beam interceptor, provided by fixed barriers;
 - (B) have the control panel in a protected area which is outside the treatment room;
 - (C) have all entrance doors to the treatment room electrically connected such that the x-ray production cannot be initiated unless all doors are closed and shall cease if any door is opened during x-ray production;
 - (D) if the radiation output of the x-ray tube is affected by any door opening, be so designed that it is possible to initiate x-ray production only by:
 - (i) closing all doors and, subsequently,
 - (ii) reinitiating the exposure by manual action at the control panel.
- (c) Operating procedures, surveys, and calibration shall comply with the following requirements:
 - (1) All new facilities and existing facilities not previously surveyed shall have a radiation protection survey made by, or under the direction of, a qualified expert. This shall also be done after any change in the facility which might produce a radiation hazard. The expert shall report his findings in writing to the person in charge of the facility, and a copy of this report shall be transmitted by the registrant to the agency at the address in Rule .0111 of this Chapter.
 - (2) The radiation output of each therapeutic x-ray machine shall be calibrated by, or under the direction of a qualified expert who is physically present at the facility during the calibration procedure. The calibration shall be repeated after any change, in or replacement of, components of the x-ray generating equipment which could cause a change in x-ray output. Calibration of the therapy beam shall be performed with a measurement instrument, the

- calibration of which is traceable to national standards for exposure or absorbed dose, and which shall have been calibrated within the preceding 12 months. Records of radiation outputs shall be provided to and maintained by the registrant.
- (3) Each therapeutic x-ray machine shall be calibrated as described in Subparagraph (c)(2) of this Rule at time intervals not exceeding one year. The calibration shall include at least the following determinations:
 - (A) the accurate determination of the air exposure rate or the dose rate at a reference point within a suitable phantom, as appropriate;
 - (B) the congruence between the radiation field and light localizer, when such is used;
 - (C) the half-value layer for every combination of kVp and filter used for radiation therapy.
 - (4) Therapeutic x-ray systems capable of operation at greater than 150 kVp, in addition to the annual calibration required in Subparagraphs (c)(2) and (3) of this Rule, shall have spot checks performed.
 - (A) The spot check methods and frequency shall be designed and in writing by a qualified expert. Spot checks shall include verification of continued congruency between the radiation field and the localizing device where an optical field illuminator is used.
 - (B) Whenever a spot check indicates a significant change in the operating characteristics of a machine, as specified in the qualified expert's spot check design, the machine shall be recalibrated as required.
 - (C) A log shall be kept of all spot check measurements.
 - (5) Therapeutic x-ray machines shall not be left unattended unless the locking device required by Part (a)(10)(E) of this Rule is set to prevent activation of the useful beam.
 - (6) Except as provided in Rule .0603(a)(1)(H) of this Section, no individual other than the patient shall be in the treatment room during exposures unless he is protected by a barrier sufficient to meet the requirements of Rule .1604 of this Chapter, and no individual other than the patient shall be in the treatment room when the kVp exceeds 150 during exposures.
 - (7) The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed 50 kVp. In such cases the holder shall wear protective gloves and apron of not less than 0.5 mm lead equivalency at 100 kVp.

*History Note: Authority G.S. 104E-7; 104E-12(a);
Eff. February 1, 1980;
Amended Eff. January 1, 1994; May 1, 1992; November 1, 1989.*

.0609 X-RAY AND ELECTRON THERAPY INSTALLATIONS ONE MeV AND ABOVE

- (a) The requirements in Paragraphs (b) to (e) of this Rule shall apply only to medical facilities using medical x-ray and electron therapy equipment with energies one MeV and above. In addition, such medical facilities shall also comply with the requirements in Section .0900 of this Chapter.
- (b) Equipment requirements are as follows:
 - (1) For existing equipment and new equipment manufactured or installed after the effective date of these Rules:
 - (A) The leakage radiation, excluding neutrons, at a distance of one meter from the source shall not exceed 0.1 percent of the useful beam dose rate at one meter from the source for any of its operating conditions.
 - (B) Within one year after the effective date of these Rules the registrant shall determine or obtain from the manufacturer for each machine the leakage radiation specifications for electrons, x-rays and neutrons existing at the points specified in Part (b)(1)(A) of this Rule for specified operating conditions. Records on radiation leakage shall be maintained at the installation.

- (C) For equipment from which neutron leakage may be a hazard, a qualified expert shall specify such additional requirements as may be necessary to protect health or minimize danger to life or property. The adequacy of these additional requirements shall be confirmed by a survey. Survey records shall be maintained by the registrant.
- (2) Adjustable or interchangeable beam limiting devices shall be provided and shall meet the following requirements:
 - (A) For existing equipment and new equipment manufactured or installed after the effective date of these Rules:
 - (i) Adjustable or interchangeable beam limiting devices shall attenuate the radiation incident on the beam limiting devices such that the dose equivalent in rems at any distance from the source does not exceed two percent of the maximum dose equivalent in the useful beam measured at an equal distance from the radiation source.
 - (ii) If the beam limiting device does not meet the specifications in Subpart (b)(2)(A)(i) of this Rule, the agency may accept auxiliary equipment or methods for accomplishing attenuation.
 - (B) Dose equivalent measurements may be averaged over an area up to but not exceeding 100 square centimeters at a distance of one meter from the target.
- (3) In equipment which uses a system of wedge filters, interchangeable field flattening filters or beam scattering devices:
 - (A) Irradiation shall not be possible until a selection of filter has been made at the treatment control panel;
 - (B) An interlock system shall be provided to prevent irradiation if the filter is not in the correct position;
 - (C) An indication of the orientation of the wedge filter with respect to the treatment field shall be provided when wedge filters are used; and
 - (D) A display shall be provided at the treatment control panel showing the filter(s) in use, including an indication of "no filters".
- (4) Equipment installed after the effective date of these Rules shall be provided with at least one radiation detector in the radiation head. This detector shall be incorporated into a primary system.
 - (A) Each primary system shall have a detector which is a transmission detector and is a full beam detector and is placed on the patient side of any fixed added filters other than a wedge filter;
 - (B) The detector(s) shall be removable only with tools or shall be interlocked to prevent incorrect positioning.
 - (C) Each detector shall be capable of independently monitoring and turning "off" the useful beam.
 - (D) Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.
 - (E) Each dose monitoring system shall have a legible display at the treatment control panel which shall:
 - (i) maintain a reading until intentionally reset;
 - (ii) in the event of power failure, have the capability of retrieving the information displayed at the time of failure.
- (5) Selection and display of dose monitor units shall comply with the following requirements:
 - (A) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.
 - (B) After useful beam termination, it shall be necessary to reset the preselected dose monitor

- units before treatment can be reinitiated.
- (C) The preselected number of dose monitor units shall be displayed at the treatment control panel until reset for the next irradiation.
- (6) Automatic termination of irradiation by the dose monitoring system shall comply with the following requirements:
- (A) Each of the monitoring systems shall be capable of independently terminating irradiation. Provisions shall be made to test the correct operation of each system.
- (B) Each primary system shall terminate irradiation when the preselected number of dose monitor units have been reached, and each secondary system shall be used as a backup.
- (7) It shall be possible to terminate irradiation and equipment movements or to go from an interruption condition to termination conditions at any time from the treatment control panel.
- (8) It shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption the equipment shall go to termination condition.
- (9) A timer shall be provided and shall meet the following requirements:
- (A) The timer shall have a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator.
- (B) The timer shall be a cumulative timer which switches "on" and "off" with the radiation and retains its reading after irradiation is interrupted or terminated. It shall be necessary to zero the elapsed time indicator and the preset time selector after irradiation is terminated, before reactivation is possible.
- (C) To guard against failure of the dose monitoring systems, the timer shall terminate irradiation when a preselected time has elapsed.
- (10) In equipment capable of both x-ray therapy and electron therapy:
- (A) Irradiation shall not be possible until a selection of radiation type, x-rays or electrons, has been made at the treatment control panel;
- (B) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel;
- (C) An interlock system shall be provided to prevent irradiation with x-rays when electron applicators are fitted and irradiation with electrons when x-ray wedge filters are fitted; and
- (D) The radiation type selected shall be displayed at the treatment control panel before and during irradiation.
- (11) In equipment capable of generating radiation beams of different energies:
- (A) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;
- (B) An interlock system shall be provided to insure that the equipment emits primarily the energy of radiation which has been selected;
- (C) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel; and
- (D) The energy selected shall be displayed at the treatment control panel before and during irradiation.
- (12) In equipment capable of both stationary-beam therapy and moving-beam therapy:
- (A) Irradiation shall not be possible until a selection of stationary-beam therapy or moving-beam therapy has been made at the treatment control panel;
- (B) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel;

- (C) An interlock system shall be provided to terminate irradiation if the movement stops during moving-beam therapy;
 - (D) Moving-beam therapy shall be so controlled that the required dose monitor units per degree of rotation is obtained; and
 - (E) The mode of operation shall be displayed at the treatment control panel.
- (13) The registrant shall determine or obtain from the manufacturer the location with reference to an accessible point on the radiation head of:
- (A) the x-ray target and the virtual source of x-rays;
 - (B) the electron window or the scattering foil; and
 - (C) all possible orientations of the useful beam.
- (14) Means shall be provided so that all radiation safety interlocks can be checked. When preselection of any of the operating conditions requires action in the treatment room and at the treatment control panel selection at one location shall not give a display at the other location until the requisite selection operations in both locations have been completed.
- (c) Facility shielding shall be adequate to meet the requirements of Section .1600 of this Chapter.
- (d) Facility design shall meet the following requirements:
- (1) Except for entrance doors, all required barriers shall be fixed barriers.
 - (2) The control panel shall be located outside the treatment room. The door must be closed during radiation production.
 - (3) A viewing system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may see the patient and the control panel from the same position. When the viewing system is by electronic means (e.g., television), an alternate viewing system shall be available.
 - (4) Provision shall be made for two-way aural communication with the patient from the control room, however, where excessive noise levels make aural communication impractical, other methods of communication shall be used.
 - (5) Treatment rooms to which access is possible through more than one entrance shall be provided with warning lights, in a readily observable position near the outside of all access doors, preferably at eye level, which will indicate when the useful beam is "on".
 - (6) Have all entrance doors to the treatment room electrically connected such that the x-ray production cannot be initiated unless all doors are closed and shall cease if any door is opened during x-ray production.
- (e) The operating procedures which follow are in addition to those in Rule .0908 of this Chapter.
- (1) Radiation protection surveys shall comply with the following requirements:
 - (A) All new facilities and existing facilities not previously surveyed shall have a radiation protection survey made by, or under the direction of, a qualified expert. This shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
 - (B) The expert shall report his findings in writing to the person in charge of the facility, and a copy of the report shall be transmitted by the registrant to the agency at the address in Rule .0111 of this Chapter.
 - (2) No person other than the patient shall be in the treatment room during treatment. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.
 - (3) The output of each therapeutic x-ray machine shall be calibrated by, or under the direct supervision of a qualified expert, before it is first used for medical purposes. Calibrations shall be repeated at least once every 12 months and after any change which might significantly increase radiation hazards. Calibration of the therapy beam shall be performed with measurement instruments, the calibration of which is traceable to national standards for exposure or absorbed dose and which shall have been calibrated within the preceding 12

months. Records of calibrations shall be provided to and maintained by the registrant. The calibration shall include at least the following determinations:

- (A) the exposure rate or dose rate as appropriate for the field sizes used and for each effective energy and for each treatment distance used for radiation therapy;
 - (B) the beam quality (e.g., half-value layer when appropriate) for every proposed combination of operating conditions used for radiation therapy;
 - (C) the congruence between the radiation field and the field indicated by the localized device when used;
 - (D) verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the side light and backpointer alignment with the isocenter, when applicable, variation in the axis of rotation for the table, gantry and jaw system and beam flatness and symmetry in air or at the specified depths in a water phantom.
- (4) Spot checks shall be performed monthly.
- (A) The spot check methods shall be in writing and shall be designed by a qualified expert.
 - (B) Whenever a spot check indicates a significant change (as specified in the qualified expert's spot check design) in the operating characteristics of a machine, the machine shall be recalibrated as required in Subparagraph (e)(3) of this Rule.
 - (C) A log shall be kept of all spot check measurements.

*History Note: Authority G.S. 104E-7; 104E-12(a);
Eff. February 1, 1980;
Amended Eff. January 1, 1994; November 1, 1989.*

.0610 VETERINARY MEDICINE RADIOGRAPHIC INSTALLATIONS

(a) The provisions of this Rule shall apply only to veterinary medicine radiographic installations. Radiographic equipment used in veterinary medicine radiographic installations shall meet the following requirements:

- (1) The protective tube housing shall be of the diagnostic type.
 - (2) Diaphragms or cones shall be provided for collimating the useful beam to the area of the image receptor and shall provide the same degree of protection as is required in the housing.
 - (3) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50-70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.
 - (4) A device shall be provided to terminate the exposure after a preset time or exposure.
 - (5) A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least six feet from the animal during all x-ray exposures or behind a protective barrier adequate to assure compliance with Rules .1604 and .1611 of this Chapter.
- (b) All wall, ceiling and floor areas shall be equivalent to or provided with primary and secondary protective barriers necessary to comply with Rules .1604 and .1611 of this Chapter.
- (c) Operating procedures shall meet the following requirements:
- (1) The operator shall stand well away from the useful beam and the animal during radiographic exposures.
 - (2) No individual other than the operator shall be in the x-ray room while exposures are being made unless such individual's assistance is required.
 - (3) When an animal must be held in position during radiography, mechanical supporting or restraining devices shall be used; except if the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and shall be so positioned that no part of the individual's body will be struck by the useful

beam. The exposure of any professional staff or ancillary personnel used for this purpose shall be monitored and permanently recorded. Exposures shall comply with Rules .1604 and .1609 of this Chapter.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. January 1, 1994; November 1, 1989.*

SECTION .0700
USE OF SEALED RADIOACTIVE SOURCES IN THE HEALING ARTS

This Section .0700, Chapter 11 of Title 15A of the North Carolina Administrative Code (T15A.11 .0700); USE OF SEALED RADIOACTIVE SOURCES IN THE HEALING ARTS; has been transferred and recodified from Section .2800, Subchapter 3G of Title 10 of the North Carolina Administrative Code (T10.03G .2800), effective January 4, 1990. The recodification was pursuant to G.S. 143B-279.3.

.0701 SCOPE

The provisions of this Section apply to all licensees who use sealed sources in the healing arts and are in addition to, and not in substitution for, other applicable provisions of the rules of this Chapter.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. May 1, 1993.*

.0702 INTERSTITIAL: INTRACAVITARY AND SUPERFICIAL APPLICATIONS

(a) Accountability, storage and transit

- (1) Each licensee shall provide accountability of sealed sources and shall keep a record of the issue and return of all sealed sources. A physical inventory shall be made at least every six months and a written record of the inventory maintained.
- (2) When not in use, sealed sources and applicators containing sealed sources shall be kept in a protective enclosure of such material and wall thickness as necessary to assure compliance with the provisions of Rules .1604, .1609 and .1611 of this Chapter.

(b) Testing sealed sources for leakage and contamination

- (1) All sealed sources with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and contamination prior to initial use and at intervals not to exceed six months. If there is reason to suspect that a sealed source might have been damaged, or might be leaking, it shall be tested for leakage before further use.
- (2) Leak tests shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample, or in the case of radium, the escape of radon at rate of 0.001 microcurie per 24 hours. Any test conducted pursuant to Subparagraph (b)(1) of this Rule which reveals the presence of 0.005 microcurie or more of removable contamination or, in the case of radium, the escape of radon at the rate of 0.001 microcurie or more per 24 hours shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with applicable provisions of Section .1600 of this Chapter. A report describing the sealed sources involved, the test results and the corrective action taken shall be submitted in writing to the agency at the address stated in Rule .0111 of this Chapter within five days after the test.
- (3) Leak test results shall be recorded in units of microcuries and maintained for inspection by the agency.

(c) Radiation surveys

- (1) The maximum radiation level at a distance of one meter from the patient in whom brachytherapy sources have been inserted shall be determined by measurement or calculation. This radiation level shall be entered on the patient's chart and other signs as required in Paragraph (d) of this Rule.
- (2) The radiation surveying in Paragraph (c) of this Rule or a special survey shall be performed and shall include measurements necessary to comply with the following requirements:
 - (A) The therapeutic use of sealed sources shall not create radiation levels in areas occupied

by patients not undergoing radiation therapy which would result in an accumulated dose in excess of 125 millirem if a patient were continuously present during the entire treatment period.

- (B) The licensee shall maintain a record of this survey and the calculation which demonstrates compliance with Subparagraph (c)(1) of this Rule.
 - (C) The licensee shall select rooms for hospitalization of these sealed source therapy patients in a manner so as to minimize radiation exposure of other patients, hospital staff, visitors and the public, especially those who are under 18 years of age or who are pregnant females.
 - (D) This Rule does not relieve the licensee of responsibility to monitor or limit occupational radiation exposure for the licensee's staff as provided in Section .1600 of this Chapter.
- (3) Immediately after implanting sources in an individual the licensee shall make a radiation survey of the individual and the area of use to confirm that no source has been misplaced. The licensee shall make a record of each survey.
 - (4) Immediately after removing the last temporary implant source from an individual, the licensee shall make a radiation survey of the individual with a radiation detection survey instrument to confirm that all sources have been removed. The licensee may not release from confinement for medical care an individual treated by temporary implant until all sources have been removed.
- (d) A licensee shall maintain accountability for all brachytherapy sources in storage or in use. After removing sources from an individual, a licensee shall return brachytherapy sources to the storage area. A licensee shall ensure that all sources taken from the storage area have been returned, and shall make a record of the source accountability and retain the record for three years.
- (e) For temporary implants, the record shall include:
 - (1) the number and activity of sources removed from storage;
 - (2) the date the sources were removed from storage;
 - (3) the number and activity of sources returned to storage; and
 - (4) the date the sources were returned to storage.
 - (f) For permanent implants, the record shall include:
 - (1) the number and activity of sources removed from storage;
 - (2) the date the sources were removed from storage;
 - (3) the number and activity of sources returned to storage;
 - (4) the date the sources were returned to storage; and
 - (5) the number and activity of sources permanently implanted in the individual.
 - (g) Signs and records
 - (1) In addition to the requirements of Rule .1624 of this Chapter, the bed, cubicle, or room of the hospital brachytherapy patient shall be marked with a sign indicating the presence of brachytherapy sources. This sign shall incorporate the radiation symbol and specify the radionuclide, activity, date, and the individual(s) to contact for radiation safety instructions. The sign is not required provided the exception in Rule .1625 of this Chapter is satisfied.
 - (2) The following information shall be included in the patient's chart:
 - (A) the radionuclide administered, number of sources, activity in millicuries and time and date of administration;
 - (B) the exposure rate at one meter, the time the determination was made, and by whom;
 - (C) the radiation symbol; and
 - (D) the precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted in Paragraph (c) of this Rule.

*History Note: Authority G.S. 104E-7; 104E-12(a);
Eff. February 1, 1980;*

Amended Eff. April 1, 1999; January 1, 1994; October 1, 1980.

.0703 TELETHERAPY

(a) Any licensee authorized under Rule .0322 of this Chapter to use teletherapy units for treating humans shall cause full calibration measurements to be performed on each teletherapy unit.

- (1) Such measurement shall be done at all of the following times:
 - (A) prior to the first use of the unit for treating humans;
 - (B) prior to treating humans whenever:
 - (i) spot-check measurements indicate that the output value differs by more than five percent from the value obtained at the last full calibration corrected mathematically for physical decay, or
 - (ii) following replacement of the radiation source or following reinstallation of the teletherapy unit in a new location, or
 - (iii) following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
 - (C) at intervals not exceeding one year.
- (2) Full calibration measurements required by Subparagraph (a)(1) of this Rule shall include determination of:
 - (A) the exposure rate or dose rate to an accuracy within plus or minus three percent for the range of field sizes and for the range of distances (or for the axis distance) used in radiation therapy;
 - (B) the congruence between the radiation field and the field indicated by the light beam localizing device;
 - (C) the uniformity of the radiation field and its dependence upon the orientation of the useful beam;
 - (D) timer accuracy; and
 - (E) the accuracy of all distance-measuring devices used for treating humans.
- (3) Full calibration measurements shall be made in accordance with the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine (Physics in Medicine and Biology, Vol. 16, No. 3, 1971, pp. 379-396).
- (4) The exposure rate or dose rate values determined in Part (a)(2)(A) of this Rule shall be corrected mathematically for physical decay for intervals not exceeding one month.
- (5) Full calibration measurements required by Subparagraph (a)(1) of this Rule and physical decay corrections required by Subparagraph (a)(4) of this Rule shall be performed by an expert qualified by training and experience in accordance with Subparagraph (d)(1) of this Rule.

(b) Any licensee authorized under Rule .0322 of this Chapter to use teletherapy units for treating humans shall cause spot-check measurements to be performed on each teletherapy unit at intervals not exceeding one month.

- (1) Required spot-check measurements shall include determination of:
 - (A) timer accuracy;
 - (B) the congruence between the radiation field and the field indicated by the light beam localizing device;
 - (C) the accuracy of all distance-measuring devices used for treating humans;
 - (D) the exposure rate, dose rate, or a quantity related in a known manner to these rates for one typical set of operating conditions; and
 - (E) the difference between the measurement made in Part (b)(1)(D) of this Rule and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).
- (2) Required spot-check measurements shall be performed in accordance with procedures established by an expert qualified by training and experience in accordance with Paragraph (d)

of this Rule.

(c) Any licensee responsible for the performance of full calibration or spot-check measurements shall be required to calibrate the instruments used in making such determinations.

- (1) Full calibration measurements required by Paragraph (a) of this Rule shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous two years and after any servicing that may have affected system calibration.
- (2) Spot-check measurements required by Paragraph (b) of this Rule shall be performed using a dosimetry system that has been calibrated in accordance with Subparagraph (c)(1) of this Rule. Alternatively, a dosimetry system used solely for spot-check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with Subparagraph (c)(1) of this Rule. This alternative calibration method shall have been performed within the previous one year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.

(d) The licensee shall determine if a person is an expert qualified by training and experience to calibrate a teletherapy unit and establish procedures for and review the results of spot-check measurements.

- (1) The licensee shall determine that the expert is qualified by his:
 - (A) being certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, roentgen-ray and gamma-ray physics, or x-ray and radium physics; or
 - (B) having the following minimum training and experience:
 - (i) a master's or doctor's degree in physics, biophysics, radiological physics or health physics;
 - (ii) one year of full-time training in therapeutic radiological physics; and
 - (iii) one year of full-time experience in a radiotherapy facility including personal calibration and spot check of at least one teletherapy unit.
- (2) The licensee who has his teletherapy units calibrated by persons who do not meet the criteria for minimum training and experience stated in Part (d)(1)(B) of this Rule may request a license amendment excepting them from these requirements.
 - (A) Such request shall include:
 - (i) the name of the proposed qualified expert;
 - (ii) a description of his training and experience including information similar to that specified in Part (d)(1)(B) of this Rule;
 - (iii) reports of at least one calibration and spot-check program based on measurements personally made by the proposed expert within the last ten years; and
 - (iv) written endorsement of the technical qualifications of the proposed expert from personal knowledge by a physicist certified by the American Board of Radiology in one of the specialties listed in Part (d)(1)(A) of this Rule.

(e) The licensee shall maintain, for inspection by the agency, records of the measurements, tests, corrective actions, and instrument calibrations made under Paragraphs (a), (b), and (c) of this Rule, and records of the licensee's evaluation of the qualified expert's training and experience made under Paragraph (d) of this Rule for the following periods of time:

- (1) Records of the full calibration measurements under Paragraph (a) of this Rule and the calibration of the instruments used to make these measurements under Paragraph (c) of this Rule shall be preserved for five years after completion of the calibration.
- (2) Records of the spot-check measurements and corrective actions under Paragraph (b) of this Rule and the calibration of instruments used to make spot-check measurements under

Paragraph (c) of this Rule shall be preserved for two years after completion of the spot-check measurements and corrective actions.

- (3) Records of the licensee's evaluation of the qualified expert's training and experience under Paragraph (d) of this Rule shall be preserved for five years after the qualified expert's last performance of a full calibration on the licensee's teletherapy unit.

(f) Each teletherapy room shall be equipped with a radiation monitoring device which continuously monitors the teletherapy beam condition and is equipped with a back-up battery power supply for emergency operation.

- (1) This device shall energize a visible signal to make the operator continuously aware of teletherapy beam conditions in order that appropriate emergency procedures may be instituted to prevent unnecessary radiation exposure.
- (2) Operating procedures shall be modified to require daily operational testing of the installed radiation monitor.
- (3) If a radiation monitor is inoperable for any reason, any person entering the teletherapy room shall use a properly operating portable radiation survey instrument or a personal dosimeter with an audible alarm to monitor for any malfunction of the source exposure mechanism which may have resulted in an exposed or partially exposed source.
- (4) Survey instruments or dosimeters shall be tested daily before use.

(g) The licensee shall cause each teletherapy unit used to treat humans to be fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(h) Inspection and servicing of the teletherapy unit shall be performed by persons specifically authorized to perform such services by a specific license issued by the agency, the U.S. Nuclear Regulatory Commission or an agreement state.

(i) A licensee shall post safety instructions at the teletherapy unit console. To satisfy this requirement, these instructions shall inform the operator of:

- (1) The procedures to be followed to ensure that only the individual for whom treatment is planned is in the treatment room before turning the primary beam of radiation on to begin a treatment or after a door interlock interruption; and
- (2) The procedure to be followed, if:
 - (A) the operator is unable to turn the primary beam of radiation off with controls outside the treatment room or if any other abnormal operation occurs; and
 - (B) the names and telephone numbers of the authorized users and radiation safety officer to be immediately contacted if the teletherapy unit or console operates abnormally.

(j) A licensee shall provide instruction in the topics identified in Paragraph (i) of this Rule to all individuals who operate a teletherapy unit.

(k) A licensee shall retain for three years a record of individuals receiving instruction required by Paragraph (j) of this Rule, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

(l) A licensee shall control access to the teletherapy room by a door at each entrance.

(m) A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that will:

- (1) prevent the operator from turning the primary beam of radiation on unless each treatment room entrance door is closed;
- (2) turn the primary beam of radiation off immediately when an entrance door is opened; and
- (3) prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

(n) A licensee shall equip each entrance to the teletherapy room with a beam condition indicator light.

(o) A licensee shall install in each teletherapy room a permanent radiation monitor capable of

continuously monitoring beam status.

- (1) A radiation monitor must provide visual notice of a teletherapy unit malfunction that results in an exposed or partially exposed source, and must be observable by an individual entering the teletherapy room.
- (2) A radiation monitor must be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup supply may be a battery system.
- (3) A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.
- (4) A licensee shall maintain a record of the check required by Subparagraph (o)(3) of this Rule for three years. The record shall include:
 - (A) the date of the check;
 - (B) notation that the monitor indicates when its detector is and is not exposed; and
 - (C) the initials of the individual who performed the check.
- (5) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in Subparagraph (o)(4) of this Rule.
- (6) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

History Note: Authority G.S. 104E-7(a)(2); 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540;

Eff. February 1, 1980;

Amended Eff. April 1, 1999; June 1, 1993; May 1, 1992; October 1, 1984; October 1,

1980.

SECTION .0800 - REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

This Section .0800, Chapter 11 of Title 15A of the North Carolina Administrative Code (T15A.11 .0800); REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT; has been transferred and recodified from Section .2900, Subchapter 3G of Title 10 of the North Carolina Administrative Code (T10.03G .2900), effective January 4, 1990. The recodification was pursuant to G.S. 143B-279.3.

.0801 PURPOSE AND SCOPE

This Section provides special requirements for analytical x-ray equipment which are in addition to, and not in substitution for, applicable requirements in the other sections of this Chapter.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980.*

.0802 DEFINITIONS

- (a) "Analytical x-ray equipment" means equipment used for x-ray diffraction or fluorescence analysis.
- (b) "Analytical x-ray system" means a group of local and remote components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials. Local components include those that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding. Remote components include power supplies, transformers, amplifiers, readout devices, and control panels.
- (c) "Fail-safe characteristics" means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.
- (d) "Normal operating procedures" mean operating procedures for conditions suitable for analytical purposes with shielding and barriers in place. These do not include maintenance but do include routine alignment procedures. Routine and emergency radiation safety considerations are part of these procedures.
- (e) "Open-beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.
- (f) "Primary beam" means ionizing radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980.*

.0803 EQUIPMENT REQUIREMENTS

- (a) A safety device which prevents the entry of any portion of an individual's body into the primary x-ray beam path of which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant or licensee may apply to the agency for an exemption from the requirement of a safety device. This application shall include:
 - (1) a description of the various safety devices that have been evaluated;
 - (2) the reason safety devices cannot be used; and
 - (3) a description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.
- (b) Open-beam configurations shall be provided with a readily discernible indication of:
 - (1) X-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner; and
 - (2) Shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after the effective date of this Rule, warning devices shall have fail-safe characteristics.

(c) Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

(d) All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

- (1) "CAUTION - HIGH INTENSITY X-RAY BEAM," or words having a similar intent, on the x-ray source housing; and
- (2) "CAUTION - RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED", or words having a similar intent, near any switch that energizes an x-ray tube, if the radiation source is an x-ray tube; or
- (3) "CAUTION - RADIOACTIVE MATERIAL", on the source housing, if the radiation source is a radionuclide.

(e) On open-beam configurations installed after the effective date of this Rule each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

(f) An easily visible warning light labeled with the words "X-RAY ON" or words having a similar intent, shall be located outside each entrance into the room containing an analytical x-ray tube and shall be illuminated only when the tube is energized; or in the case of a radioactive source, shall be illuminated only when the shutter is open. On equipment installed after the effective date of this Rule, warning lights shall have fail-safe characteristics.

(g) Each x-ray tube housing shall be so constructed that when all shutters are closed the leakage radiation measured at a distance of five centimeters from its surface is not capable of producing a dose in excess of 2.5 mrem in one hour.

(h) Each x-ray generator shall be supplied with a protection cabinet which limits leakage radiation measured at a distance of five centimeters from its surface such that it is not capable of producing a dose in excess of 0.04 mrem in one hour.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980.*

.0804 AREA REQUIREMENTS

(a) The local components of an analytical x-ray system shall be so located and arranged and shall include sufficient shielding or access control that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in Rule .1611 of this Chapter. For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating. A registrant or licensee may apply to the agency for an exemption from this requirement pursuant to Rule .0106(a) of this Chapter.

(b) Surveys

- (1) Radiation surveys, as required by Rule .1613 of this Chapter, of all analytical x-ray systems sufficient to show compliance with Paragraph (a) of this Rule, shall be performed:
 - (A) upon installation of the equipment;
 - (B) following any change in the initial arrangement, number or type of local components in the system;
 - (C) following any maintenance requiring the disassembly or removal of a local component in the system which could affect the radiation exposure to personnel;
 - (D) radiation monitoring shall be performed during maintenance.
- (2) A licensee or registrant may apply to the agency for approval of procedures differing from those in Subparagraph (b)(1) of this Rule, provided that the licensee or registrant demonstrates satisfactory compliance with Paragraph (a) of this Rule.

(c) Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words "CAUTION - X-RAY EQUIPMENT", or words having a similar intent.

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

.0805 OPERATING REQUIREMENTS

(a) Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No person shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless the person has obtained written approval of the person responsible for radiation safety.

(b) No person shall bypass a safety device unless the person has obtained the approval of the person responsible for radiation safety. Such approval shall be for a specified period of time. When a safety device has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING", or words having a similar intent, shall be placed on the radiation source housing and the control panel during the period such bypassing is in effect.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980.*

.0806 PERSONNEL REQUIREMENTS

(a) Instructions of personnel shall comply with the following:

- (1) No person shall be permitted to operate or maintain analytical x-ray equipment unless the person has received instruction in:
 - (A) identification of possible radiation hazards and biological effects associated with the use of the equipment;
 - (B) significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in these cases;
 - (C) proper operating procedures for the equipment;
 - (D) appropriate use and limitation of dosimetric devices;
 - (E) proper procedures for reporting an actual or suspected exposure.

(2) Each licensee or registrant shall maintain, for inspection by the agency, records of training which demonstrate that the requirements of this Rule have been met.

(b) Personnel monitoring or wrist dosimetric devices shall be provided to, and shall be used by:

- (1) analytical x-ray equipment workers using systems having an open beam configuration and not equipped with a safety device; and
- (2) personnel maintaining analytical x-ray equipment if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980.*

SECTION .0900 - REQUIREMENTS FOR PARTICLE ACCELERATORS

This Section .0900, Chapter 11 of Title 15A of the North Carolina Administrative Code (T15A.11 .0900); REQUIREMENTS FOR PARTICLE ACCELERATORS; has been transferred and recodified from Section .3000, Subchapter 3G of Title 10 of the North Carolina Administrative Code (T10.03G .3000), effective January 4, 1990. The recodification was pursuant to G.S. 143B-279.3.

.0901 PURPOSE AND SCOPE

(a) This Section establishes procedures for the licensing and the use of particle accelerators.

(b) In addition to the requirements of this Section, all licensees are subject to the requirements of Sections .0100, .0200, .1000, and .1600 of this Chapter. Licensees engaged in industrial radiographic operations are subject to the requirements of Section .0500 of this Chapter, and licensees engaged in the healing arts are subject to Rule .0350 of this Chapter and the applicable requirements of Section .0600 of this Chapter. Licensees engaged in the production of radioactive material or possessing radioactive material incidental to an accelerator are subject to the requirements of Section .0300 of this Chapter.

(c) In addition to the requirements of this Section, all particle accelerator licensees are subject to the annual fee provisions contained in Section .1100 of this Chapter.

*History Note: Authority G.S. 104E-7; 104E-9(a)(8); 104E-19(a);
Eff. February 1, 1980;
Amended Eff. January 1, 1994; June 1, 1989; July 1, 1982.*

.0902 LICENSING REQUIREMENTS

No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a license issued pursuant to these Rules or as otherwise provided for in these Rules. The general procedures for licensing of particle accelerator facilities are included in Section .0903 of this Chapter.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. May 1, 1993.*

.0903 REQUIREMENTS FOR ISSUANCE OF A LICENSE FOR ACCELERATORS

Application for use of a particle accelerator will be approved only if the agency determines that:

- (1) The applicant and his operators are qualified by reason of training and experience to use the accelerator in such a manner as to minimize danger to public health and safety or property;
- (2) The applicant's proposed equipment, facilities, operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;
- (3) The applicant has appointed a radiation safety officer;
- (4) The applicant has established a radiation safety committee to approve that the operation of the particle accelerator is in accordance with applicable radiation protection Sections of this Chapter; and
- (5) The applicant for the use of a particle accelerator in the healing arts shall be a physician licensed to practice medicine in the state of North Carolina. The individuals designated on the application as users shall have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980.*

.0904 LIMITATIONS

- (a) No licensee shall permit any person to act as a particle accelerator operator until such person:
- (1) has been instructed in radiation safety and shall have demonstrated an understanding thereof;
 - (2) has received copies of, and instruction in, this Section and the applicable requirements of this Chapter, pertinent licensing conditions and the licensee's operating and emergency procedures; and
 - (3) has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed in his assignment.
- (b) Either the radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if this action is deemed necessary to minimize danger to public health and safety or property.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980.*

.0905 SHIELDING AND SAFETY DESIGN

- (a) A qualified expert registered by the agency pursuant to Rule .0205 of this Chapter, shall be consulted in the design of a particle accelerator installation. A qualified expert shall perform a radiation survey when the accelerator is first capable of producing radiation to verify that radiation levels and shielding effectiveness meet the applicable requirements in this Chapter. A copy of the survey shall be submitted to the agency by the licensee prior to its use for its licensed purpose.
- (b) Plans for construction of accelerator installations shall be submitted to the agency.
- (c) Each particle accelerator installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with Rules .1604 and .1611 of this Chapter.

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

.0906 CONTROLS AND INTERLOCK SYSTEMS

- (a) Instrumentation, readouts and controls on the particle accelerator control console shall be clearly identified and easily discernible.
- (b) All entrances into a target room or other high radiation area shall conform to the requirements of Rule .1615 of this Chapter.
- (c) When an interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the interlock has been tripped and, subsequently at the main control console.
- (d) Each safety interlock shall operate independently of all other safety interlocks.
- (e) All safety interlocks shall be fail-safe, i.e., designed so that any defect or component failure in the interlock system prevents operation of the accelerator.
- (f) A "Scram button" or other emergency power cut-off switch shall be located and easily identifiable in all high radiation areas and at the control console. Such a cut-off switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without first manually resetting the cut-off switch.

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

.0907 WARNING DEVICES

(a) All locations designated as high radiation areas, and entrances to such locations shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

(b) Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such high radiation area. This warning device shall be clearly discernible in all high radiation areas and all radiation areas.

(c) Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with Rule .1624 of this Chapter.

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

.0908 OPERATING PROCEDURES

(a) Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

(b) Only a switch on the accelerator control console shall be routinely used to turn the accelerator beam "on" and "off". The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

(c) All safety and warning devices, including interlocks shall be checked for proper operability at least every six months unless more frequent checks are required by the agency. Results of such tests shall be maintained for two years at the accelerator facility for inspection by the agency.

(d) Electrical circuit diagrams of the accelerator, and the associated interlock systems, shall be kept current and maintained for inspection by the agency.

(e) If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

- (1) authorized by the radiation safety officer;
- (2) recorded in a permanent log and a notice posted at the accelerator control console and at the location of the bypassed interlock; and
- (3) terminated as soon as possible.

(f) A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980.*

.0909 RADIATION MONITORING REQUIREMENTS

(a) Portable monitoring equipment shall be available at each particle accelerator facility. Such equipment shall be tested for proper operation monthly and calibrated at intervals not to exceed one year, and after each servicing and repair.

(b) A radiation protection survey shall be performed and documented by a qualified expert registered by the agency pursuant to Rule .0205 of this Chapter, when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas. The licensee shall submit the report of the qualified expert to the agency at the address found in Rule .0111 of this Chapter.

(c) Except for facilities designed for human exposure, radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and interlock systems and capable of providing a remote and local readout with visual or audible alarms at the control panel and other appropriate locations.

(d) All area monitors shall be tested for proper operation at least every six months unless more frequent checks are required by the agency.

(e) Whenever applicable, periodic surveys shall be made to determine the amount of airborne

particulate radioactivity present in areas of airborne hazards.

(f) Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination in target and other pertinent areas.

(g) All area surveys shall be made in accordance with the written procedures established by a qualified expert registered by the agency pursuant to Rule .0205 of this Chapter, or the radiation safety officer of the particle accelerator facility.

(h) Records of all radiation protection surveys, calibration results, instrumentation tests, and smear results shall be kept current and on file at each accelerator facility for two years for inspection by the agency.

*History Note: Authority G.S. 104E-7; 104E-12(a);
Eff. February 1, 1980;
Amended Eff. October 1, 1980.*

.0910 VENTILATION SYSTEMS

(a) Adequate ventilation shall be provided in areas where airborne radioactivity may be produced to comply with Rule .1604 of this Chapter.

(b) The licensee shall not vent, release or otherwise discharge airborne radioactive material to an unrestricted area in excess of the limits specified in Rule .1611 of this Chapter.

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. January 1, 1994; May 1, 1992.*

SECTION .1000 - NOTICES: INSTRUCTIONS: REPORTS AND INSPECTIONS

This Section .1000, Chapter 11 of Title 15A of the North Carolina Administrative Code (T15A.11 .1000); NOTICES: INSTRUCTIONS: REPORTS AND INSPECTIONS; has been transferred and recodified from Section .3100, Subchapter 3G of Title 10 of the North Carolina Administrative Code (T10.03G .3100), effective January 4, 1990. The recodification was pursuant to G.S. 143B-279.3.

.1001 SCOPE

This Section establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in work under a license or registration and options available to such individuals in connection with agency inspections of licensees or registrants to ascertain compliance with the provisions of the Act and rules, orders and licenses issued thereunder regarding radiological working conditions. The rules in this Section apply to all persons who receive, possess, use, own or transfer sources of radiation licensed by or registered with the agency pursuant to the rules in Sections .0200, .0300, .0900 and of this Chapter.

*History Note: Authority G.S. 104E-7; 104E-12;
Eff. February 1, 1980;
Amended Eff. May 1, 1993; June 1, 1989.*

.1002 POSTING OF NOTICES TO WORKERS

- (a) Each licensee or registrant shall post current copies of the following documents:
- (1) the rules in this Section and in Section .1600 of this Chapter;
 - (2) the license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;
 - (3) the operating procedures applicable to work under the license or registration;
 - (4) any notice of violation involving radiological working conditions, any order issued pursuant to Section .0100 of this Chapter and any response from the licensee or registrant.
- (b) If posting of a document specified in Subparagraphs (a)(1), (2) or (3) of this Rule is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.
- (c) The agency form "Notice to Employees" shall be posted by each licensee or registrant wherever individuals work in or frequent any portion of a restricted area.
- (d) The agency form "Notice to Employees" contains information to employees regarding employer's responsibility, worker's responsibility, the subjects covered by this Section, reports on radiation exposure history, inspections, and any other information that the agency may include.
- (e) Documents, notices or forms posted pursuant to this Rule shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.
- (f) Agency documents posted pursuant to Subparagraph (a)(4) of this Rule shall be posted within two working days after receipt of the documents from the agency; the licensee's or registrant's response, if any, shall be posted within two working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

*History Note: Authority G.S. 104E-7; 104E-10;
Eff. February 1, 1980;
Amended Eff. January 1, 1994; May 1, 1992.*

.1003 INSTRUCTIONS TO WORKERS

(a) All individuals who, in the course of employment, are likely to receive in a year an occupational dose in excess of 100 millirem (1 millisievert) shall be kept informed of the storage, transfer, or use of radioactive material or of radiation in such portions of the restricted area; shall be instructed in the health protection problems associated with exposure to such radioactive material or radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed; shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of this Chapter and licenses for the protection of personnel from exposures to radiation or radioactive material occurring in such areas; shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may lead to or cause a violation of rules in this Chapter and licenses or unnecessary exposure to radiation or radioactive material; shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and shall be advised as to the radiation exposure reports which workers may request pursuant to Rule .1004 of this Section. The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.

(b) In determining those individuals subject to the requirements of Paragraph (a) of this Rule, licensees or registrants shall take into consideration assigned activities during normal and abnormal situations involving exposure to all sources of radiation and radioactive material which can reasonably be expected to occur during the life of the licensed or registered facility. The extent of these instructions shall be commensurate with the potential radiological health protection problems present in the workplace.

*History Note: Authority G.S. 104E-7; 104E-10; 104E-12;
Eff. February 1, 1980;
Amended Eff. April 1, 1999.*

.1004 NOTIFICATIONS AND REPORTS TO INDIVIDUALS

(a) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of any individual shall be reported to the individual as specified in this Rule. The information reported shall include data and results obtained pursuant to rules of this Chapter, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to provisions of this Chapter. Each notification and report shall: be in writing; include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's social security number; include the individual's exposure information; and contain the following statement:

This report is furnished to you under the provisions of Section 15A NCAC 11 .1000; NOTICES, INSTRUCTIONS, REPORTS AND INSPECTIONS. You should preserve this report for further reference.

(b) At the request of any worker, each licensee or registrant shall advise such worker annually of the worker's radiation dosage and exposure to radioactive materials as shown in records maintained by the licensee or registrant pursuant to Paragraphs (a) and (c) of this Rule.

(c) At the request of a worker formerly engaged in work controlled by the licensee or the registrant, each licensee or registrant shall furnish to the worker a report of the worker's radiation dosage and exposure to radioactive materials. Such report shall be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later; shall cover, within the period of time specified in the request, each calendar quarter in which the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation machines registered with the agency; and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

(d) When a licensee or registrant is required pursuant to Rule .1647 of this Chapter to report to the agency any overexposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on his exposure data included therein. Such reports shall be transmitted at a time no later than the transmittal to the agency.

*History Note: Authority G.S. 104E-7; 104E-10; 104E-12;
Eff. February 1, 1980;
Amended Eff. January 1, 1994.*

.1005 PRESENCE OF REPRESENTATIVES DURING INSPECTIONS

(a) Each licensee or registrant shall afford to the agency at all reasonable times opportunity to inspect radioactive materials, radiation machines, activities, facilities, premises, and records required to be maintained by provisions of this Chapter.

(b) During an inspection, agency inspectors may consult privately with workers as specified in Rule .1006 of this Section. The licensee or registrant may accompany agency inspectors during other phases of an inspection.

(c) If, at the time of inspection, an individual has been authorized by the workers to represent them during agency inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(d) Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in Rule .1003 of this Section.

(e) Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection.

(f) A consultant or representative to the licensee, registrant, or workers shall be afforded the opportunity to accompany the agency inspectors during the inspection of physical working conditions.

(g) Notwithstanding the other provisions of this Rule, agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

*History Note: Authority G.S. 104E-7; 104E-10; 104E-11;
Eff. February 1, 1980.*

.1006 CONSULTATION WITH WORKERS

(a) Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of this Chapter and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(b) During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violation of the Act, provisions of this Chapter, or license condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material or a registered radiation machine under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of Rule .1007 of this Section.

(c) The provisions of Paragraph (b) of this Rule shall not be interpreted as authorization to disregard instructions pursuant to Rule .1003 of this Section.

*History Note: Authority G.S. 104E-7; 104E-10;
Eff. February 1, 1980;*

Amended Eff. May 1, 1993.

.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, Raleigh, North Carolina 27611-7687. 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. May 1, 1992; November 1, 1989.*

.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, and Natural Resources, P.O. Box 27687, Raleigh, North Carolina 27611-7687, 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, 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, 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, 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. May 1, 1992; November 1, 1989.*

SECTION .1100 - FEES

This Section .1100, Chapter 11 of Title 15A of the North Carolina Administrative Code (T15A.11 .1100); FEES; has been transferred and recodified from Section .3200, Subchapter 3G of Title 10 of the North Carolina Administrative Code (T10.03G .3200), effective January 4, 1990. The recodification was pursuant to G.S. 143B-279.3.

.1101 PURPOSE AND SCOPE

(a) This Section establishes annual fees to cover the anticipated costs of inspection, educational and training activities of the agency.

(b) The fees are imposed on persons registered pursuant to provisions of Section .0200 of this Chapter, on persons licensed pursuant to provisions of Sections .0300 and .0900 of this Chapter, and on certain persons applying for out-of-state reciprocal recognition.

(c) Notwithstanding Paragraph (b) of this Rule, no fee shall be imposed on any person in conjunction with the person's possession and use of any luminous safety device or luminous gunsight pursuant to the general licenses in Rules .0309 and .0311 of this Chapter. For purposes of this Section, "luminous safety device" means an exit marker, hazard warning sign, safety related marker, or other safety equipment containing one or more radioactive material powered light sources for the purpose of improving legibility or visibility.

*History Note: Authority G.S. 104E-9(8); 104E-19(a);
Eff. July 1, 1982;
Amended Eff. July 1, 1989; May 1, 1983.*

.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, and Natural Resources, P. O. Box 27687, Raleigh, North Carolina 27611-7687. 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. May 1, 1993; May 1, 1992; July 1, 1989.*

.1103 NOTICES OF PAYMENT DUE

Within five days after the due dates established in Paragraphs (a) and (b) of Rule .1102 of this Section, the agency shall mail to each licensee and registrant, who has not already submitted payment, a notice which indicates the due date, delinquent date and the amount of fees due.

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

.1104 DELINQUENT AND UNCOLLECTIBLE FEES

(a) Payment of fees established in this Section shall be delinquent, if not received by the agency within 60 days after the due date specified in Paragraphs (a) and (b) of Rule .1102 of this Section.

(b) If a licensee or registrant remits a fee in the form of a check or other instrument which is uncollectible from the paying institution, the agency shall notify the licensee or registrant by certified mail and allow the licensee or registrant 15 days to correct the matter.

(c) If payment of fees is uncollectible from the paying institution or not submitted to the agency by the delinquent date, the agency may institute appropriate legal action to collect.

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

.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	\$ 12.50
Chiropractors	C	\$ 70.00	\$ 12.50
Dentists	D	\$ 70.00	\$ 12.50
Educational	E	\$ 50.00	\$ 10.00
Government	G	\$ 50.00	\$ 10.00
Podiatrists	H	\$ 70.00	\$ 12.50
Industrial	I	\$ 70.00	\$ 12.50
Industrial Medical	IM	\$100.00	\$ 17.50
Health Departments	L	\$100.00	\$ 17.50
Hospitals	M	\$150.00	\$ 22.50
Physicians	P	\$ 70.00	\$ 12.50
Industrial Radiography	R	\$150.00	\$ 22.50
Services	S	\$100.00	\$ 0.00
Veterinarians	V	\$ 50.00	\$ 10.00
Other	Z	\$ 70.00	\$ 12.50

(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
-other	\$ 325.00
Specific license	
-industrial radiography (with temporary subsites)	\$1,175.00
-industrial radiography (in plant only)	\$ 600.00
-manufacture or distribution	\$ 325.00
-medical institution other than teletherapy	\$ 275.00
-medical private practice	\$ 200.00
-medical teletherapy with one teletherapy unit and	\$ 225.00
-each additional teletherapy unit	\$ 50.00
-industrial gauges	\$ 175.00
-moisture-density gauges	\$ 75.00
-gas chromatographs	\$ 75.00
-educational institutions	\$ 275.00
-services/consultants	\$ 75.00
-other	\$ 125.00
General licenses	
-industrial gauges	\$ 75.00
-IN VITRO testing and others	\$ 75.00

(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
-each additional accelerator	\$ 50.00

(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. July 1, 1989.*

SECTION .1200 - LAND DISPOSAL OF RADIOACTIVE WASTE

This Section .1200, Chapter 11 of Title 15A of the North Carolina Administrative Code (T15A.11); LAND DISPOSAL OF RADIOACTIVE WASTE; has been transferred and recodified from Section .3300, Subchapter 3G of Title 10 of the North Carolina Administrative Code (T10.03G .3300), effective January 4, 1990. The recodification was pursuant to G.S. 143B-279.3.

.1201 PURPOSE AND SCOPE

(a) This Section establishes the procedures, criteria, and terms and conditions upon which the agency issues licenses authorizing land disposal of low-level radioactive waste received from other persons for disposal. Disposal of low-level radioactive waste by the specific licensee who generates such waste is subject to the provisions of Rule .1628 of this Chapter.

(b) The rules in this Section do not apply to the disposal of:

- (1) low-level radioactive waste which is higher than Class C waste as defined in Rule .1628 of this Chapter;
- (2) byproduct material as defined in Section 11e.(2) of the Atomic Energy Act of 1954, as amended, in quantities greater than 10,000 kilograms and containing more than five millicuries of radium-226; or
- (3) licensed radioactive material pursuant to provisions of Rule .1628 of this Chapter.

(c) Nothing in this Section shall relieve any person of responsibility for complying with other applicable North Carolina laws and rules.

(d) This Section is designed to fulfill two objectives:

- (1) to meet the requirement of compatibility with the U.S. Nuclear Regulatory Commission regulations, and
- (2) to provide general guidance for the design, operation, closure and institutional control of a low-level radioactive waste disposal facility that has features to enhance its performance and provide additional confidence in its integrity.

As described in 10 CFR Part 61, Section 61.7 Concepts, land disposal is intended to further four safety objectives:

- (1) protection of the public from releases of radioactivity,
- (2) protection of an inadvertent intruder,
- (3) protection of workers at the facility, and
- (4) assurance of long-term stability after closure. There is every indication in research reports and environmental impact statements that land disposal with attention to site selection, waste classification, waste form, segregation and stability will limit radiation doses to those within the cited performance objectives of 10 CFR Part 61. Supplementary engineered barriers are included in the rules for North Carolina, however, to fulfill a further objective, viz,
- (5) protection against the possibility of unforeseen differences between expected and actual behavior of the disposal system.

The five goals are to be sought through the design, construction, and operation of a system that involves a carefully chosen combination of features that are described in existing rules plus additional requirements for engineered barriers. The total 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: 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, carboic 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: 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 Section and the rules in Section .0300 of this Chapter.

(b) Each person shall file an application with the agency pursuant to Rule .0317 of this Chapter and obtain a license as provided in this Section before commencement of construction of a land disposal facility. Failure to comply with this requirement may be grounds for denial of a license.

*History Note: Authority G.S. 104E-7; 104E-10(b); 104E-25; 104E-26;
Eff. December 1, 1987;
Amended Eff. May 1, 1993.*

.1204 CONTENT OF APPLICATION

An application for a license to receive waste from other persons and possess and dispose of wastes containing or contaminated with radioactive material by land disposal shall consist of general information, specific technical information, environmental information, technical and environmental analyses, institutional information, and financial information as set forth in Rules .1205 through .1210 of this Section.

*History Note: Authority G.S. 104E-7; 104E-10(b); 104E-25; 104E-26;
Eff. December 1, 1987.*

.1205 GENERAL INFORMATION

(a) The general information shall include each of the following:

- (1) identity of the applicant including:
 - (A) the full name, address, telephone number, and description of the business or occupation of the applicant;
 - (B) if the applicant is a partnership, the name and address of each partner and the principal location where the partnership does business;
 - (C) if the applicant is a corporation or an unincorporated association,
 - (i) the state where it is incorporated or organized and the principal location where it does business, and
 - (ii) the names and addresses of its directors and principal officers;
 - (D) if the applicant is acting as an agent or representative of another person in filing the application, all information required under this Paragraph shall be supplied with respect to the other person; and
 - (E) if the applicant proposes to contract the operation of the disposal facility to another person, the full name, address, and telephone number of the management contractor, the full name and address of each applicable principal, partner, or director of the contractor, the state where it is organized, and the principal location where it does business;
- (2) qualifications of the applicant:
 - (A) the applicable organizational structure of the applicant, both off site and on site, including a description of lines of authority and assignments of responsibilities, whether in the form of administrative directives, contract provisions, or otherwise;
 - (B) the technical qualifications, including training, experience, and professional licensure, registration or certification of the applicant and members of the applicant's staff to engage in the proposed activities, to include the minimum training, experience, and professional licensure, registration or certification requirements for personnel filling key positions

- described in Part (a)(2)(A) of this Rule;
 - (C) a description of the applicant's personnel training program;
 - (D) the plan to maintain an adequate complement of trained personnel on site to carry out waste receipt, handling, and disposal operations in a safe manner;
 - (E) prior experience in the generation, processing, use, transportation or disposal of radioactive material or in the treatment, storage, transportation or disposal of hazardous waste including copies of all notices of violations; assessments of any administrative, civil, criminal or other penalties in connection therewith; and all information as to any finding or determination that the applicant engaged in any of the above mentioned activities without having in effect any license or permit required for such activity;
 - (F) disclosure of any prior determination of civil or criminal liability with respect to any other federal or state law or regulation, including but not limited to any law or regulation governing the transfer of securities, which may reflect on the applicant's character, reputation or ability to comply with all requirements imposed on a licensee; and
 - (G) upon request by the agency, a copy of any application which the applicant may previously have submitted for any license or permit required for any activity listed in Part (a)(2)(E) of this Rule; information as to the disposition of such application including a copy of the license or permit, information as to any restriction, suspension, revocation or cancellation of any such license or permit; and any other information which may be requested by the agency as to the applicant's experience and operating practices with respect to the activities listed in Part (a)(2)(E) of this Rule;
- (3) a description of:
- (A) the location of the proposed disposal site;
 - (B) the general character of the proposed activities;
 - (C) the types and quantities of waste to be received, possessed, and disposed of;
 - (D) plans for use of land disposal facility for purposes other than disposal of wastes during operation, after closure or both;
 - (E) the proposed facilities and equipment;
 - (F) the proposed manifest and recording system;
 - (G) the treatment of any waste to be shipped off site;
 - (H) anticipated operating life of the facility; and
 - (I) the precicensing and operational public information program which addresses
 - (i) state and local government;
 - (ii) media and public;
 - (iii) acceptability within the community where the facility is to be located; and
 - (iv) the program being implemented to ensure concerns of the public are being met; and
- (4) proposed time schedules for construction, receipt of waste, and first emplacement of waste at the proposed land disposal facility.
- (b) The following are additional requirements applicable to the information required in Parts (a)(2)(E) through (G) of this Rule:
- (1) All information will be provided by the applicant with respect to the applicant itself, any predecessor or parent entity, any officer, director, partner or other principal of the applicant; any stockholder or other entity holding five percent or more of the stock of, or other interest in, the applicant; and any subsidiary or other entity in which the applicant has an interest.
 - (2) All information will be provided for a period of not less than 20 years or as may be determined by the agency, with respect to a particular applicant or class of information, to be necessary to discharge agency responsibility in G.S. 104E-10.1(a).
 - (3) With the approval of the agency, the applicant may submit any of the information, except as to the disposal of low-level radioactive waste, in summary form; provided that any summary must

fairly and accurately reflect the applicant's experience and operating practices and must indicate the nature and extent of all violations of law and applicable rules.

- (4) The agency may request that the applicant provide any supplemental information needed to effect the purpose of Parts (a)(2)(E) through (G) of this Rule. All such supplementary information provided by or on behalf of the applicant will become a part of the application.

*History Note: Authority G.S. 104E-7; 104E-10(b); 104E-10.1; 104E-25; 104E-26;
Eff. December 1, 1987;
Amended Eff. June 1, 1993.*

.1206 SPECIFIC TECHNICAL INFORMATION

(a) The specific technical information shall include the following information needed for demonstration that the performance objectives and the applicable technical requirements of this Section will be met:

- (1) a description of the principal design criteria and their relationship to the performance objectives, along with identification of operating facilities of the same or similar design;
- (2) a description of the design basis natural events or phenomena and their relationship to the principal design criteria;
- (3) a description of codes and standards which the applicant has applied to the design and which will apply to construction of the land disposal facility;
- (4) a description of the design features of the land disposal facility, the disposal units and engineered barriers, to include those design features related to:
 - (A) infiltration of water;
 - (B) leachate collection and removal;
 - (C) integrity of covers for disposal units and structural stability of backfill, engineered barriers, and covers;
 - (D) contact of wastes with standing water and groundwater;
 - (E) disposal site drainage;
 - (F) disposal site closure and stabilization;
 - (G) elimination to the extent practicable of long-term disposal site maintenance, inadvertent intrusion, occupational exposures, and disposal site monitoring;
 - (H) adequacy of the size of the buffer zone for monitoring and potential mitigative measures; and
 - (I) retrieval;
- (5) a description of the construction and operation of the land disposal facility, to include, as a minimum:
 - (A) the methods of construction of disposal units and engineered barriers;
 - (B) waste emplacement;
 - (C) the procedures for and areas of waste segregation;
 - (D) accurate drawings and descriptions of on-site buildings including, but not limited to, construction, foundation details, ventilation, plumbing and fire suppression systems, and proximity to creeks or culverts;
 - (E) types of intruder barriers;
 - (F) on-site traffic and drainage systems;
 - (G) physical security system;
 - (H) survey control program;
 - (I) methods and areas of waste storage;
 - (J) facilities for and methods of handling waste including improperly packaged shipments;
 - (K) methods to control surface water and groundwater access to the wastes;
 - (L) methods to be employed in the handling and disposal of wastes containing chelating agents or other nonradiological substances that might affect the meeting of the

- performance objectives of this Section; and
- (M) a flow diagram of waste handling and disposal operations, a description and accurate drawings of handling equipment, and any special handling techniques to be employed;
- (6) a description of the types, chemical and physical forms, quantities, classification, and specifications of the radioactive material proposed to be received, possessed, handled, and disposed of at the land disposal facility, which shall include:
 - (A) estimated volume and activity of each waste class to be received annually at the facility, and
 - (B) method for control of the rate at which waste is received;
 - (7) a description of the quality control program, including audits and managerial controls, for the determination of natural disposal site characteristics and for quality control during the design, construction, operation, and closure of the land disposal facility and during the receipt, handling, and emplacement of waste;
 - (8) a description of the radiation safety program for control and monitoring of radioactive effluents to ensure compliance with the performance objective in Rule .1223 of this Section and occupational radiation exposure to ensure compliance with the requirements of Section .1600 of this Chapter and to control contamination of personnel, vehicles, equipment, buildings, and the disposal site; which description shall address
 - (A) both routine operations and accidents; and
 - (B) procedures, instrumentation, facilities, and equipment;
 - (9) an emergency response plan which addresses:
 - (A) on-site response;
 - (B) public alert and notification;
 - (C) roles of local, county, state and regional agencies;
 - (D) training and public information; and
 - (E) if available, copies of most current emergency response plans submitted to the U.S. Nuclear Regulatory Commission or an agreement state;
 - (10) a manual of operating procedures and emergency procedures including, but not limited to, those for fires, spills or other events which result in contamination;
 - (11) a description of the administrative procedures that the applicant will apply to control activities at the land disposal facility including hours of proposed operation;
 - (12) a description of the radiation protection program including provisions for keeping radiation doses to workers and to members of the public as low as reasonably achievable (ALARA) and within applicable limits specified in the rules of this Chapter;
 - (13) a description of the natural and demographic disposal site characteristics as determined by disposal site selection and characterization activities where the description must include geologic, geotechnical, hydrologic, meteorologic, climatologic, air quality, natural radiation background and biotic features of the disposal site and vicinity; where the site characterization shall include sufficient and suitable data for design and performance analysis; and where the minimum requirements include, but are not limited to, the following:
 - (A) geologic description to include:
 - (i) regional geologic framework including stratigraphy, tectonics, structure, physiography, seismology and geomorphology;
 - (ii) site specific stratigraphy, lithology, structural geology, geochemistry, topography, and an analysis of landforms including any evidence of destructive geomorphic processes;
 - (iii) a regional geologic map at a scale of 1:62,500;
 - (iv) a site specific topographic map at a scale of 1:1,200; and
 - (v) a site specific geologic map at a scale of 1:1,200 with accompanying cross-sections;

- (B) geotechnical description to include:
 - (i) soil and saprolite characteristics related to slope stability, cover integrity, erosion, compaction characteristics for backfill materials, foundation analyses, gradations for proposed filler material, and possible interactions between the soils and waste containers; and
 - (ii) bedrock characteristics related to foundation analyses and hydrology;
- (C) hydrologic description to include:
 - (i) surface water hydrology including the upstream drainage area contributing flow across the site and the downstream drainage area to a distance of approximately ten miles;
 - (ii) an inventory of existing surface water users and public water supplies within approximately ten miles downstream of the site;
 - (iii) an inventory of potential surface water impoundments that will be precluded by siting of a disposal facility;
 - (iv) an inventory and description of all significant hydrologic units underlying the site to a depth of 100 feet below the level of waste disposal;
 - (v) site specific data sufficient to describe the characteristics, present water quality, occurrence and movement of water in both the unsaturated and saturated zones;
 - (vi) an inventory of existing groundwater users within approximately two miles of the site, both from groundwater wells and at points of groundwater discharge, e.g. springs;
 - (vii) identification of the nearest downgradient groundwater users and the nearest municipal supply relying on groundwater; and
 - (viii) an inventory of potential groundwater supplies that will be precluded by siting of a disposal facility;
- (D) meteorologic description to include:
 - (i) determination of a water budget for the disposal site;
 - (ii) typical weather patterns; and
 - (iii) determination of the frequency, probability, and potential consequences of severe meteorological phenomena;
- (E) climatologic description to include:
 - (i) normal seasonal fluctuations and extremes predicated from historical records;
 - (ii) air temperatures and soil temperatures;
 - (iii) frost penetration; and
 - (iv) solar radiation;
- (F) air quality description to include:
 - (i) measurement of suspended particulates; and
 - (ii) the level of airborne radionuclides contributed by atmospheric fallout, natural radiation released from the soil, and agricultural activities;
- (G) natural radiation background description to include:
 - (i) sampling of air, soil (both on and off site), water (both on and off site), flora, fauna, and farm products (including grains and milk); and
 - (ii) both total background and contribution from individual radionuclides; and
- (H) biotic description to include:
 - (i) an accurate, site-specific inventory of flora and fauna in and within three miles of the site;
 - (ii) inventory and distribution of livestock and crops within three miles of the site;
- (14) an identification of the known natural resources at the disposal site, whose exploitation could result in inadvertent intrusion into the wastes after removal of active institutional control;
- (15) a description of baseline, operational, and long-term environmental monitoring programs to

- include:
- (A) inspection and monitoring of waste packages prior to disposal;
 - (B) criteria and procedures to stop acceptance of waste at the facility, including action levels; and
 - (C) if available, a copy of the last environmental monitoring reports filed with the U.S. Nuclear Regulatory Commission or agreement state program or other authorities;
- (16) decontamination, decommissioning and site closure plans, including:
- (A) those design features which are intended to facilitate disposal site closure and to eliminate the need for ongoing active maintenance;
 - (B) schedule;
 - (C) procedure, including documentation that procedure is effective; and
 - (D) radioactive waste disposal plan; and
- (17) a description of an action plan which would be implemented in the event of unforeseen differences between expected and actual behavior of the disposal system and which includes:
- (A) a description of conditions which require remedial action, such as:
 - (i) erosion and other damage to the stability of the site;
 - (ii) failure of physical security features, equipment or procedures;
 - (iii) deterioration of trench or disposal unit covers;
 - (iv) deterioration of leachate collection system;
 - (v) clogging or siltation of monitoring and observation wells;
 - (vi) the presence of leachate in individual disposal units;
 - (vii) the migration of disposed radioactive material;
 - (viii) changes in site characteristics or other events which cause or threaten to cause failure of the facility to meet the performance objectives of this Section;
 - (ix) specific action levels, events or other conditions for which the licensee will institute specific remedial actions; and
 - (x) presence of radioactive concentrations in groundwater above preoperationally determined background;
 - (B) provisions for early identification of conditions requiring remedial action, such as:
 - (i) detection of water in any disposal unit;
 - (ii) detection of radioactive contamination in groundwater with sufficient sampling locations and frequencies to permit identification of the disposal unit(s) causing the contamination;
 - (iii) establishment of specific sampling locations, sampling frequencies and sample types as part of the licensee's environmental monitoring program;
 - (iv) methods and frequencies for detection of water or leachate in disposal units or trenches;
 - (v) any methods and associated frequencies for inspecting, testing, maintaining or otherwise assessing the condition and performance of disposal units, trenches and covers;
 - (vi) method and frequency for monitoring condition and physical stability of the site;
 - (vii) any special monitoring, inspection or testing which the licensee will institute in response to specific natural or man-made occurrences which may affect the ability of the facility to meet the performance objectives of this Section; and
 - (viii) any periodic or ongoing evaluation of site characteristics or changes in site characteristics which relate to the ability of the facility to meet the performance objectives of this Section;
 - (C) a description of the corrective measures that will be taken to correct the condition and otherwise assure compliance with the performance objectives and technical requirements of this Section, such as:

- (i) continued vigilance;
- (ii) water and leachate detention;
- (iii) pumping or repair of the disposal unit;
- (iv) procedures for timely repair or waste retrieval after problem detection;
- (v) redesign of disposal units;
- (vi) repair or redesign of engineered barriers;
- (vii) revision of site operating procedures, site personnel training, waste segregation practices, and monitoring and testing programs;
- (viii) revision of disposal methodology; and
- (ix) revision of site waste acceptability criteria; and
- (D) identification of facility features which facilitate remedial actions, such as:
 - (i) design of disposal units and engineered barriers which allows access for remedial action; and
 - (ii) other features necessary to implement the action plan.

(b) Prior to implementation of detailed site investigations, the applicant or the North Carolina Low-Level Radioactive Waste Management Authority shall develop a site characterization plan and submit it for approval by the agency to ensure that:

- (1) all available data on the site is obtained;
- (2) unnecessary laboratory and field investigations are not done;
- (3) required or desired data is obtained;
- (4) a proper sequencing and timely acquisition of the required or desired data is planned and executed;
- (5) site survey data stations will be designed and located, insofar as feasible, so as to serve as planned permanent monitoring stations as necessary; and
- (6) technical and administrative coordination of laboratory and field efforts is planned and executed.

(c) As site characterization proceeds, the applicant or the North Carolina Low-Level Radioactive Waste Management Authority and the agency shall together review the site characterization results and the site characterization plan at least once every 90 days to ensure that the plan is still valid. The site characterization plan shall be modified as required by the agency.

(d) Time-variant site characteristics that require site-specific measurements shall be measured at such frequency and duration so as to adequately define the seasonal range of the values. The minimum period of measurement shall be one year and shall be supplemented, where possible, with regional data covering a longer time period.

*History Note: Authority G.S. 104E-7; 104E-9(3); 104E-10(b); 104E-25; 104E-26;
Eff. December 1, 1987;
Amended Eff. January 1, 1994; May 1, 1992.*

.1207 ENVIRONMENTAL INFORMATION

A license application for land disposal of waste shall include site-specific environmental information (or reconnaissance level information when appropriate) which addresses and quantifies to the extent practicable, but is not limited to, the following:

- (1) statement of need and a description of the proposed activities identifying the location of the proposed site, the character of the proposed activities, and any plans for use of the facility for purposes other than handling and disposal of waste;
- (2) area and site characteristics including:
 - (a) historical and cultural landmarks, state and national parks, wilderness and wilderness study areas, archaeology, and demography;
 - (b) all buildings to a three mile radius;

- (c) existing and projected populations and land use in the general area to a ten mile radius;
- (d) nearby drinking water supply watersheds, groundwater recharge areas, flood plains, wetland areas and other natural resources such as endangered species habitats, proximity to parks, forests, wilderness areas and historical sites, and air quality; and
- (e) proximity to other low-level radioactive waste or hazardous waste facilities;
- (3) any irreversible or irretrievable commitments of natural resources which would be involved should the area be developed as a disposal site;
- (4) to the extent performed by the applicant, site selection process, including considerations of alternative sites and the interrelationships between location of waste generators, transportation costs and means, site characteristics, and compatibility with current land uses;
- (5) to the extent performed or selected by the applicant, project alternatives, including a discussion of the alternatives considered by the applicant for handling and disposal of waste;
- (6) radiological and nonradiological impacts of the proposed action, including:
 - (a) surface and groundwater impacts;
 - (b) socioeconomic impacts;
 - (c) short- and long-term impacts on public health and safety;
 - (d) impacts resulting from irreversible or irretrievable commitments of resources; and
 - (e) aesthetic factors such as the visibility, appearance and noise level of the facility;
- (7) transportation routes, route safety, method of transportation, and environmental effects of postulated operational and transportation accidents to include:
 - (a) identification of accident modes with complete failure modes and effects analysis;
 - (b) all credible accidents and projected off-site impacts, including those occurring in transportation of the waste to or from the facility; and
 - (c) mitigation of accidents and protection of the public;
- (8) a list of all governmental permits, licenses, approvals, and other entitlements obtained or which must be obtained in connection with the proposed action along with the current status of applications for and issuance of such permits, licenses, approvals, and other entitlements;
- (9) a description of the maximum projected quantity and concentration of each radionuclide and toxic or hazardous constituent of the waste released annually to the air, to the water and to the soil;
- (10) a description of the maximum projected radiation doses to off-site populations; and
- (11) a description of the maximum projected off-site radionuclide concentrations in air, soil, water and food.

History Note: Authority G.S. 104E-7; 104E-9(3); 104E-10(b); 104E-15; 104E-25; 104E-26; Eff. December 1, 1987.

.1208 TECHNICAL AND ENVIRONMENTAL ANALYSES

The specific technical and environmental information shall also include the following analyses needed to demonstrate that the performance objectives of this Section will be met:

- (1) pathways analyzed in demonstrating protection of the general population from releases of radioactivity shall include air, soil, groundwater, surface water, plant uptake, and exhumation by burrowing animals. The analyses shall:
 - (a) clearly identify and differentiate between the roles performed by the natural disposal site characteristics and design features in isolating and segregating the wastes; and
 - (b) clearly demonstrate that there is reasonable assurance that the potential exposures to humans from the release of radioactivity will not exceed the limits set forth in Rule .1223 of this Section.
- (2) Analyses of the protection of individuals from inadvertent intrusion shall include demonstration that there is reasonable assurance that the waste classification and segregation requirements

- will be met and that adequate barriers to inadvertent intrusion will be provided.
- (3) Analyses of the protection of individuals during operations shall include assessments of expected exposures due to routine operations and likely accidents during handling, storage, and disposal of waste. The analyses shall provide reasonable assurance that exposures will be controlled to meet the requirements of Section .1600 of this Chapter.
 - (4) Analyses of the long-term stability of the disposal site and the need for ongoing active maintenance after closure shall be based upon analyses of active natural processes such as erosion, mass wasting, slope failure, settlement of wastes and backfill, infiltration through covers over disposal units and adjacent soils, and surface drainage of the disposal site. The analyses shall provide reasonable assurance that there will not be a need for ongoing active maintenance of the disposal site following closure.

*History Note: Authority G.S. 104E-7; 104E-9(3); 104E-10(b); 104E-25; 104E-26;
Eff. December 1, 1987;
Amended Eff. January 1, 1994.*

.1209 INSTITUTIONAL INFORMATION

The institutional information shall include:

- (1) a certification by the custodial agency or federal government which owns the disposal site that the custodial agency or federal government is prepared to accept transfer of the license when the provisions of Rule .1220 of this Section are met, and will assume responsibility for custodial care after site closure and postclosure observation and maintenance;
- (2) evidence that arrangements have been made for assumption of ownership in fee by the state or federal government before the agency issues a license where the proposed disposal site is on land not owned by the state or federal government;
- (3) a description of the ownership of the land and fixtures that are part of the proposed disposal site; which description must include a plat plan describing the site and identifying the ownership of the surface and subsurface estates included, and, where portions of the site have been leased or will be leased to others, the terms of the lease agreement; and
- (4) a description of the contractual terms and conditions of any agreement for the management or operation of the proposed disposal site.

*History Note: Authority G.S. 104E-6.1; 104E-7; 104E-10(b); 104E-10.2; 104E-25; 104E-26;
Eff. December 1, 1987.*

.1210 FINANCIAL INFORMATION

(a) The financial information shall be sufficient to demonstrate that the financial qualifications of the applicant are adequate to carry out the activities for which the license is sought and meet other financial assurance requirements of this Section. In addition to information required in Rule .1205 of this Section, the applicant shall provide the following financial information:

- (1) financial organization of the company;
- (2) a list of all subsidiary companies and their locations;
- (3) audited financial statements for the most recent calendar or fiscal year;
- (4) interim statements, if it has been six months or more since the end of the reporting year;
- (5) a detailed schedule of liability insurance coverage applicable to low-level radioactive waste, listing:
 - (A) each insurance company's name,
 - (B) amount of coverage,
 - (C) any limitations on coverage,
 - (D) duration of insurance policies, and

- (E) whether the company is licensed by the North Carolina Insurance Commissioner;
- (6) status and nature of any outstanding civil action to which the applicant is a party, and of any administrative or criminal proceeding against the applicant; and the same information with respect to any corporation, partnership, firm, company or association which holds an interest of five percent or more in the applicant, or in which the applicant holds any interest; subject to the following provisions:
 - (A) upon request by the agency, the information required by this Subparagraph shall include a copy of any document which is a part of public record in any such action or proceeding;
 - (B) with the approval of the agency, the applicant may submit any of the information required by this Subparagraph in summary form, provided that any summary must fairly and accurately reflect the scope and content of such information;
 - (C) with the approval of the agency, the applicant may exclude information which would otherwise be required by this Subparagraph provided that the applicant identifies the types of information to be omitted and satisfies the agency that such types of information are not material to the applicant's ability to operate a facility under this Section; and
 - (D) unless specifically requested by the agency, the following types of actions if brought in North Carolina, or equivalent types of actions if brought in any other jurisdiction, are excluded from the reporting requirements of this Subparagraph:
 - (i) small claims actions as defined in G.S. 7A-210,
 - (ii) infractions as defined in G.S. 14-3.1, and
 - (iii) misdemeanors under Chapter 20 (Motor Vehicles) of the General Statutes; and
- (7) details of any other resources such as reserves or bonds to cover potential damages.
- (b) The applicant shall describe the financial responsibility and liability coverage for:
 - (1) all injuries to public, property, workers and environment;
 - (2) failure to operate as designed; and
 - (3) post-closure monitoring and surveillance.
- (c) The information required in Paragraphs (a) and (b) of this Rule shall be updated annually to the extent that such information is not provided in the annual certified financial statement required in Rule .1238 of this Section.

*History Note: Authority G.S. 104E-7; 104E-10(b); 104E-10.1; 104E-25; 104E-26;
Eff. December 1, 1987;
Amended Eff. June 1, 1993.*

.1211 FILING AND DISTRIBUTION OF APPLICATION

- (a) An application for a license under this Section, and any amendments thereto, shall be filed with the agency, and shall be signed under oath by the applicant or the applicant's authorized representative who shall furnish documentation conferring authority. The application filed with the agency shall consist of one signed original and 12 true copies.
- (b) Additional copies of the application shall be retained by the applicant for distribution in accordance with written instructions from the agency.

*History Note: Authority G.S. 104E-7; 104E-10; 104E-25;
Eff. December 1, 1987.*

.1212 ELIMINATION OF REPETITION

In its application, the applicant may incorporate, by reference, information contained in previous applications, statements, or reports filed with the agency if these references are clear and specific.

History Note: Authority G.S. 104E-7; 104E-9(3); 104E-25;

Eff. December 1, 1987.

.1213 UPDATING OF APPLICATION

(a) The application shall be as complete as possible in the light of information that is available at the time of submittal.

(b) It shall be the responsibility of the applicant to supplement its application in a timely manner in order to reflect any material changes in the information required as a part of the application or available to the applicant, so as to permit the agency to review any such information prior to issuance of a license.

*History Note: Authority G.S. 104E-7; 104E-9(3); 104E-25; 104E-26;
Eff. December 1, 1987.*

.1214 STANDARDS FOR ISSUANCE OF A LICENSE

A license for the receipt, possession, and disposal of waste containing or contaminated with radioactive material shall be issued by the agency upon finding that the issuance of the license and operation of the facility will not constitute an unreasonable risk to the health and safety of the public or have a long-term detrimental impact on the environment, and that:

- (1) The applicant is qualified by reason of training and experience to carry out the disposal operations requested in a manner that adequately protects public health and minimizes danger to life, property or the environment;
- (2) The applicant's proposed disposal site, disposal design, land disposal facility operations (including equipment, facilities, and procedures), disposal site closure, and postclosure institutional care are adequate to protect the public health and safety in that they provide reasonable assurance that the general population will be protected from releases of radioactivity as specified in this Section;
- (3) The applicant's proposed disposal site, disposal site design, land disposal facility operations (including equipment, facilities, and procedures), disposal site closure, and postclosure institutional control are adequate to protect the public health and safety in that they will provide reasonable assurance that individual inadvertent intruders are protected in accordance with this Section;
- (4) The applicant's proposed land disposal facility operations (including equipment, facilities, and procedures) are adequate to protect the public health and safety in that they will provide assurance that the standards for radiation protection set out in Section .1600 of this Chapter will be met;
- (5) The applicant's proposed disposal site, disposal site design, land disposal facility operations, disposal site closure, and postclosure institutional control are adequate to protect the public health and safety and the environment in that they will provide reasonable assurance that long-term stability of the disposed waste and the disposal site will be achieved and will eliminate to the extent practicable the need for ongoing active maintenance of the disposal site following closure;
- (6) The applicant has provided reasonable assurance that the applicable technical requirements of this Section will be met;
- (7) The applicant's proposal for institutional control provides reasonable assurance that such control will be provided for the length of time found necessary to ensure the findings in Items (2) through (5) of this Rule and that the institutional control meets the requirements in this Section;
- (8) The information on financial assurances meets the requirements of this Section;
- (9) Any additional information as requested by the agency pursuant to Rule .0317 of this Chapter is adequate; and
- (10) The requirements of this Section have been met; and

(11) The applicant proposes a facility to be operated pursuant to G.S. 104G.

History Note: Authority G.S. 104E-7; 104E-9(a)(3); 104E-10(b); 104E-12; 104E-13(a); 104E-18; 104E-25; 104E-26; Eff. December 1, 1987; Amended Eff. January 1, 1994.

.1215 CONDITIONS OF LICENSE

(a) A license issued under this Section, or any right thereunder, may not be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the agency finds, after securing full information, that the transfer is in accordance with the provisions of the North Carolina Radiation Protection Act (Act) and gives its consent in writing in the form of a license amendment.

(b) At any time before termination of the license, the licensee shall submit written statements under oath upon request of the agency to enable the agency to determine whether or not the license should be modified, suspended, or revoked.

(c) The license shall be transferred to the custodial agency only on the full implementation of the final closure plan as approved by the agency, including postclosure observation and maintenance.

(d) The licensee shall be subject to the provisions of the Act now or hereafter in effect, and to all rules and orders of the agency.

(e) Any license may be revoked, suspended or modified in whole or in part for any material false statement in the application or any misstatement of fact required under the Act, or because of conditions revealed by any application or statement of fact or any report, record, or inspection or other means which would warrant the agency to refuse to grant a license on the original application, or for failure to operate the facility in accordance with the terms of the license, or for any violation of, or failure to observe any of the terms and conditions of the Act, or any rule, license or order of the agency.

(f) Each person licensed by the agency pursuant to the rules in this Section shall confine possession and use of radioactive materials to the locations and purposes authorized in the license.

(g) No waste may be disposed of until the agency has inspected the land disposal facility and has found it to be in conformance with the description, design, and construction described in the application for a license.

(h) The agency may, in accordance with 46 FR 7540, incorporate in any license at the time of issuance, or thereafter, by appropriate order, additional requirements and conditions with respect to the licensee's receipt, possession, and disposal of waste as it deems appropriate or necessary in order to:

(1) protect the health and safety of the public and the environment, or minimize danger to life or property; and

(2) require reports and the keeping of records, and to provide for inspections of activities under the license that may be necessary or appropriate to effectuate the purposes of the Act and rules thereunder.

(i) The agency may incorporate in any license at the time of issuance, or thereafter, by appropriate order, a requirement that the licensee provide the agency with continuing information with respect to any information required as a part of the license application.

(j) Except as provided otherwise by the agency pursuant to Paragraph (h) of this Rule and consistent with G.S. 104E-25(h), the licensee shall not accept or dispose of:

(1) liquid waste which has not been solidified in a manner deemed acceptable by the agency as meeting the requirements in G.S. 104E-25(h);

(2) any waste containing chelating agents in concentrations greater than one-tenth of one percent by weight unless:

(A) the chelating agent content does not exceed eight percent by weight, and

(B) the waste has been solidified and meets the stability requirements for class B and C

waste as may be specified by the agency after consideration of current regulatory guides on waste form of the U.S. Nuclear Regulatory Commission, provided however that high integrity containers alone are not acceptable to achieve this stability requirement; and

(3) such other waste as the agency may prohibit as necessary to ensure that the performance objectives of this Section will be met.

(k) Each license will be issued for a period of five years from the date of issuance. The authority to dispose of wastes expires on the date stated in the license except as provided in Rule .1217 of this Section.

History Note: Authority G.S. 104E-7; 104E-10(b); 104E-12; 104E-13(a); 104E-25; 104E-26; 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540; Eff. December 1, 1987; Amended Eff. June 1, 1993.

.1216 AMENDMENT OF LICENSE

(a) An application for amendment of a license shall be filed in accordance with Rules .1211, .1212 and .1213 of this Section, and shall fully describe the changes desired.

(b) In determining whether an amendment to a license will be approved, the agency will apply the criteria set forth in Rule .1214 of this Section.

History Note: Authority G.S. 104E-7; 104E-10(b); 104E-25; Eff. December 1, 1987.

.1217 APPLICATION FOR RENEWAL OR CLOSURE

(a) Any expiration date on a license applies only to the above ground activities and to the authority to dispose of waste. Failure to renew the license shall not relieve the licensee of responsibility for implementing site closure, postclosure observation, and transfer of the license to the custodial agency. An application for renewal or an application for closure under Rule .1218 of this Section shall be filed at least 90 days prior to license expiration.

(b) Applications for renewal of a license shall be filed in accordance with Rules .1204 through .1213 of this Section. Applications for closure shall be filed in accordance with Rules .1211, .1212, .1213 and .1218 of this Section.

(c) In any case in which a licensee has timely filed an application for renewal of a license, the license for continued receipt and disposal of licensed materials shall not expire until the agency has taken final action on the application for renewal.

(d) In determining whether a license will be renewed, the agency will apply the criteria set forth in Rule .1214 of this Section.

(e) Upon approval of an application for renewal pursuant to provisions of this Rule, the agency will issue the license renewal amendment to expire five years from the date of final agency action on the application for renewal.

History Note: Authority G.S. 104E-7; 104E-10; 104E-10.1; 104E-18; 104E-25; Eff. December 1, 1987.

.1218 CONTENTS OF APPLICATION FOR CLOSURE

(a) Prior to final closure of the disposal site, or as otherwise directed by the agency, the applicant shall submit an application to amend the license for closure. This closure application shall include a final revision and specific details of the disposal site closure plan included as part of the license application submitted under Rule .1206 of this Section that includes each of the following:

(1) any additional geologic, geochemical, hydrologic, or other data obtained during the operational

- period pertinent to the long-term containment of emplaced wastes;
- (2) the results of tests, experiments, or any other analyses relating to backfill of excavated areas, closure and sealing, waste migration and interaction with emplacement media, or any other tests, experiments, or analyses pertinent to the long-term containment of emplaced waste within the disposal site;
- (3) any proposed revision of plans for:
 - (A) decontamination and dismantlement of surface facilities;
 - (B) backfilling of excavated areas; or
 - (C) stabilization of the disposal site for postclosure care; and
- (4) any significant new information regarding the environmental impact of closure activities and long-term performance of the disposal site.

(b) Upon review and consideration of an application to amend the license for closure submitted in accordance with Paragraph (a) of this Rule, the agency may issue an amendment authorizing closure if there is reasonable assurance that the long-term performance objectives of this Section will be met.

History Note: Authority G.S. 104E-7; 104E-9(3); 104E-10; 104E-10.1; 104E-18; 104E-25; 104E-26; 104G-13; 104G-14; Eff. December 1, 1987; Amended Eff. May 1, 1993.

.1219 POSTCLOSURE OBSERVATION AND MAINTENANCE

Following completion of closure authorized in Rule .1218 of this Section, the licensee shall observe, monitor, and carry out necessary maintenance and repairs at the disposal site until the site closure is complete and the license is transferred by the agency in accordance with Rule .1220 of this Section. Responsibility for the disposal site shall be maintained by the licensee for five years. A shorter or longer time period for postclosure observation and maintenance may be established and approved as part of the site closure plan, based on site-specific conditions.

History Note: Authority G.S. 104E-7; 104E-10; 104E-10.1; 104E-18; 104E-25; 104G-13; 104G-14; Eff. December 1, 1987.

.1220 TRANSFER OF LICENSE

Following closure and the period of postclosure observation and maintenance, the licensee may apply for an amendment to transfer the license to the custodial agency. The license shall be transferred when the agency finds:

- (1) that the closure of the disposal site has been made in conformance with the licensee's disposal site closure plan, as amended and approved as part of the license;
- (2) that reasonable assurance has been provided by the licensee that the performance objectives of this Section are met;
- (3) that any funds and necessary records for care will be transferred to the Long-Term Care Fund and the custodial agency, respectively;
- (4) that sufficient funds have accumulated in the Long-Term Care Fund to support anticipated agency and custodial agency costs for all future observation, monitoring, maintenance and remedial actions;
- (5) that the postclosure monitoring program is operational for implementation by the custodial agency; and
- (6) that the custodial agency or the federal agency which will assume responsibility for institutional control of the disposal site is prepared to assume responsibility and ensure that the institutional requirements found necessary under Item (7) of Rule .1214 of this Section will be met.

History Note: Authority G.S. 104E-7; 104E-10; 104E-10.1; 104E-12; 104E-16; 104E-18; 104E-25; 104E-26; 104G-13; 104G-14; Eff. December 1, 1987; Amended Eff. May 1, 1993.

.1221 TERMINATION OF LICENSE

(a) Following any period of institutional control needed to meet the requirements found necessary under Rule .1214 of this Section, the custodial agency may apply for an amendment to terminate the license.

(b) This application shall be filed, and will be reviewed, in accordance with the provisions of Rule .1211 of this Section and Paragraph (a) of this Rule.

(c) A license will be terminated only when the agency finds:

- (1) that the institutional control requirements found necessary under Item (7) of Rule .1214 of this Section have been met; and
- (2) that any additional requirements resulting from new information developed during the institutional control period have been met, and that permanent monuments or markers warning against intrusion have been installed.

History Note: Authority G.S. 104E-7; 104E-10; 104E-25; 104G-13; 104G-14; Eff. December 1, 1987; Amended Eff. May 1, 1993.

.1222 PERFORMANCE OBJECTIVES: GENERAL REQUIREMENT

Land disposal facilities shall be sited, designed, operated, closed, and controlled after closure so that reasonable assurance exists that exposures to humans do not exceed the limits established in the performance objectives in Rules .1223 through .1225 of this Section.

History Note: Authority G.S. 104E-7; 104E-10; 104E-25; 104E-26; Eff. December 1, 1987.

.1223 PROTECTION OF POPULATION FROM RELEASES OF RADIOACTIVITY

(a) The design goal of the engineered barrier and other requirements in this Section is confinement of the disposed waste and contained radioactivity for at least the designed life of the required engineered barriers, with reasonable assurance that any release of radioactivity or radiation will not exceed the limits stated in Paragraph (b) of this Rule and will be as low as reasonably achievable as provided in Paragraph (c) of this Rule.

(b) Land disposal facilities shall not cause external radiation levels or release concentrations of radioactive material to the general environment in groundwater, surface water, air, soil, plants, or animals that result in an annual equivalent dose to any member of the public, above background as determined in accordance with Rule .1231 of this Section, exceeding:

- (1) 25 millirems to the whole body,
- (2) 75 millirems to the thyroid, or
- (3) 25 millirems to any other organ.

(c) In accordance with the ALARA plan required by Rule .1206 of this Section, the licensee shall maintain releases of radioactivity in effluents to the general environment and resultant radiation dose to the public as low as reasonably achievable below the limits imposed in Paragraph (b) of this Rule.

History Note: Authority G.S. 104E-7; 104E-10; 104E-25; 104E-26; Eff. December 1, 1987; Amended Eff. May 1, 1993.

.1224 PROTECTION OF INDIVIDUALS FROM INADVERTENT INTRUSION

Design, operation, and closure of the land disposal facility shall ensure protection of any individual inadvertently intruding into the disposal site and occupying the site or contacting the waste at any time after active institutional controls over the disposal site are removed.

*History Note: Authority G.S. 104E-7; 104E-10; 104E-25; 104E-26;
Eff. December 1, 1987.*

.1225 PROTECTION OF INDIVIDUALS DURING OPERATIONS

(a) Operations at the land disposal facility shall be conducted in compliance with the standards for radiation protection set out in Section .1600 of this Chapter, except as provided in Rule .1223 of this Section for the off-site public.

(b) In accordance with the ALARA plan required by Rule .1206 of this Section, the licensee shall maintain occupational radiation doses as low as reasonably achievable below the occupational radiation dose limits established in Section .1600 of this Chapter.

*History Note: Authority G.S. 104E-7; 104E-10; 104E-25; 104E-26;
Eff. December 1, 1987;
Amended Eff. January 1, 1994.*

.1226 STABILITY OF THE DISPOSAL SITE AFTER CLOSURE

The disposal facility shall be sited, designed, used, operated, and closed to achieve long-term stability of the disposal site and to eliminate to the extent practicable the need for ongoing active maintenance of the disposal site following closure so that only surveillance, monitoring, and minor custodial care are required.

*History Note: Authority G.S. 104E-7; 104E-10; 104E-25; 104E-26;
Eff. December 1, 1987.*

.1227 TECHNICAL REQUIREMENTS FOR LAND DISPOSAL FACILITIES

The technical requirements for land disposal facilities are set forth in Rules .1228 through .1234 of this Section.

*History Note: Authority G.S. 104E-7; 104E-10; 104E-25; 104E-26;
Eff. December 1, 1987;
Amended Eff. May 1, 1993.*

.1228 DISPOSAL SITE SUITABILITY REQUIREMENTS

(a) The disposal site shall be capable of being characterized, modeled, analyzed, and monitored.

(b) Within the region where the facility is to be located, a disposal site should be selected so that projected population growth and future developments are not likely to affect the ability of the disposal facility to meet the performance objectives of this Section.

(c) Areas shall be avoided having known natural resources which, if exploited, would result in failure to meet the performance objectives of this Section.

(d) The disposal site shall be well drained and free of areas of flooding or frequent ponding. Waste disposal shall not take place in a 100-year flood plain, coastal high-hazard area or wetland, as defined in Executive Order 11988, "Floodplain Management Guidelines."

(e) Upstream drainage areas shall be minimized to decrease the amount of runoff which could erode or inundate disposal units.

(f) The disposal site shall provide sufficient depth to the water table that groundwater intrusion,

perennial or otherwise, into the waste will not occur, provided however that the depth to the water table shall be sufficient to ensure that the bottom of the disposal facility may be at least seven feet above the seasonal high water table as provided in G.S. 104E-25(j).

(g) Areas shall be avoided that are the recharge areas of sole source aquifers or drinking water supply watersheds unless it can be demonstrated with reasonable assurance that the disposal site will be designed, constructed, operated, and closed without an unreasonable risk to an aquifer or drinking water supplies.

(h) Waste disposal shall not take place within 1000 feet of drinking water wells, except for on-site wells controlled by the licensee and used to supply water solely to the facility. This minimum distance may be increased in any lateral direction when required by site-specific conditions.

(i) The hydrogeologic unit used for disposal shall not discharge groundwater to the surface within the disposal site.

(j) Areas shall be avoided where tectonic processes such as faulting, folding, seismic activity, or vulcanism may occur with such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of this Section, or may preclude defensible modeling and prediction of long-term impacts.

(k) Areas shall be avoided where surface geologic processes such as mass wasting, erosion, slumping, landsliding, or weathering occur with such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of this Section, or may preclude defensible modeling of long-term impacts.

(l) The disposal site shall not be located where nearby facilities or activities could adversely impact the ability of the site to meet the performance objectives of this Section or significantly mask the environmental monitoring program.

*History Note: Authority G.S. 104E-7; 104E-10; 104E-25; 104E-26;
Eff. December 1, 1987.*

.1229 SITE DESIGN FOR LAND DISPOSAL

(a) Shallow land burial is prohibited as provided in G.S. 104E-20(b).

(b) Site design features shall be directed toward long-term isolation and avoidance of the need for continuing active maintenance after site closure.

(c) The disposal site design and operation shall be compatible with the disposal site closure and stabilization plan and lead to disposal site closure that provides reasonable assurance that the performance objectives of this Section will be met.

(d) The disposal site shall be designed to complement and improve, where appropriate, the ability of the disposal site's natural characteristics to assure that the performance objectives of this Section will be met.

(e) Covers shall be designed to minimize water infiltration, to direct percolating or surface water away from the disposed waste, and to resist degradation by surface geologic processes and biotic activity.

(f) Surface features shall direct surface water drainage away from disposal units at velocities and gradients which will not result in erosion that will require ongoing active maintenance.

(g) The disposal site shall be designed to minimize the contact of water with waste during storage, the contact of standing water with waste during disposal, and the contact of percolating or standing water with wastes after disposal.

(h) The disposal units shall incorporate engineered barriers. The disposal units and incorporated engineered barriers shall be designed and constructed to meet the performance objectives, technical requirements and design criteria in G.S. 104E-25 and the following additional requirements:

- (1) The engineered barriers shall provide reasonable assurance that they will complement, and where appropriate improve, the land disposal facility's ability to isolate the radioactive waste through the institutional control period;

- (2) Engineered barrier structural integrity shall be maintained under normal and abnormal conditions of operation;
- (3) Engineered barriers shall prevent contact between the surrounding earth and the waste, except for earth that may be used as fill material within the disposal unit; and
- (4) The disposal units shall be constructed or emplaced in a manner which will ensure that the bottom of the disposal facility is at least seven feet above the seasonal high water table or more if necessary to meet the performance objectives of this Section.

(i) The licensee shall develop, operate and maintain the site in a manner that will not diminish the hydrogeological performance of the site below the requirements contained in the rules of this Section.

*History Note: Authority G.S. 104E-7; 104E-10; 104E-25; 104E-26;
Eff. December 1, 1987;
Amended Eff. May 1, 1993; May 1, 1992.*

.1230 FACILITY OPERATION AND DISPOSAL SITE CLOSURE

(a) Wastes designated as Class A pursuant to Rule .1650 of this Chapter shall be segregated from other wastes by placement in disposal units which are sufficiently separated from disposal units for the other waste classes so that any interaction between Class A wastes and other wastes will not result in the failure to meet the performance objectives of this Section. This segregation is not necessary for Class A wastes if they meet the stability requirements in Rule .1651(b) of this Chapter.

(b) Wastes designated as Class C pursuant to Rule .1650 of this Chapter shall be disposed of so that the top of the waste is a minimum of five meters below the top surface of the cover or shall be disposed of with intruder barriers that are designed to protect against an inadvertent intrusion for at least 500 years.

(c) Wastes shall be emplaced in a manner that maintains the package integrity during emplacement, minimizes the void spaces between packages, and permits the void spaces to be filled.

(d) Void spaces between waste packages shall be filled with earth or other material to reduce future subsidence within the fill.

(e) Waste shall be placed and covered in a manner that limits the radiation dose rate at the surface of the cover to levels that at a minimum will permit the licensee to comply with all provisions of Rule .1611 of this Chapter at the time the license is transferred pursuant to Rule .1220 of this Section.

(f) The boundaries and locations of each disposal unit shall be accurately located and mapped by means of land survey. Disposal units shall be marked in such a way that the boundaries of each unit can be easily defined. Three permanent survey marker control points, referenced to the North American Datum of 1983 (NAD83) and the current North American Vertical Datum (NAVD), as defined and maintained by the National Geodetic Survey, shall be established on the site to facilitate surveys. The three established control stations shall be positioned both horizontally and vertically by surveys tied to the NAD83 and NAVD as maintained in the North Carolina Geodetic Survey record files. All such surveys shall comply with standards and specifications in "Standards and Specifications for Geodetic Control Networks (September 1984)" and "Geometric Geodetic Survey Accuracy Standards and Specifications for Geodetic Surveys using GPS Relative Positioning Techniques" of the Federal Geodetic Control Committee, as approved by North Carolina Geodetic Survey.

(g) A buffer zone of land shall be maintained between any buried waste and the disposal site boundary and beneath the disposed waste. The buffer zone shall be of adequate dimensions to carry out environmental monitoring activities specified in Rule .1231(c) of this Section and to permit mitigative measures if needed.

(h) Closure and stabilization measures as set forth in the approved site closure plan shall be carried out as each disposal unit is filled and covered.

(i) Active waste disposal operations shall not have an adverse effect on completed closure and stabilization measures.

(j) Mixed waste is prohibited. The Radiation Protection Commission may waive the prohibition of disposal of mixed waste provided the Radiation Protection Commission determines that the following conditions are met:

- (1) The disposal will conform to all other rules in this Section; and
- (2) The disposal will conform to all requirements of the federal Low-Level Radioactive Waste Policy Amendments Act of 1985, G.S. 104E as amended, G.S. 130A Article 9 as amended, and regulations issued pursuant thereunto.

*History Note: Authority G.S. 104E-7; 104E-10; 104E-25; 104E-26; 150B-19(6);
Eff. December 1, 1987;
Amended Eff. January 1, 1994.*

.1231 ENVIRONMENTAL MONITORING

(a) A preoperational monitoring program shall be conducted to provide basic environmental data on the disposal site characteristics and to determine the pre-existing background radiation levels. At the time a license application is submitted, a preoperational monitoring program shall have been conducted to provide basic environmental data on the disposal site characteristics. The data shall include information about the ecology, meteorology, climate, hydrology, geology, geochemistry, and seismology of the disposal site. For those characteristics that are subject to seasonal variation, data must cover at least a 12 month period.

(b) During the land disposal facility site construction and operation, the licensee shall maintain a monitoring program where:

- (1) Measurements and observations shall be made and recorded to provide data to evaluate the potential health and environmental impacts during both the construction and the operation of the facility, and to enable the evaluation of long-term effects and the need for mitigative measures; and
- (2) The monitoring program shall be capable of providing early warning of releases of radionuclides before they reach the disposal site boundary.

(c) After the disposal site is closed, the licensee responsible for postoperational surveillance of the disposal site shall maintain a monitoring program where:

- (1) The monitoring program is based on the operating history and the closure and stabilization of the disposal site; and
- (2) The monitoring program shall be capable of providing early warning of releases of radionuclides before they reach the disposal site boundary, and shall include sufficient numbers, types and locations of wells to permit detection of groundwater radioactive contamination.

*History Note: Authority G.S. 104E-7; 104E-10(b); 104E-25; 104E-26;
Eff. December 1, 1987.*

.1232 VARIANCE

*History Note: Authority G.S. 104E-7; 104E-9(3); 104E-10(b); 104E-25; 104E-26;
Eff. December 1, 1987;
Repealed Eff. July 1, 1990 in accordance with G.S. 150B-59(c).*

.1233 WASTE CLASSIFICATION AND CHARACTERISTICS

- (a) Waste shall be classified in accordance with provisions of Rule .1650 of this Chapter.
- (b) Waste shall meet the applicable characteristics prescribed in Rule .1651 of this Chapter.
- (c) Each container of waste shall be labelled in accordance with provisions of Rule .1652 of this Chapter.

*History Note: Authority G.S. 104E-7; 104E-10(b); 104E-25; 104E-26;
Eff. December 1, 1987;
Amended Eff. January 1, 1994.*

.1234 INSTITUTIONAL REQUIREMENTS

(a) Disposal of waste received from other persons may be permitted only on land owned in fee simple by the State of North Carolina or the federal government at a facility which is sited and operated pursuant to provisions of G.S. 104G.

(b) The custodial agency shall conduct an institutional control program to physically control access to the disposal site following transfer of control of the disposal site from the disposal site operator.

(c) The institutional control program shall also include, but not be limited to, conducting an environmental monitoring program at the disposal site, periodic surveillance, minor custodial care, and other requirements as determined by the agency; and administration of funds to cover the costs for these activities.

(d) The period of institutional controls will be determined by the agency, but shall be no less than 100 years following transfer of control of the disposal site to the custodial agency.

(e) Notwithstanding the period of institutional control which may be required by the agency pursuant to Paragraph (d) of this Rule, such institutional control may not be relied upon for the purpose of meeting site performance criteria for more than 100 years following transfer of control of the disposal site to the custodial agency.

*History Note: Authority G.S. 104E-6.1; 104E-7; 104E-10.2; 104E-16; 104E-18; 104E-25; 104E-26;
Eff. December 1, 1987.*

.1235 APPLICANT QUALIFICATIONS AND ASSURANCES

The applicant shall show that it either possesses the necessary funds or has reasonable assurance of obtaining the necessary funds, or by a combination of the two, to cover the estimated costs of conducting all licensed activities over the planned operating life of the project.

*History Note: Authority G.S. 104E-7; 104E-10(b); 104E-10.1; 104E-25; 104E-26;
Eff. December 1, 1987.*

.1236 FUNDING OF CLOSURE: STABILIZATION: INSTITUTIONAL CONTROLS

(a) The applicant shall provide assurances prior to the commencement of operations that sufficient funds will be available to carry out disposal site closure, stabilization and institutional controls, including:

- (1) decontamination or dismantlement of land disposal facility structures; and
- (2) closure and stabilization of the disposal site so that following transfer of the disposal site to the custodial agency, the need for ongoing active maintenance is eliminated to the extent practicable and only minor custodial care, surveillance, and monitoring are required.

(b) The amount of the assurances in Paragraph (a) of this Rule shall be established by the Commission and shall be based on agency-approved cost estimates reflecting the agency-approved plan for disposal site closure and stabilization and agency estimates of the costs which may be associated with the period of institutional controls. In estimating such costs, the agency shall consider applicant-prepared cost estimates which shall take into account total costs that would be incurred if an independent contractor were hired to perform the closure and stabilization work.

(c) The licensee shall submit the financial or surety arrangements annually for review by the agency to assure that sufficient funds will be available for completion of the closure plan and for anticipated-institutional care.

(d) The amount of the licensee's financial or surety arrangement shall change in accordance with

changes in the predicted costs of closure, stabilization and institutional care. Factors affecting closure, stabilization and institutional care cost estimates include inflation, increases in the amount of disturbed land, changes in engineering plans, closure and stabilization that has already been accomplished, and any other conditions affecting costs. The financial or surety arrangements shall be sufficient at all times to cover the costs of closure, stabilization and institutional care of the disposal units that are expected to be used before the next license renewal.

(e) The amount of the licensee's financial and surety arrangements as determined in Paragraph (d) of this Rule may be reduced annually by the actual amount of funds deposited by the licensee in the Long-Term Care Fund pursuant to such fees as may be established by the North Carolina Low-Level Radioactive Waste Management Authority under the provisions of G.S. 104G-15.

(f) The financial or surety arrangement shall be written for a specified period of time, shall run in favor of the Long-Term Care Fund, and shall be automatically renewed unless the person who issues the surety notifies the agency, the site owner, and the principal (the licensee) not less than 90 days prior to the renewal date of its intention not to renew. In such a situation, the licensee must submit a replacement surety within 30 days after notification of cancellation. If the licensee fails to provide a replacement surety acceptable to the agency within 30 days after notification of cancellation, the agency may require the North Carolina Low-Level Radioactive Waste Management Authority to collect on the original surety for deposit in the Long-Term Care Fund.

(g) Proof of forfeiture shall not be necessary to collect the surety so that, in the event that the licensee does not provide an acceptable replacement surety within the required time, the surety shall be automatically collected prior to its expiration. The conditions described in this Paragraph and in Paragraph (f) of this Rule shall be clearly stated on any surety instrument.

(h) Financial or surety arrangements generally acceptable to the Commission and agency include: surety bonds, cash deposits, certificates of deposit, deposits of government securities, escrow accounts, irrevocable letters or lines of credit, trust funds, and combinations of the above or such other types of arrangements as may be approved by the agency, consistent with provisions of G.S. 104E-18. Self-insurance, or any arrangement which essentially constitutes self-insurance, will not satisfy the surety requirement for private sector applicants.

(i) The licensee's financial or surety arrangement shall remain in effect until the closure and stabilization program has been completed and approved by the agency, custody of the site and disposed waste has been accepted by the custodial agency, and the license has been terminated by the agency.

(j) In order to avoid unnecessary duplication of expense, the agency will accept sureties that have been consolidated with earmarked financial or surety arrangements established to meet requirements of federal or other state agencies for such decontamination, closure, and stabilization. The agency will accept these arrangements only if they are considered adequate to satisfy the requirements of Paragraphs (a) to (i) of this Rule and that portion of the surety which covers the closure of the disposal site is clearly identified and committed for use in accomplishing these activities.

History Note: Authority G.S. 104E-7; 104E-16; 104E-17; 104E-18; 104E-19(b); 104E-25; 104E-26; Eff. December 1, 1987.

.1237 RECORDS: REPORTS: TESTS: AND INSPECTIONS

Requirements for records, reports, tests and inspections are described in Rules .1238 through .1241 of this Section.

History Note: Authority G.S. 104E-7; 104E-11; 104E-12; 104E-25; 104E-26; Eff. December 1, 1987.

.1238 MAINTENANCE OF RECORDS: REPORTS AND TRANSFERS

(a) Each licensee shall maintain any records and make any reports in connection with the licensed

activities, as may be required by the conditions of the license or by the rules.

(b) Records which are required by the rules or by license conditions shall be maintained for a period specified by the appropriate rules or by license conditions. If a retention period is not otherwise specified, these records shall be maintained and transferred to the agency as specified in the rules in Section .1600 of this Chapter as a condition of license termination unless the agency otherwise authorizes their disposition.

(c) Records which shall be maintained pursuant to this Section may be the original or a copy or microfilm, provided the records are capable of being clearly and legibly reproduced. The following records shall be maintained in a permanent form specified by or approved by the agency in writing:

- (1) the location and inventory of disposed waste, to include generator-specific and other information which may be required by the agency;
- (2) personnel exposure, bioassay and other personnel dose assessment records;
- (3) geologic, hydrologic and other site characterization records; and
- (4) any other records that the agency deems appropriate to be maintained in a permanent form based on a determination that retention of the records is necessary to ensure protection of the public and environment during the institutional control period.

(d) If there is a conflict between the agency's rules or license conditions pertaining to the retention period for the same type of record, the longer retention period specified takes precedence.

(e) Notwithstanding Paragraphs (a) through (d) of this Rule, copies of records of the location and the quantity of wastes contained in the disposal site shall be transferred to the agency upon transfer of the license to the custodial agency or upon termination of the license.

(f) Following receipt and acceptance of a shipment of waste, the licensee shall record the date of receipt and disposal of the waste, the location in the disposal site, the condition of the waste packages as received, any discrepancies between materials listed on the manifest and those received, and any evidence of leaking or damaged packages or radiation or contamination levels in excess of limits specified in U.S. Department of Transportation and agency rules. The licensee shall briefly describe any repackaging operations of any of the waste packages included in the shipment, plus any other information required by the agency as a license condition.

(g) Each licensee authorized to dispose of waste received from other persons shall file a copy of its financial report or a certified financial statement annually with the agency in order to update the information base for determining financial qualifications.

(h) Each licensee authorized to dispose of waste materials received from other persons pursuant to this Section shall submit annual reports to the agency in accordance with Subparagraphs (h)(1) through (h)(4) of this Rule.

- (1) Reports shall be submitted by the end of the first calendar quarter of each year for the preceding year.
- (2) If the quantities of radioactive materials released during the reporting period, monitoring results, or maintenance performed are significantly different from those expected in the materials previously reviewed as part of the licensing action, the reports shall cover this specifically.
- (3) The reports shall include:
 - (A) specification of the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in airborne effluents during the preceding year;
 - (B) the results of the environmental monitoring program;
 - (C) a summary of licensee disposal unit survey and maintenance activities;
 - (D) the location and inventory of disposed waste, including location of each discrete waste shipment or portion thereof;
 - (E) a summary, by waste class, of activities and quantities of radionuclides disposed of;
 - (F) any instances in which observed site characteristics were significantly different from those described in the application for a license; and
 - (G) any other information the agency may require.

- (4) Reports shall be submitted in duplicate to the agency. The agency shall transfer one copy of each report to the State Records Center for permanent retention.
- (i) Any transfer of radioactive materials by the licensee is subject to the requirements in Rule .0343 of this Chapter.

History Note: Authority G.S. 104E-7; 104E-9(a)(3); 104E-12; 104E-15; 104E-25; 104E-26; Eff. December 1, 1987; Amended Eff. January 1, 1994.

.1239 TESTS AT LAND DISPOSAL FACILITIES

Each licensee shall perform, or permit the agency to perform, any tests the agency deems appropriate or necessary for the administration of the rules of this Section, including tests of:

- (1) wastes and facilities used for the receipt, storage, handling, and disposal of wastes;
- (2) radiation detection and monitoring instruments; and
- (3) other equipment and devices used in connection with the receipt, possession, handling, storage, or disposal of waste.

History Note: Authority G.S. 104E-7; 104E-10(b); 104E-25; 104E-26; Eff. December 1, 1987; Amended Eff. May 1, 1993.

.1240 AGENCY INSPECTIONS OF LAND DISPOSAL FACILITIES

- (a) Each licensee shall afford to the agency at all reasonable times opportunity to inspect:
 - (1) waste not yet disposed of;
 - (2) the premises, equipment, operations, and facilities in which wastes are received, possessed, handled, treated, stored or disposed of; and
 - (3) records kept by the licensee pursuant to the applicable rules of this Chapter.
- (b) Authorized representatives of the agency may copy and take away copies of, for the agency's use, any record required to be kept pursuant to provisions of this Section.

History Note: Authority G.S. 104E-7; 104E-10(b); 104E-11; 104E-12; 104E-25; 104E-26; Eff. December 1, 1987; Amended Eff. May 1, 1993.

.1241 INSPECTION

- (a) The agency may require at any disposal site that the licensee provide appropriate office and storage space for a resident inspector who is employed by the agency.
- (b) The agency may require the licensee to refuse acceptance of low-level radioactive waste from any generator, if the agency makes one or more of the following determinations:
 - (1) the generator has shipped waste to the licensee's facility without filing the manifest required in Rule .1633 of this Chapter;
 - (2) the generator has improperly described waste in a manifest contrary to the requirements in Rule .1633 of this Chapter;
 - (3) the generator has shipped to the licensee's facility waste which is prohibited by any rule of this Chapter or by condition of the site operator's license;
 - (4) the generator has shipped to the licensee's facility improperly labeled or packaged containers of waste; or
 - (5) the generator has failed to comply with applicable rules of this Chapter.
- (c) In the event that the agency prohibits the licensee from receiving waste from any generator pursuant to Paragraph (b) of this Rule, the agency shall notify the licensee and the generator both

verbally and in writing, stating the nature and basis for the prohibition, the corrective actions required to terminate the prohibition and the rights of the affected persons regarding the prohibition.

*History Note: Authority G.S. 104E-7; 104E-10(b); 104E-11; 104E-12; 104E-25; 104E-26;
Eff. December 1, 1987;
Amended Eff. January 1, 1994.*

.1242 NOTIFICATIONS AND REPORTS

(a) The licensee shall submit to the agency monthly reports of all containers or shipments of waste which arrive at the site and are found by licensee personnel to be in violation of any provision of the rules of this Chapter. The monthly reports shall include the name, mailing address, telephone number, radioactive material license number, and description and date of the violation; shall cover a period of one calendar month; and shall be submitted to the agency within 20 days after the end of the calendar month covered by the report.

(b) The licensee shall immediately notify the agency in the event that the licensee determines that the limits imposed in Paragraph (b) of Rule .1223 of this Chapter have been exceeded.

(c) The licensee shall notify the agency within 30 days after the licensee determines that on-site migration in groundwater of disposed radioactivity has occurred along with an explanation of the remedial actions taken in accordance with applicable requirements in this Section.

(d) The licensee shall notify the agency within 24 hours after the licensee determines that off-site migration of disposed radioactivity has occurred.

(e) The licensee shall also notify the agency in accordance with applicable requirements in Section .1600 of this Chapter.

*History Note: Authority G.S. 104E-7; 104E-9(3); 104E-10(b); 104E-25; 104E-26;
Eff. December 1, 1987;
Amended Eff. January 1, 1994.*

SECTION .1300
REQUIREMENTS FOR WIRELINE-SERVICE OPERATORS AND
SUBSURFACE-TRACER STUDIES

This Section .1300, Chapter 11 of Title 15A of the North Carolina Administrative Code (T15A.11 .1300); REQUIREMENTS FOR WIRELINE-SERVICE OPERATORS AND SUBSURFACE-TRACER STUDIES; has been transferred and recodified from Section .3400, Subchapter 3G of Title 10 of the North Carolina Administrative Code (T10.03G .3400), effective January 4, 1990. The recodification was pursuant to G.S. 143B-279.3.

.1301 PURPOSE AND SCOPE

(a) The rules in this Section apply to all licensees who use sources of radiation for wireline-service operations including mineral logging, radioactive markers, or subsurface tracer studies.

(b) The requirements of this Section are in addition to, and not in substitution for, the requirements of Sections .0100, .0300, .0900, .1000, .1100 and .1600 of this Chapter.

*History Note: Authority G.S. 104E-7;
Eff. June 1, 1989;
Amended Eff. January 1, 1994.*

.1302 DEFINITIONS

As used in this Section, the following definitions apply:

- (1) "Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary jobsites.
- (2) "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.
- (3) "Logging supervisor" means the individual who provides personal supervision of the utilization of sources of radiation at the well site.
- (4) "Logging tool" means a device used subsurface to perform well-logging.
- (5) "Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.
- (6) "Personal supervision" means guidance and instruction by the supervisor who is physically present at the jobsite and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required.
- (7) "Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.
- (8) "Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.
- (9) "Subsurface-tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.
- (10) "Temporary jobsite" means a location to which radioactive materials have been dispatched to perform wireline-service operations or subsurface-tracer studies.
- (11) "Well-bore" means a drilled hole in which wireline-service operations and subsurface-tracer studies are performed.
- (12) "Well-logging" means the lowering and raising of measuring devices or tools which may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well or adjacent formations.
- (13) "Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.

- (14) "Wireline-service operations" means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.

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

.1303 WRITTEN AGREEMENTS REQUIRED

No licensee shall perform wireline-service operations with a sealed source unless, prior to commencement of the operation, the licensee has a written agreement with the well operator, well owner, drilling contractor, or land owner. The written agreement required in this Rule shall certify that:

- (1) In the event a sealed source is lodged downhole, a reasonable effort to recover the source will be made; and
- (2) In the event a decision is made to abandon the sealed source downhole, the requirements of Rule .1324(c) and (d) of this Section shall be met.

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

.1304 LIMITS ON LEVELS OF RADIATION

Sources of radiation shall be used, stored, and transported in such a manner that the transportation requirements of Section .0300 of this Chapter and the dose limitation requirements of Section .1600 of this Chapter are met.

*History Note: Authority G.S. 104E-7;
Eff. June 1, 1989;
Amended Eff. January 1, 1994.*

.1305 STORAGE PRECAUTIONS

(a) Each source of radiation, except accelerators, shall be provided with a storage and transport container. The container shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of or exposure to the source of radiation.

(b) Sources of radiation shall be stored in a manner which will minimize the danger from explosion or fire.

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

.1306 TRANSPORT PRECAUTIONS

Transport containers shall be physically secured to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

*History Note: Authority G.S. 20-167.1; 104E-7; 104E-10(b); 104E-15(a);
Eff. June 1, 1989;
Amended Eff. May 1, 1993.*

.1307 RADIATION SURVEY INSTRUMENTS

(a) The licensee shall maintain sufficient calibrated and operable radiation survey instruments at each field station to make physical radiation surveys as required by this Section and by Section .1600 of this Chapter. Instrumentation shall be capable of measuring 0.1 milliroentgen per hour through at least 50

milliroentgens per hour.

(b) Each radiation survey instrument shall be calibrated:

- (1) at intervals not to exceed six months and after each instrument servicing;
- (2) at energies and radiation levels appropriate for use; and
- (3) so that accuracy within plus or minus 20 percent of the true radiation level can be demonstrated on each scale.

(c) Calibration records shall be maintained for a period of three years for inspection by the agency.

*History Note: Authority G.S. 104E-7; 104E-12(a)(1);
Eff. June 1, 1989;
Amended Eff. January 1, 1994.*

.1308 LEAK TESTING OF SEALED SOURCES

(a) Each licensee using sealed sources of radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the agency for six months after the next required leak test is performed or until transfer or disposal of the sealed source.

(b) Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state. The test sample shall be taken from the surface of the source, source holder, or from the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate. The test sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample.

(c) Each sealed source of radioactive material shall be tested at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source shall not put into use until tested. If, for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

(d) If the test reveals the presence of 0.005 microcurie or more of leakage or contamination, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with these Rules. A report describing the equipment involved, the test results, and the corrective action taken shall be filed with the agency.

(e) The following sources are exempt from the periodic leak test and notification requirements of this Rule:

- (1) hydrogen-3 sources;
- (2) sources of radioactive material with a half-life of 30 days or less;
- (3) sealed sources of radioactive material in gaseous form;
- (4) sources of beta- or gamma-emitting radioactive material with an activity of 100 microcuries or less; and
- (5) sources of alpha-emitting radioactive material with an activity of ten microcuries or less.

*History Note: Authority G.S. 104E-7; 104E-12(a);
Eff. June 1, 1989;
Amended Eff. May 1, 1993.*

.1309 QUARTERLY INVENTORY

Each licensee shall conduct a quarterly physical inventory to account for all sources of radiation. Records of inventories shall be maintained for two years from the date of the inventory for inspection by the agency and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory, and the name of the individual conducting the

inventory.

*History Note: Authority G.S. 104E-7; 104E-12(a)(1);
Eff. June 1, 1989;
Amended Eff. May 1, 1993.*

.1310 UTILIZATION RECORDS

(a) Each licensee shall maintain current utilization records showing the following information for each source of radiation:

- (1) make, model number, and a serial number or a description of each source of radiation used;
- (2) the identity of the well-logging supervisor or field unit to whom assigned;
- (3) locations where used and dates of use; and
- (4) in the case of tracer materials and radioactive markers, the radionuclide and activity used in a particular well.

(b) The licensee shall maintain the utilization records, required in Paragraph (a) of this Rule, for inspection by the agency for a period of two years from the date of the recorded event(s).

*History Note: Authority G.S. 104E-7; 104E-12(a)(1);
Eff. June 1, 1989;
Amended Eff. May 1, 1993.*

.1311 DESIGN: PERFORMANCE: AND CERTIFICATION CRITERIA

(a) Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations and manufactured after October 1, 1989, shall be certified by the manufacturer, or other testing organization acceptable to the agency, to meet the following minimum criteria:

- (1) be of doubly encapsulated construction;
- (2) contain radioactive material whose chemical and physical forms are as insoluble and non-dispersible as practical; and
- (3) individually pressure tested to at least 24,656 pounds per square inch absolute without failure.

(b) For sealed sources, except those containing radioactive material in gaseous form, acquired after October 1, 1989, in the absence of a certificate from a transferor certifying that an individual sealed source meets the requirements of this Rule, the sealed source shall not be put into use until such determinations and testing have been performed.

(c) Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations after October 1, 1989, shall be certified by the manufacturer, or other testing organization acceptable to the agency, as meeting the sealed source performance requirements for oil well-logging as contained in the American National Standard N542, "Sealed Radioactive Sources, Classification" adopted November 1, 1977, and effective on October 1, 1989.

(d) Certification documents shall be maintained for inspection by the agency for a period of two years after source disposal. If the source is abandoned downhole, the certification documents shall be maintained until the agency authorizes disposition.

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

.1312 LABELING

(a) General requirements are as follows:

- (1) Each source, source holder, or logging tool containing radioactive material shall bear a durable, legible, and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

CAUTION
RADIOACTIVE MATERIAL

- (2) The marking or labeling required in Subparagraph (a)(1) of this Rule shall be on the smallest component transported as a separate piece of equipment.
- (3) Each transport container shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

CAUTION
RADIOACTIVE MATERIAL
NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)

- (b) The word "danger" may be substituted for the word "caution" in the signs described in this Rule.

*History Note: Authority G.S. 104E-7; 104E-12(a)(1);
Eff. June 1, 1989.*

.1313 INSPECTION AND MAINTENANCE

(a) Each licensee shall conduct, at intervals not to exceed six months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to assure proper labeling and proper physical condition. The licensee shall maintain records of inspection and maintenance for a period of two years for inspection by the agency.

(b) If any inspection conducted pursuant to Paragraph (a) of this Rule reveals damage to labeling or components critical to radiation safety, the licensee shall remove the device from service until repairs have been made.

(c) The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state.

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

.1314 TRAINING REQUIREMENTS

- (a) No licensee shall permit any individual to act as a logging supervisor until such individual has:
 - (1) received, in a course recognized by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state, instruction in the subjects outlined in Rule .1325 of this Section and demonstrated an understanding thereof;
 - (2) read, received instruction in and demonstrated an understanding of the rules contained in this Section and the applicable rules in Sections .0100, .1000, and .1600 of this Chapter or their equivalent, conditions of appropriate license or certificate of registration, and the licensee's operating and emergency procedures; and
 - (3) demonstrated competence to use sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.
- (b) No licensee shall permit any individual to assist in the handling of sources of radiation until such individual has:
 - (1) read or received instruction in the licensee's operating and emergency procedures and

- demonstrated an understanding thereof; and
- (2) demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.
 - (c) The licensee shall provide safety reviews for logging supervisors and logging assistants at least once during each calendar year.
 - (d) The licensee shall maintain employee training records for inspection by the agency for two years following termination of employment.

*History Note: Authority G.S. 104E-7; 104E-12(a)(1); 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540;
Eff. June 1, 1989;
Amended Eff. January 1, 1994.*

.1315 OPERATING AND EMERGENCY PROCEDURES

The licensee's operating and emergency procedures shall include instructions in at least the following:

- (1) handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in Section .1600 of this Chapter;
- (2) methods and occasions for conducting radiation surveys;
- (3) methods and occasions for locking and securing sources of radiation;
- (4) personnel monitoring and the use of personnel monitoring equipment;
- (5) transportation to temporary jobsites and field stations, including the packaging and placing of sources of radiation in vehicles, placarding of vehicles, and securing sources of radiation during transportation;
- (6) minimizing exposure of individuals in the event of an accident;
- (7) procedure for notifying proper personnel in the event of an accident;
- (8) maintenance of records;
- (9) inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools;
- (10) procedure to be followed in the event a sealed source is lodged downhole; and
- (11) procedures to be used for picking up, receiving, and opening packages containing radioactive materials.

*History Note: Authority G.S. 104E-7;
Eff. June 1, 1989;
Amended Eff. January 1, 1994.*

.1316 PERSONNEL MONITORING

(a) No licensee shall permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears either a film badge or a thermoluminescent dosimeter (TLD).

(b) Each film badge or TLD required in Paragraph (a) of this Rule shall be assigned to and worn by only one individual.

(c) The licensee shall maintain personnel monitoring records for inspection until the agency authorizes disposal.

*History Note: Authority G.S. 104E-7; 104E-12(a)(2);
Eff. June 1, 1989.*

.1317 SECURITY

During each logging or tracer application, the logging supervisor or other designated employee of the licensee shall maintain direct surveillance of the operation to protect against unauthorized or unnecessary entry into a restricted area, as defined in Section .0100 of this Chapter.

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

.1318 HANDLING TOOLS

The licensee shall provide and require the use of tools that will assure remote handling of sealed sources other than low-activity calibration sources.

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

.1319 SUBSURFACE-TRACER STUDIES

(a) Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.

(b) No licensee shall cause the injection of radioactive material as part of a subsurface-tracer element study without prior written authorization from any other agency which may regulate or require prior approval for such injection.

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

.1320 PARTICLE ACCELERATORS

No licensee shall permit above-ground testing of particle accelerators, designed for use in well-logging, which results in the production of radiation, except in areas of facilities controlled or shielded so that the applicable requirements of Rules .1604 and .1611 of this Chapter are met.

*History Note: Authority G.S. 104E-7;
Eff. June 1, 1989;
Amended Eff. January 1, 1994.*

.1321 RADIATION SURVEYS

(a) The licensee shall make and record radiation surveys and calculations for each area where radioactive materials are stored.

(b) The licensee shall make and record radiation surveys and calculations for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys and calculations shall include each source of radiation or combination of sources to be transported in the vehicle.

(c) After removal of the sealed source from the logging tool and before departing the jobsite, the licensee shall use the logging tool detector or a survey meter to assure that the logging tool is free of contamination.

(d) The licensee shall make and record radiation surveys at the jobsite or well-head for each tracer operation, except those using hydrogen-3, carbon-14, and sulfur-35. These surveys shall include measurements of radiation levels before and after the operation.

(e) Records required pursuant to Paragraphs (a) through (d) of this Rule shall include the dates, the identification of individual(s) making the survey, the identification of survey instrument(s) used, and an

exact description of the location of the survey. The licensee shall maintain records of these surveys for inspection by the agency for two years after completion of the survey.

*History Note: Authority G.S. 104E-7; 104E-12(a)(1);
Eff. June 1, 1989.*

.1322 DOCUMENTS AND RECORDS REQUIRED AT FIELD STATIONS

Each licensee shall maintain at any field station, for inspection by the agency, the following documents and records for the specific devices, sources and personnel used at the field station:

- (1) appropriate license or equivalent document;
- (2) operating and emergency procedures;
- (3) applicable regulations;
- (4) records of the latest survey instrument calibrations made pursuant to Rule .1307 of this Section;
- (5) results of the most recent leak test performed pursuant to Rule .1308 of this Section;
- (6) quarterly inventories required in Rule .1309 of this Section;
- (7) utilization records required in Rule .1310 of this Section;
- (8) records of inspection and maintenance required in Rule .1313 of this Section;
- (9) survey records required in Rule .1321 of this Section; and
- (10) certificate or authorization documents.

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

.1323 DOCUMENTS AND RECORDS REQUIRED AT TEMPORARY JOBSITES

Each licensee conducting operations at a temporary jobsite shall have the following documents and records available at that site for inspection by the agency:

- (1) operating and emergency procedures;
- (2) survey records required in Rule .1321 of this Section for the period of operation at the site;
- (3) evidence of current calibration for the radiation survey instruments in use at the site;
- (4) when operating in the state under reciprocity, a copy of the appropriate license, certificate of registration, or equivalent documents(s); and
- (5) certificate of training and/or document showing authorized use of material.

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

.1324 NOTIFICATION OF INCIDENTS: ABANDONMENT: AND LOST SOURCES

(a) The licensee shall comply with the applicable notification requirements in Section .1600 of this Chapter for incidents and sources lost in other than downhole logging operations.

(b) Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:

- (1) monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations; and
- (2) notify the agency immediately by telephone if radioactive contamination is detected at the surface or if the source appears to be damaged.

(c) When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:

- (1) advise the well-operator of the rules of the appropriate state agency with jurisdiction over abandonment and appropriate method of abandonment, which shall include:
 - (A) the immobilization and sealing in place of the radioactive source with a concrete plug;

- (B) the setting of a whipstock or other deflection device; and
- (C) the mounting of a permanent identification plaque, at the surface of the well, containing the appropriate information required by Paragraph (d) of this Rule;
- (2) notify the agency by telephone, giving the circumstances of the loss and requesting approval of the proposed abandonment procedures; and
- (3) file a written report with the agency within 30 days of the abandonment, setting forth the following information:
 - (A) date of occurrence and a brief description of attempts to recover the source; and
 - (B) a description of the radioactive source involved, including radionuclide, quantity, and chemical and physical form;
 - (i) surface location and identification of well,
 - (ii) results of efforts to immobilize and set the source in place,
 - (iii) depth of the radioactive source,
 - (iv) depth of the top of the cement plug,
 - (v) depth of the well, and
 - (vi) information contained on the permanent identification plaque.
- (d) Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque for posting the well or well-bore. This plaque shall:
 - (1) be constructed of long-lasting material, such as stainless steel or monel, and
 - (2) contain the following information engraved on its face:
 - (A) the word "CAUTION";
 - (B) the radiation symbol without the conventional color requirement;
 - (C) the date of abandonment;
 - (D) the name of the well-operator or well owner;
 - (E) the well name and well identification number(s) or other designation;
 - (F) the sealed source(s) by radionuclide and quantity of activity;
 - (G) the source depth and the depth to the top of the plug; and
 - (H) an appropriate warning, depending on the specific circumstances of each abandonment, which may include:
 - (i) "Do not drill below plug back depth",
 - (ii) "Do not enlarge casing", or
 - (iii) "Do not re-enter the hole" before contacting the Division of Radiation Protection at the address in Rule .0111 of this Chapter.
- (e) The licensee shall immediately notify the agency by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable water source. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss, and explain efforts planned or being taken to mitigate the consequences.

*History Note: Authority G.S. 104E-7;
 Eff. June 1, 1989;
 Amended Eff. January 1, 1994; May 1, 1992.*

.1325 SUBJECTS IN TRAINING COURSES FOR LOGGING SUPERVISORS

Training courses for logging supervisors shall address at least the following subjects:

- (1) fundamentals of radiation safety:
 - (a) characteristics of radiation;
 - (b) units of radiation dose and quantity of radioactivity;
 - (c) significance of radiation dose:
 - (i) radiation protection standards,

- (ii) biological effects of radiation dose,
 - (d) levels of radiation from sources of radiation;
 - (e) methods of minimizing radiation dose:
 - (i) working time,
 - (ii) working distance,
 - (iii) shielding,
- (2) radiation detection instrumentation to be used:
 - (a) use of radiation survey instruments;
 - (b) operation;
 - (c) calibration;
 - (d) limitations;
 - (e) survey techniques;
 - (f) use of personnel monitoring equipment;
- (3) equipment to be used:
 - (a) handling equipment;
 - (b) sources of radiation;
 - (c) storage and control of equipment;
 - (d) operation and control of equipment;
- (4) the requirements of pertinent federal and state regulations;
- (5) the licensee's written operating and emergency procedures;
- (6) the licensee's record keeping procedures.

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

SECTION .1400 - TANNING FACILITIES

Rules .1401 - .1419 of this Section .1400, Chapter 11 of Title 15A of the North Carolina Administrative Code (T15A.11 .1400); TANNING FACILITIES; has been transferred and recodified from Section .3500, Subchapter 3G of Title 10 of the North Carolina Administrative Code (T10.03G .3500), effective January 4, 1990. The recodification was pursuant to G.S. 143B-279.3.

.1401 PURPOSE AND SCOPE

(a) This Section provides for the registration and regulation of facilities and equipment which employ ultraviolet and other lamps for the purpose of tanning the skin of the living human body through the application of ultraviolet radiation.

(b) Except as otherwise provided in this Section, tanning facilities are exempt from the Rules in Sections .0100 through .1300 of this Chapter to the extent that such facilities do not receive, own, possess or use radioactive material or other sources of ionizing radiation as defined in G.S. 104E-5.

(c) Nothing in this Section shall be interpreted as limiting the intentional exposure of patients to ultraviolet radiation for the purpose of treatment or therapy other than skin tanning, provided such treatment or therapy is supervised by a licensed practitioner of the healing arts in the lawful practice of their profession, in accordance with the requirements of their professional licensing board to prescribe and supervise such treatment.

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

.1402 COMPLIANCE WITH OTHER LAWS

Nothing in this Section shall relieve any person of responsibility for complying with other pertinent North Carolina laws and regulations.

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

.1403 DEFINITIONS

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

- (1) "Agency" means the North Carolina Department of Environment, Health, 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) "Individual" means any human being.
- (4) "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) "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) "Registrant" means any person who is registered with the agency as required by provisions of this Section.
- (7) "Registration" means registration with the agency in accordance with provisions of this Section.
- (8) "Tanning components" means any constituent tanning equipment part, to include ballasts, starters, lamps, reflectors, acrylic shields, timers, and airflow cooling systems.
- (9) "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) "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) "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) "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. May 1, 1993; May 1, 1992.*

.1404 EXEMPTIONS

- (a) Any person is exempt from the provisions of this Section to the extent that such person:
 - (1) uses equipment which emits ultraviolet radiation incidental to its proper operation, and
 - (2) does not use the equipment in Subparagraph (a)(1) of this Rule to deliberately expose parts of the living human body to ultraviolet radiation for the purpose of skin tanning.
- (b) Any individual is exempt from the provisions of this Section to the extent that such individual owns tanning equipment exclusively for personal use.
- (c) Tanning equipment while in transit or storage incidental thereto is exempt from the provisions of this Section.

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

.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 registration 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;
- (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) 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;
- (11) each person operating a tanning facility shall not allow any individual under 18 years of age to be the operator of tanning equipment; and
- (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. June 1, 1993; May 1, 1992.*

.1406 ISSUANCE OF CERTIFICATE OF REGISTRATION

(a) Upon determination that an application meets the requirements of this Section, the agency will issue a certificate of registration.

(b) The agency may incorporate in the certificate of registration, at the time of issuance or thereafter by appropriate rule or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of tanning equipment and tanning facilities as the agency deems appropriate or necessary.

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

.1407 EXPIRATION OF CERTIFICATE OF REGISTRATION

Except as provided in Rule .1408(b) of this Section, each certificate of registration shall expire at midnight on the expiration date stated therein.

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

.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 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.*

.1409 REPORT OF CHANGES

The registrant shall notify the agency in writing before 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.*

.1410 TRANSFER OF CERTIFICATE OF REGISTRATION

No certificate of registration may be transferred from one person to another person or from one tanning facility to another tanning facility.

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

.1411 APPROVAL NOT IMPLIED

No person, in any advertisement, shall refer to the fact that such person or such person's facility is registered with the agency pursuant to the provisions of this Section, and no person shall state or imply that any activity under such registration has been approved by the agency.

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

.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.

(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. June 1, 1993.*

.1413 CONSTRUCTION AND OPERATION OF TANNING EQUIPMENT

Except as otherwise ordered or approved by the agency, each tanning facility shall be constructed, operated and maintained in accordance with the requirements in Rules .1414 to .1418 of this Section.

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

.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 millimeters and five 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.

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

Amended Eff. June 1, 1993.

.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.

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

.1416 ADDITIONAL REQUIREMENTS FOR STAND-UP BOOTHS

Tanning booths designed for stand-up use shall also comply with the following additional requirements:

- (1) Booths shall have physical barriers or other means, such as handrails or floor markings, to indicate the proper exposure distance between ultraviolet lamps and the consumer's skin.
- (2) Booths shall be constructed with sufficient strength and rigidity to withstand the stress of use and the impact of a falling person.
- (3) Access to booths shall be of rigid construction with doors which are non-latching and open outwardly.
- (4) Booths shall be equipped with handrails and non-slip floors.

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

.1417 PROTECTIVE EYEWEAR REQUIRED

(a) The registrant shall provide protective eyewear to each consumer for use during any use of tanning equipment.

(b) The protective eyewear in Paragraph (a) of this Rule shall meet the requirements of 21 CFR Part 1040, Section 1040.20(c)(5).

(c) Tanning facility operators shall ensure that consumers wear the protective eyewear required by this Rule by means of post exposure observation.

(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. November 1, 1989.*

.1418 RECORDS: REPORTS AND OPERATING REQUIREMENTS

(a) Prior to initial exposure, the tanning facility operator shall provide each consumer the opportunity to read a copy of the warning specified in Rule .1414(b) of this Section and request that the consumer sign a statement that the information has been read and understood. For illiterate or visually impaired persons unable to sign their name, the warning statement shall be read by the operator, in the presence of a witness, and the witness and the operator shall sign the statement.

(b) The registrant shall maintain a record of each consumer's total number of tanning visits including dates and durations of tanning exposures.

(c) The registrant shall submit to the agency a written report of injury for which medical attention was sought or obtained from the use of registered tanning equipment within five working days after occurrence. The report shall include:

- (1) the name of the affected individual,
- (2) the name and location of the tanning facility involved,
- (3) the nature of the actual or alleged injury, and
- (4) any other information relevant to the actual or alleged injury, to include the date and duration of exposure and any documentation of medical attention sought or obtained.

(d) The registrant shall not allow individuals under the age of 18 to use tanning equipment unless the individual provides a consent form and a statement, described in Paragraph (a) of this Rule, signed by that individual's parent or legal guardian.

(e) The registrant shall replace defective or burned out lamps, bulbs or filters with a type intended for use in the affected tanning equipment as specified by the manufacturer's product label and having the same spectral distribution (certified equivalent lamp).

(f) The registrant shall replace ultraviolet lamps and bulbs, which are not otherwise defective or damaged, at such frequency or after such duration of use as may be recommended by the manufacturer of such lamps and bulbs.

(g) The registrant shall certify that all tanning equipment operators are adequately trained in at least the following:

- (1) the requirements of this Section,
- (2) procedures for correct operation of the tanning facility and tanning equipment,
- (3) recognition of injury or overexposure to ultraviolet radiation,
- (4) the tanning equipment manufacturer's procedures for operation and maintenance of the tanning equipment,
- (5) the determination of skin type of customers and appropriate determination of duration of exposure to registered tanning equipment, and
- (6) emergency procedures to be followed in case of injury.

(h) Effective January 1, 1993 the registrant shall allow operation of tanning equipment only by persons who have successfully completed formal training courses which cover the topics in Subparagraphs (g)(1) to (6) of this Rule and have been approved by the agency.

(i) The registrant shall maintain a record of operator training required in Paragraphs (g) and (h) of this Rule for inspection by authorized representatives of the agency.

(j) No registrant shall possess, use, operate or transfer tanning equipment or their ultraviolet radiation sources in such a manner as to cause any individual under 18 years of age to be exposed to radiation emissions from such equipment except in accordance with Paragraph (d) of this Rule.

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

.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, Raleigh, North Carolina 27611-7687 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. May 1, 1992.*

.1420 PROPOSED SERVICING

Effective August 1, 1993, each person registered pursuant to Rule .1405 of this Section shall prohibit any person from furnishing tanning equipment services to their tanning equipment or facility until such person provides evidence that they are registered with the agency as a provider of services in accordance with the provisions of Rule .1421 of this Section.

*History Note: Authority G.S. 104E-7(a)(7);
Eff. May 1, 1993.*

.1421 APPLICATION FOR REGISTRATION OF SERVICING OR SERVICES

(a) Each person who offers tanning equipment services to any agency registrant, shall apply for registration of such services with the agency within 60 days following the effective date of this Rule or, thereafter, prior to furnishing or offering to furnish any of these services.

(b) The application for registration required in Paragraph (a) of this Rule shall be completed on an approved agency form.

(c) Persons applying for registration under Paragraph (a) of this Rule shall certify that they have read and understand the requirements of the rules in this Section.

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

.1422 REPORTS AND INSTALLATION

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.

*History Note: Authority G.S. 104E-7(a)(7);
Eff. May 1, 1993.*

.1423 FEES AND PAYMENT

(a) This Rule establishes annual fees on 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 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.

(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, Raleigh, NC 27611-7687 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.
- (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:

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

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

SECTION .1500 - LICENSES FOR DISPOSAL SITE ACCESS

.1501 PURPOSE AND SCOPE

(a) This Section establishes the procedures, criteria, and terms and conditions upon which the agency issues site access licenses required pursuant to the provisions of G.S. 104E-10.3 and G.S. 104E-27.

(b) No person shall transfer waste to a disposal facility located in North Carolina unless such person holds a valid site access license issued by the agency pursuant to the rules in this Section.

(c) The agency shall issue a site access license to an applicant only after the agency determines that the applicant:

(1) has implemented best management practices, including prevention, minimization, reduction, segregation and hold-for-decay storage as required by the rules in this Section; and

(2) is reducing waste volume to the extent technologically and economically feasible.

(d) Site access licenses issued pursuant to the rules in this Section shall authorize access only to disposal facilities operated pursuant to the provisions of G.S. 104G and licensed pursuant to the rules in Section .1200 of this Chapter. Upon issuance of a site access license pursuant to the rules in this Section, the agency shall certify to the North Carolina Low-Level Radioactive Waste Management Authority that a generator is reducing waste volume to the extent technologically and economically feasible.

(e) Nothing in this Section or in site access licenses issued pursuant to this Section shall relieve any person from responsibility for complying with the conditions of the applicant's existing license for the possession and use of radioactive materials or any applicable requirements in the other sections of this Chapter or in state and federal laws and regulations, including, but not limited to, those of the U.S. Department of Transportation, the U.S. Nuclear Regulatory Commission, the North Carolina Department of Transportation, the Southeast Interstate Low-Level Radioactive Waste Management Compact, and the North Carolina Low-Level Radioactive Waste Management Authority.

(f) The rules in this Section are applicable to generators, collectors and processors of low-level radioactive waste which will be transferred to a low-level radioactive waste disposal facility located within the State of North Carolina for disposal.

(g) The rules in this Section are applicable to those waste forms deemed acceptable according to the North Carolina low-level radioactive disposal facility license as issued by the agency. The rules in this Section shall not be construed to authorize the disposal of any waste that is not authorized for disposal under Section .1200 of this Chapter.

(h) The agency shall not issue any site access license prior to January 1, 1995 or prior to the agency issuing an operating license for a low-level radioactive waste disposal facility in North Carolina pursuant to Section .1200 of this Chapter, whichever is the later.

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

.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: 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: 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 disposal facility;
- (7) certifications and additional information required by other applicable rules in this Section; and
- (8) other relevant information necessary for the agency to determine compliance with these Rules.

(b) The agency may at any time after the filing of the application, and before the expiration of a site access license, require further statements and information to enable the agency to determine whether to grant, deny, modify, suspend or revoke a site access license.

(c) Each application for a site access license shall be signed by the manager of the facility for which the site access license is requested or by his designee, provided that such designation shall be confirmed to the agency, in writing, by the manager.

(d) Except as provided in Paragraph (e) of this Rule, applications and documents submitted to the agency are public documents and shall be made available for public inspection.

(e) Notwithstanding Paragraph (d) of this Rule, the applicant may request that specific parts of the application and supporting documents which consist of proprietary information be withheld from public inspection. Such request shall include a detailed justification for each part which is proposed to be withheld. The agency may approve such requests in whole or in part, if the agency determines that public disclosure is not required in the public interest and would adversely affect the interest of the applicant. All agency approvals shall be made in writing and shall be available for public inspection.

(f) The applicant shall submit the application for a site access license required by this Section to the agency at the address in Rule .0111 of this Chapter.

(g) If the facility is not located in North Carolina, the applicant shall also submit a copy of the application to the state radiation protection regulatory agency in, or if none, to such other state agency designated by the state in which the facility is located.

(h) If the facility is licensed by the U.S. Nuclear Regulatory Commission, the applicant shall also submit a copy of the application to the U.S. Nuclear Regulatory Commission.

*History Note: Authority G.S. 104E-10.3; 104E-27; 104E-29; 132-1.2;
Eff. January 1, 1995.*

.1505 APPLICATION FOR SITE ACCESS LICENSE - WASTE GENERATORS

If the applicant for a site access license is a waste generator, the application required in Rule .1504 of this Section shall include the following additional information:

- (1) general description of the activities which involve the production of waste along with the radioactive material license numbers under which such activities are conducted;

- (2) general description of existing on-site waste management, to include facilities, equipment, procedures and programs for:
 - (a) limiting the production of contaminated material and contained radioactivity which must be managed, and the estimated annual impact on the amount of material and radioactivity;
 - (b) reducing the volume and contained radioactivity of waste which will be shipped, or transferred to collectors for shipment, to off-site disposal facilities, and the estimated annual impact on the volume and contained radioactivity shipped or transferred;
 - (c) classifying, stabilizing, solidifying liquids, packaging and monitoring waste prior to shipment or transfer to a collector for shipment to a disposal facility located in North Carolina; and
 - (d) quality assurance and quality control;
- (3) description of existing off-site waste management, to include:
 - (a) name, address, telephone number, type of processing and radioactive material license number of each off-site processor to which waste referenced in Sub-Item (2)(b) of this Rule will be shipped; and
 - (b) estimated annual impact on the volume and contained radioactivity which will ultimately be shipped to a disposal facility located in North Carolina;
- (4) description of planned changes in on-site and off-site management described in Items (2) and (3) of this Rule, to include anticipated date for implementation and estimated annual impact on the volume and contained radioactivity of waste which will be disposed at a disposal facility located in North Carolina;
- (5) history of off-site waste disposal for the past five years, to include:
 - (a) identification of all disposal facilities which received waste for disposal; and
 - (b) the total volume and contained radioactivity of waste disposed each year;
- (6) description of the projected waste which will be disposed at a disposal facility located in North Carolina for each of the next five years, to include the projected volume and contained radioactivity for Class A, Class B and Class C waste;
- (7) any regulatory notices of violation and corrective actions related to on-site and off-site management described in Items (2) and (3) of this Rule during the past five years; and
- (8) description of the applicant's notification and emergency response program in the event of accidents during transportation. This description shall include the qualifications and responsibilities of the driver.

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

.1506 CONTENT OF APPLICATION FOR WASTE COLLECTORS

If the applicant for a site access license is a waste collector, the application required in Rule .1504 of this Section shall include the following additional information:

- (1) radioactive material license numbers under which waste collection activities are conducted;
- (2) complete description of the applicant's current waste collection and handling program, to include:
 - (a) a list of the states in which waste collection services will be provided;
 - (b) a list of the waste processors and waste disposal facilities to which collected waste may be shipped;
 - (c) procedures for:
 - (i) waste collection at customer facilities;
 - (ii) handling, identifying, accounting for, and segregating the waste shipped to waste processors and waste disposal facilities;

- (iii) ensuring that waste shipped to a waste disposal facility located in North Carolina is collected only from persons who hold a currently valid site access license issued pursuant to the rules in this Section;
- (iv) ensuring that packages, labels, vehicles, placards, and radiation and contamination levels comply with applicable state and federal regulations;
- (v) quality assurance and quality control;
- (vi) notifications and emergency response in the event of accidents during transportation, including the qualifications and responsibilities of the driver;
- (3) a list of the waste processing and disposal facilities to which collected waste was shipped during the past five years; and
- (4) any regulatory notices of violation and corrective actions related to on-site and off-site management described in Items (2) and (3) of this Rule during the past five years.

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

.1507 CONTENT OF APPLICATION FOR WASTE PROCESSORS

If the applicant for a site access license is a waste processor, the application required in Rule .1504 of this Section shall include the following additional information:

- (1) the applicable information required by Rule .1505 of this Section, if the waste processor is located within the Southeast Compact and generates waste which will be disposed at a disposal facility located in North Carolina;
- (2) a list of the states from which waste may be received for processing;
- (3) description of waste processing services and management, to include:
 - (a) the radioactive material license numbers under which such activities are conducted;
 - (b) the types of waste processing services, description of the wastes which may be processed and the estimated impact of the processing on:
 - (i) volume and contained radioactivity of processed waste which will be shipped to off-site disposal facilities; and
 - (ii) suitability of processed waste for disposal;
 - (c) procedures and program for:
 - (i) handling, identifying, accounting for, and segregating waste attendant to processing and shipment to off-site waste disposal facilities;
 - (ii) ensuring that processed waste shipped to a waste disposal facility located in North Carolina is waste generated by persons who hold a currently valid site access license issued pursuant to the rules in this Section;
 - (iii) classifying, stabilizing, solidifying liquids, packaging and monitoring waste prior to shipment, or transfer to a collector or the generator for shipment, to a disposal facility located in North Carolina;
 - (iv) preparing manifests and correlating manifests with the original manifests prepared by the waste generators for processed waste which will be disposed at a disposal facility located in North Carolina;
 - (v) ensuring that packages, labels, and radiation and contamination levels comply with applicable state and federal regulations;
 - (vi) quality assurance and quality control; and
 - (vii) ensuring that waste generated by the processor is residual waste resulting from the processor's activities and that such waste can not be identified as waste attributed to a particular generator.
- (4) a list of the waste disposal facilities to which processed waste was shipped during the past five years;

- (5) for each of the past five years, a summary of the volumes and types of waste processed and the resulting volumes of processed waste shipped off-site;
- (6) description of the applicant's notification and emergency response program in the event of accidents during transportation. This description shall include the qualifications and responsibilities of the driver; and
- (7) any regulatory notices of violation and corrective actions related to on-site and off-site management described in Items (2) and (3) of this Rule during the past five years.

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

.1508 CERTIFICATION OF COMPLIANCE WITH APPLICABLE REQUIREMENTS

(a) Each shipper who prepares packages of waste for shipment to a disposal facility located in North Carolina shall certify that:

- (1) the packages and contained waste comply with all disposal site restrictions and acceptance criteria and with all applicable state and federal laws and regulations including, but not limited to, those governing manifests, labeling, radiation and contamination levels and package design and performance; and
- (2) the prior notification required by Rule .1509 of this Section will be made for each shipment of waste.

(b) Each shipper who transports packages of waste, using shipper-controlled drivers or vehicles, to a disposal facility located in North Carolina shall certify that such transportation, transport vehicles, placarding, and driver training will comply with all applicable disposal facility license conditions and acceptance criteria, and state and federal laws and regulations.

(c) The certification requirements specified in this Rule shall be in written form and shall accompany each separate shipment of waste shipped to the North Carolina disposal facility.

(d) The disposal facility operator shall provide to the agency for each shipment of accepted waste at the North Carolina disposal facility a copy of the written certification that accompanied each shipment of waste.

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

.1509 PRIOR NOTIFICATION FOR WASTE SHIPMENTS

(a) Prior to each shipment of waste to a disposal facility located in North Carolina, both the agency and the facility operator shall receive written notice from the shipper no less than 72 hours and no earlier than 30 days before the expected date of arrival of the shipment at the disposal facility.

(b) The prior notification required in Paragraph (a) of this Rule shall be filed on a "Radioactive Waste Shipment Prior Notification Form", or appropriate form(s) approved by the agency and which shall include the following:

- (1) name and address of shipper;
- (2) person responsible for waste shipment, including:
 - (A) name;
 - (B) title; and
 - (C) telephone number;
- (3) site access license number of the shipper and the site access license number of any other generator, processor, or collector involved with the waste;
- (4) shipment identification number originated by and obtained from the disposal facility operator;
- (5) location from which waste will be shipped;
- (6) name and address of consignee;

- (7) scheduled date of departure of shipment;
- (8) estimated date of arrival of shipment;
- (9) carrier;
- (10) trailer number and owner, if available;
- (11) type of transport vehicle;
- (12) transportation route;
- (13) type of package or cask model number;
- (14) type of container in cask;
- (15) package or cask specification;
- (16) complete waste description;
- (17) physical and chemical form;
- (18) total number of packages;
- (19) prominent radionuclides;
- (20) total curies;
- (21) waste class and stability;
- (22) total cubic feet;
- (23) U.S. Department of Transportation Sub Type, such as Low Specific Activity;
- (24) U.S. Department of Transportation Identification Number;
- (25) indication of highway route controlled quantity;
- (26) such other relevant information necessary for the agency to determine compliance with these Rules;
- (27) signature block certifying validity of information provided; and
- (28) signature block for consignee.

(c) The shipper shall immediately notify the agency and the facility operator of any cancellations or changes in the prior notification form which may occur immediately prior to the shipment departing from the facility enroute to the disposal facility; including, but not limited to the date of arrival, total number of packages, curie content, volume, or waste classification. This notification may be transmitted via documented telephone conversation, or the use of telecopy or facsimile machine.

(d) No shipment of waste to a disposal facility in North Carolina shall commence until the shipper has received and documented confirmation from the operator of the disposal facility that the information provided on the prior notification form and any changes, as identified by the requirements in Paragraph (c) of this Rule, comply with the conditions of the facility operator's license.

(e) With each separate shipment of waste to the North Carolina disposal facility the shipper shall provide to the carrier a copy of the prior notification form required by Paragraph (a) of this Rule for delivery to the disposal facility operator. This copy shall reflect any changes made pursuant to Paragraph (c) of this Rule.

(f) Following the acceptance of each shipment of waste at the North Carolina disposal facility, the disposal facility operator shall sign the prior notification form and submit signed copies to the agency and to the shipper within one week after acceptance.

(g) The prior notification form required in this Rule is in addition to the manifest requirements in Rule .1510 of this Section.

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

.1510 RADIOACTIVE SHIPMENT MANIFEST

(a) A manifest completed by the shipper, on forms supplied by the disposal facility operator, shall accompany each shipment of waste to a disposal facility located in North Carolina and shall include all information and certifications required by the rules in this Chapter and the disposal facility operator's license conditions.

(b) If the shipper is a waste processor, the manifest required in Paragraph (a) of this Rule shall reflect any consolidation of the original waste generator manifests and any residual waste generated by the processor.

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

.1511 FINANCIAL QUALIFICATIONS AND REQUIREMENTS

(a) The purpose of this Rule is to defray expenses incurred by the State of North Carolina for any project or activity for emergency response to and decontamination of radioactive waste transportation accidents involving the possible or actual release of radioactive materials and to defray the costs to the State for performing or supervising decontamination and to otherwise protect the public health and safety.

(b) The agency shall not issue a site access license until the applicant has satisfied the surety bond or insurance requirements in this Rule.

(c) The applicant must deposit and maintain with the agency a minimum cash or corporate surety bond in the amount of five hundred thousand dollars (\$500,000), or provide the agency satisfactory evidence of liability insurance or provide a certificate of insurance as an added insured on a policy held by a site access licensee that satisfies the insurance requirements of this Rule.

- (1) For purposes of the rules in this Section, liability insurance shall mean coverage of one million (\$1,000,000) per occurrence and five million (\$5,000,000) aggregate;
- (2) Any insurance carried pursuant to Section .2210 of Title 42 of the United States Code and 10 CFR 140 shall be sufficient to meet the requirements of this Rule; and
- (3) Liability insurance shall be specific to the packaging, transportation, storage and delivery of radioactive waste.

(d) An applicant maintaining liability insurance for the purpose of this Rule shall provide to the agency a certificate of insurance from their insurer indicating the policy number, limits of liability, policy date and specific coverage for packaging, transportation, storage and delivery of radioactive waste.

(e) A cash or corporate surety bond previously posted for the purposes of this Rule shall be returned to the site access licensee upon written notification to the agency of his intention to cease shipments of radioactive waste to the North Carolina disposal facility, provided such bond shall be returned only after the last such shipment has been accepted safely at the disposal facility.

(f) Agencies of the State of North Carolina shall not be subject to the requirements of this Rule.

(g) Notwithstanding Paragraph (c) of this Rule, the agency may require greater surety bond or insurance, based on agency analysis of the potential cost to the State for the activities in Paragraph (a) of this Rule, provided that:

- (1) the agency shall provide written notification to the site access licensee or applicant for a site access license of the proposed amount and agency analysis; and
- (2) the agency shall provide 30 days from the date of notification for the site access licensee or applicant for a site access license to submit a proposed alternate amount and basis for consideration by the agency.

(h) The indemnitor on such a bond or an insurance company for any purpose of this Rule shall be licensed to do business in the State of North Carolina.

*History Note: Authority G.S. 104E-10.3; 104E-18; 104E-27;
Eff. January 1, 1995.*

.1512 WASTE MANAGEMENT AND REDUCTION REQUIREMENTS

(a) The purpose of this Rule is to define those elements which may constitute a sound waste management program and to require each applicant for a site access license or renewal of an existing

site access license to explain how each element is implemented or, if not implemented, why its omission is justified.

(b) Those elements and sub-elements which constitute sound waste management practices include, but are not limited to, the following:

- (1) waste avoidance:
 - (A) process controls;
 - (B) training;
 - (C) material selection;
 - (D) leak prevention;
 - (E) segregation;
 - (F) recycling;
 - (G) reduction in size of facility contaminated areas; and
 - (H) radionuclide selection;
- (2) volume or activity reduction:
 - (A) storage for decay:
 - (i) waste containing no radionuclides with a radioactive half-life exceeding 90 days:
 - (I) hold for decay of contained radioactivity and subsequent disposal as non low-level radioactive waste; and
 - (II) hold for partial decay;
 - (ii) waste containing radionuclides with a radioactive half-life exceeding 90 days - hold for partial decay;
 - (B) decontamination of equipment, materials or other items:
 - (i) on-site; and
 - (ii) off-site;
 - (C) sorting:
 - (i) on-site; and
 - (ii) off-site;
 - (D) compaction:
 - (i) on-site:
 - (I) super compaction; and
 - (II) other compaction;
 - (ii) off-site super compaction;
 - (E) incineration:
 - (i) on-site; and
 - (ii) off-site.

(c) The applicant shall indicate the extent to which each of the elements and sub-elements listed in Paragraph (b) of this Rule and any other waste management practices are being employed in the applicant's waste management program.

(d) For each element and sub-element listed in Paragraph (b) of this Rule that is not employed in the applicant's waste management program, the applicant shall provide a justification for its omission which shall include an evaluation of the omission in accordance with the ALARA principle and shall include a schedule for implementation, if future implementation is planned.

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

.1513 ISSUANCE AND EXPIRATION OF SITE ACCESS LICENSES

(a) The agency will issue a site access license only after the following determinations are made and upon agency certification to the North Carolina Low-Level Radioactive Waste Management Authority that the generator is reducing waste volume to the extent technologically and economically feasible:

- (1) The applicant has submitted a license application which adequately demonstrates the applicant's ability to satisfy all requirements in the rules of this Section;
- (2) The applicant has a waste management program which incorporates best management practices, including prevention, minimization, reduction, segregation, and hold for decay storage, as provided in Rule .1512 of this Section;
- (3) The applicant is reducing waste volume and contained radioactivity to the extent technologically and economically feasible, including off-site processing, before waste is disposed at a disposal facility located in North Carolina, or has made a commitment to institute such methods in accordance with a timetable specifically approved by the agency;
- (4) The applicant has filed the bonds, insurance or other security with the agency as required in Rule .1511 of this Section; and
- (5) The applicant will ship waste to a disposal facility located in North Carolina only when such waste is generated in the Southeast Compact region, except as provided otherwise for waste generated by waste processors and authorized pursuant to Item (1) of Rule .1507 of this Section or as provided in Rule .1503(c) of this Section.

(b) Except as provided in Rules .1514 and .1517 of this Section, a site access license shall be effective for a period of five years subject to payment of applicable fees imposed by the rules in Section .1100 of this Chapter.

(c) Notwithstanding the provisions of Paragraph (b) of this Rule, any site access license is subject to modification, revocation or suspension in accordance with provisions of Rule .1516 of this Section.

(d) The licensee shall apply for amendment of the site access license in accordance with Rule .1515 of this Section prior to making changes in the waste management program described in the license application that would diminish the effectiveness of the waste management program, including but not limited to, any change resulting in an increase of waste volume and radiation exposure.

(e) If any information required by Paragraph (a) of Rule .1504 changes, the licensee shall notify the agency of such changes in writing no later than 60 days after the change and file an application for amendment, if so directed by the agency.

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

.1514 SITE ACCESS LICENSE RENEWAL

(a) An application for renewal of a site access license shall be filed in accordance with Rule .1504 of this Section.

(b) When a site access licensee has filed an application in proper form for renewal not less than 30 days prior to expiration of his existing license, the existing site access license shall not expire until the agency has taken final action on the application.

(c) When a site access licensee files an application for renewal less than 30 days prior to expiration of his existing site access license, the licensee shall not have access to a disposal facility located in North Carolina after the expiration date until the agency has issued final approval of the application.

(d) As a precondition for renewal of a site access license, the applicant shall satisfy the provisions of Rule .1512 of this Section.

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

.1515 SITE ACCESS LICENSE AMENDMENT

(a) An application for amendment of a site access license shall be filed in accordance with Rule .1504 of this Section and shall specify the manner in which the licensee desires the site access license to be

amended and the grounds for the amendment.

(b) In determining whether an amendment to a site access license will be approved, the agency shall apply the criteria set forth in Rule .1513 of this Section.

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

.1516 MODIFICATION, REVOCATION, AND TERMINATION OF LICENSES

Site access licenses are subject to modification, suspension, revocation and termination in accordance with the provisions of Rule .0344 of this Chapter.

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

.1517 TEMPORARY OR EMERGENCY ACCESS

(a) The agency may grant temporary or emergency access to a disposal facility located in North Carolina to a generator in the Southeast Compact region, only if:

- (1) access is necessary in order to eliminate an immediate and serious threat to the public health and safety;
- (2) the determination is made that the threat cannot be mitigated by any other alternative consistent with the public health and safety, including ceasing the activities that generate the waste; and
- (3) the waste form and content of the waste to be disposed, meets all acceptability requirements as stated in the facility operator's license.

(b) The agency may grant temporary or emergency access to a disposal facility located in North Carolina to a generator outside the Southeast Compact region, only after:

- (1) Such access has been granted by the U.S. Nuclear Regulatory Commission in accordance with applicable provisions of federal regulations and of the Low-Level Radioactive Waste Policy Amendments Act of 1985; and
- (2) The agency has reviewed the U.S. Nuclear Regulatory Commission's decision to grant temporary or emergency access.

(c) Temporary or emergency access to a disposal facility located in North Carolina is subject to the applicable site access licensing requirements in this Section and to the fee requirements in Section .1100 of this Chapter.

(d) Notwithstanding the provisions of Rule .1513 of this Section, a site access license, authorizing temporary or emergency access, shall be effective only for the period of time and the specific waste for which temporary or emergency access was granted.

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

SECTION .1600 - STANDARDS FOR PROTECTION AGAINST RADIATION

.1601 PURPOSE AND SCOPE

(a) The rules in this Section establish standards for protection against ionizing radiation resulting from activities conducted under licenses and registrations issued by the agency pursuant to the rules in this Chapter.

(b) It is the purpose of the rules in this Section to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant in such a manner that the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in the rules in this Section. However, nothing in this Section shall be construed as limiting actions that may be necessary to protect health and safety.

(c) The rules in this Section apply to persons licensed or registered by the agency to receive, possess, use, transfer, or dispose of radioactive material or other sources of radiation. The limits in this Section do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to voluntary participation in medical research programs, or to exposure from individuals administered radioactive material and released in accordance with Rule .0358 of this Chapter.

(d) Nothing in this Section shall relieve a licensee engaged in operation of a radioactive waste disposal facility, as defined in Rule .0104 of this Chapter, from responsibility for complying with the requirements in Section .1200 of this Chapter.

(e) Effective January 1, 1994 all licensees and registrants shall comply with the rules in this Section and cease to comply with the requirements in Section .0400 of this Chapter, except as provided otherwise in Rule .1602 of this Section.

*History Note: Authority G.S. 104E-7(a)(2);
Eff. January 1, 1994;
Amended Eff. August 1, 1998.*

.1602 IMPLEMENTATION

(a) If the requirements of this Section are more restrictive than a license or registration condition established prior to January 1, 1994, the licensee or registrant shall comply with this Section unless exempted by Paragraph (c) of this Rule.

(b) If any existing license or registration condition is more restrictive than a requirement in this Section, the licensee or registrant shall comply with such condition until there is a license or registration amendment or license or registration renewal that modifies or removes the condition.

(c) If a license or registration condition established prior to January 1, 1994 exempts a licensee or registrant from a requirement in this Section, the exemption shall remain in effect until there is a license or registration amendment or license or registration renewal that modifies or removes the condition.

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

.1603 RADIATION PROTECTION PROGRAMS

(a) Each licensee or registrant shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed or registered activities and sufficient to ensure compliance with the provisions of this Section. Recordkeeping requirements relating to these programs are provided in Rule .1636 of this Section.

(b) The licensee or registrant shall use procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public and

releases of radioactive materials in effluents to unrestricted areas that are as low as is reasonably achievable (ALARA).

(c) The licensee or registrant shall annually review the radiation protection program content and implementation.

(d) To implement the ALARA requirements of Paragraph (b) of this Rule, and notwithstanding the requirements of Rule .1611 of this Section, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 0.01 rem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in Rule .1647 of this Section and promptly take appropriate corrective action to ensure against recurrence.

*History Note: Authority G.S. 104E-7(a)(2);
Eff. January 1, 1994;
Amended Eff. August 1, 1998.*

.1604 OCCUPATIONAL DOSE LIMITS FOR ADULTS

(a) The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures as provided in Rule .1608 of this Section, to the following dose limits:

- (1) an annual limit, which is the more limiting of:
 - (A) the total effective dose equivalent being equal to five rems (0.05Sv); or
 - (B) the sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv); and
- (2) the annual limits to the lens of the eye, to the skin, and to the extremities which are:
 - (A) an eye dose equivalent of 15 rems (0.15 Sv), and
 - (B) a shallow-dose equivalent of 50 rems (0.50 Sv) to the skin or to each of the extremities.

(b) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. Dose limits for planned special exposures are provided in Item (5) of Rule .1608 of this Section.

(c) The assigned deep-dose equivalent and shallow-dose equivalent shall be for the part of the body receiving the highest exposure. The deep-dose equivalent, eye dose equivalent and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

(d) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table 1 of Appendix B to 10 CFR §§ 20.1001 - 20.2401 and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits.

(e) In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. Requirements for annual limits on intake for uranium are provided in Appendix B to 10 CFR §§ 20.1001 - 20.2401.

(f) The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. Requirements for determining prior occupational exposure are provided in Rule .1638(e) of this Section.

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

.1605 REQUIREMENTS FOR SUMMATION OF EXTERNAL, INTERNAL DOSES

(a) If the licensee is required to monitor under both Items (1) and (2) of Rule .1614 of this Section, the licensee shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee is required to monitor only by Rule .1614(1) of this Section or only by Rule .1614(2) of this Section, then summation is not required to demonstrate compliance with the dose limits. The licensee may demonstrate compliance with the requirements for summation of external and internal doses by meeting one of the conditions specified in Paragraph (b) of this Rule and the conditions in Paragraphs (c) and (d) of this Rule. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

(b) If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep-dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

- (1) the sum of the fractions of the inhalation ALI for each radionuclide, or
- (2) the total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or
- (3) the sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For the purposes of this Rule an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighing factors, w_T , and the committed dose equivalent, $H_{T,50}$ per unit intake is greater than 10 percent of the maximum weighted value of $H_{T,50}$ (i.e., $w_T H_{T,50}$) per unit intake for any organ or tissue.

(c) If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

(d) The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be further evaluated.

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

.1606 EXTERNAL DOSE FROM AIRBORNE RADIOACTIVE MATERIAL

Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep-dose equivalent, eye dose equivalent, and shallow-dose equivalent from external exposure to the radioactive cloud. Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep-dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep-dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

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

.1607 DETERMINATION OF INTERNAL EXPOSURE

(a) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required by Rule .1614 of this Section, take suitable and timely measurements of:

- (1) concentrations of radioactive materials in air in work areas; or
- (2) quantities of radionuclides in the body; or
- (3) quantities of radionuclides excreted from the body; or
- (4) combinations of these measurements.

(b) Unless respiratory protective equipment is used, as provided in Rule .1620 of this Section, or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

(c) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee may:

- (1) use that information to calculate the committed effective dose equivalent, provided the licensee documents that information in the individual's record; and
- (2) upon prior approval of the agency, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material (e.g., aerosol size distribution or density); and
- (3) separately assess the contribution of fractional intakes of Class D, W, or Y compounds of given radionuclide to the committed effective dose equivalent. Requirements for annual limits on intake are provided in Appendix B to 10 CFR §§ 20.1001 - 20.2401.

(d) If the licensee chooses to assess intakes of Class Y material using the measurements given in Subparagraph (a)(2) or (3) of this Rule, the licensee may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by Rules .1646 or .1647 of this Section, in order to permit the licensee to make additional measurements basic to the assessments.

(e) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

- (1) the sum of the ratios of the concentration to the appropriate DAC value (e.g., D, W, Y) from Appendix B to 10 CFR §§ 20.1001 - 20.2401 for each radionuclide in the mixture; or
- (2) the ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

(f) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

(g) When a mixture of radionuclides in air exists, licensees may disregard certain radionuclides in the mixture if:

- (1) the licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in Rule .1604 of this Section and in complying with the monitoring requirements in Rule .1614 of this Section;
- (2) the concentration of any radionuclide disregarded is less than 10 percent of its DAC; and
- (3) the sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

(h) In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of five rems (0.05 Sv) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

(i) When the ALI and the associated DAC are determined by the nonstochastic organ dose limit of 50 rems (0.5 Sv), the stochastic ALI, which is the intake of radionuclides that would result in a committed effective dose equivalent of five rems (0.05 Sv), is listed in parentheses in Table 1 of Appendix B to 10 CFR §§ 20.1001 - 20.2401. In this case, the licensee may, as a simplifying assumption, use the stochastic ALIs to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALIs, the licensee shall also demonstrate that the limit in Part (a)(1)(B) of Rule .1604 of this Section is met.

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

.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 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.*

.1609 OCCUPATIONAL DOSE LIMITS FOR MINORS

The annual occupational dose limits for minors are 10 percent of the annual dose limits specified for adult workers in Rule .1604 of this Section.

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

.1610 DOSE TO AN EMBRYO/FETUS

(a) The licensee or registrant shall ensure that the dose 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 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 to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

(d) If the dose 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.*

.1611 DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

(a) Each licensee or registrant shall conduct operations so that:

- (1) The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contribution from the licensee's disposal of radioactive material into sanitary sewerage in accordance with Rule .1630 of this Section, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Rule .0358 of this Chapter and from voluntary participation in medical research programs; and
- (2) The dose in any unrestricted area from external sources of radiation, exclusive of the dose contribution from patients administered radioactive material and released in accordance with Rule .0358 of this Chapter, does not exceed 0.002 rem (0.02 mSv) in any one hour.

(b) If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

(c) A licensee, registrant, license applicant or registration applicant may apply to the agency for prior authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). The licensee, registrant, license applicant or registration applicant shall include the following information in this application:

- (1) demonstration of the need for and the expected duration of operations in excess of the limit in Paragraph (a) of this Rule;
- (2) the licensee's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and
- (3) the procedures to be followed to maintain the dose as low as is reasonably achievable.

(d) The agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

*History Note: Authority G.S. 104E-7(a)(2);
Eff. January 1, 1994;
Amended Eff. August 1, 1998.*

.1612 COMPLIANCE WITH DOSE LIMITS FOR MEMBERS OF THE PUBLIC

(a) The licensee or registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and measurements and surveys of radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in Rule .1611 of this Section.

(b) A licensee or registrant shall show compliance with the annual dose limit in Rule .1611 of this Section by:

- (1) demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or
 - (2) demonstrating that:
 - (A) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table 2 of Appendix B to 10 CFR §§ 20.1001 - 20.2401; and
 - (B) If an individual were continually present in an unrestricted area, the dose from external sources of radiation would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.
- (c) Upon approval from the agency, the licensee may adjust the effluent concentration values in Appendix B to 10 CFR §§ 20.1001 - 20.2401, Table 2, for members of the public, to take into account the actual physical and chemical characteristics of the effluents (e.g., aerosol size distribution, solubility, density, radioactive decay equilibrium, chemical form).

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

.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 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.*

.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,
 - (b) minors and declared pregnant women likely to receive, in one 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
 - (c) 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; and
 - (b) minors and declared pregnant women likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.05 rem (0.5 mSv).

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

.1615 CONTROL OF ACCESS TO HIGH RADIATION AREAS

(a) The licensee or registrant shall ensure that each entrance or access point to a high radiation area has at least one of the following features:

- (1) a control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep-dose equivalent of 0.1 rem (1 mSv) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates;
- (2) a control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or
- (3) entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

(b) In place of the controls required by Paragraph (a) of this Rule for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(c) Any licensee, registrant or applicant for a license or registration may apply to the agency for approval of alternative methods for controlling access to high radiation areas. The agency will approve alternatives if the licensee, registrant or applicant demonstrates that the alternative methods of control will prevent unauthorized entry into a high radiation area.

(d) The licensee or registrant shall establish the controls required by Paragraphs (a) and (c) of this Rule in a way that does not prevent individuals from leaving a high radiation area.

(e) Control is not required for each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation provided that:

- (1) the packages do not remain in the area longer than three days; and
- (2) the dose rate at one meter from the external surface of any package does not exceed 0.01 rem (0.1 mSv) per hour.

(f) Control of entrance or access to rooms or other areas in hospitals is not required solely because of the presence of patients containing radioactive material, provided that 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.

History Note: Authority G.S. 104E-7(a)(2);

Eff. January 1, 1994.

.1616 CONTROL OF ACCESS TO VERY HIGH RADIATION AREAS

In addition to the requirements in Rule .1615 of this Section, the licensee or registrant shall also institute the additional measures required in Rule .1617 of this Section to ensure that an individual is not able to gain unauthorized or inadvertent access to very high radiation areas.

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

.1617 ACCESS TO VERY HIGH RADIATION AREAS: IRRADIATORS

(a) Each area in which there may exist radiation levels in excess of 500 rads (5 grays) in one hour at one meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

- (1) Each entrance or access point shall be equipped with entry control devices which:
 - (A) function automatically to prevent any individual from inadvertently entering the area when very high radiation levels exist;
 - (B) permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (1 mSv) in one hour; and
 - (C) prevent operation of the source of radiation if the source would produce radiation levels in the area that could result in a deep-dose equivalent to an individual in excess of 0.1 rem (1 mSv) in one hour.
- (2) Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by Subparagraph (a)(1) of this Rule:
 - (A) The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (1 mSv) in one hour; and
 - (B) Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.
- (3) The licensee or registrant shall provide control devices so that, upon failure or removal of physical radiation barriers other than the shielded storage container:
 - (A) The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (1 mSv) in one hour; and
 - (B) Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.
- (4) When the shield for the stored source of radiation is a liquid, the licensee or registrant shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.
- (5) Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of Subparagraphs (a)(3) and (4) of this Rule.
- (6) Each area shall be equipped with a clearly identified control device which can prevent the source of radiation from being put into operation.

- (7) Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in sufficient time for any individual in the area to operate the control device required by Subparagraph (a)(6) of this Rule.
- (8) Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.
- (9) Each area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source in the area is below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (1 mSv) in one hour.
- (10) The entry control devices required in Subparagraph (a)(1) of this Rule shall have been tested for proper functioning. Recordkeeping requirements relating to these tests are provided in Rule .1643 of this Section.
 - (A) Testing shall be conducted prior to initial operation of the source of radiation on any day, unless operations were continued uninterrupted from the previous day;
 - (B) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintended interruption; and
 - (C) The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.
- (11) The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.
- (12) Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for processed materials shall be equipped to detect and signal the presence of any loose radiation sources that are carried toward such an exit and to automatically prevent loose radiation sources from being carried out of the area.

(b) Any licensee, registrant or applicant for a license or registration for sources of radiation that are subject to Paragraph (a) of this Rule and that will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of Paragraph (a) of this Rule, such as those for the automatic control of radiation levels, may apply to the agency for approval of the use of alternative safety measures. Any alternative safety measures shall provide a degree of personnel protection at least equivalent to those specified in Paragraph (a) of this Rule. At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such radiation sources are used.

(c) The entry control devices required by Paragraphs (a) and (b) of this Rule shall be established in such a way that no individual will be prevented from leaving the area.

(d) This Rule applies to radiation from non-self-shielded irradiators. This Rule does not apply to sources of radiation that are used in therapy, in radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual. This Rule also does not apply to sources of radiation from which the radiation is incidental to some other use.

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

.1618 USE OF PROCESS OR OTHER ENGINEERING CONTROLS

The licensee shall use, to the extent practicable, process or other engineering controls (e.g., containment or ventilation) to control the concentrations of radioactive material in air.

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

.1619 USE OF OTHER CONTROLS TO RESTRICT INTERNAL EXPOSURE

When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes of radionuclides by one or more of the following means:

- (1) the control of access to the area;
- (2) the limitation of exposure times of personnel in the area;
- (3) the use of respiratory protection equipment; or
- (4) other controls.

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

.1620 USE OF INDIVIDUAL RESPIRATORY PROTECTION EQUIPMENT

(a) If the licensee uses respiratory protection equipment to limit intakes pursuant to Rule .1619 of this Section the licensee shall:

- (1) use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health/Mine Safety and Health Administration (NIOSH/MSHA);
- (2) if the licensee wishes to use equipment that has not been tested or certified by NIOSH/MSHA, has not had certification extended by NIOSH/MSHA, or for which there is no schedule for testing or certification, submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use;
- (3) implement and maintain a respiratory protection program that includes:
 - (A) air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures;
 - (B) surveys and bioassays, as appropriate, to evaluate actual intakes;
 - (C) testing of respirators for operability immediately prior to each use;
 - (D) written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and record keeping; and
 - (E) determination by a physician prior to initial fitting of respirators, and at least every 12 months thereafter or periodically at a frequency determined by a physician, that the individual user is physically able to use the respiratory protection equipment;
- (4) issue a written policy statement on respirator usage covering:
 - (A) the use of process or other engineering controls, instead of respirators;
 - (B) the routine, non-routine, and emergency use of respirators; and
 - (C) the periods of respirator use and relief from respirator use.
- (5) advise each respirator user that the user may leave the area at any time for relief from

respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief; and

- (6) use equipment within limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.
- (b) In estimating exposure of individuals to airborne radioactive materials, the licensee may make allowance for respiratory protection equipment used to limit intakes pursuant to Rule .1619 of this Section, provided that the following conditions, in addition to those in Paragraph (a) of this Rule, are satisfied:

- (1) The licensee selects respiratory protection equipment that provides a protection factor, as specified in Appendix A to 10 CFR §§ 20.1001 - 20.2401, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B to 10 CFR §§ 20.1001 - 20.2401, Table 1, Column 3. If the selection of a respiratory protection device with a protection factor greater than the peak concentration is inconsistent with the goal specified in Rule .1619 of this Section of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor only if such a selection would result in keeping the total effective dose equivalent ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than estimated, the corrected value shall be used. If the exposure is later found to be less than estimated, the corrected value may be used.
- (2) The licensee shall obtain authorization from the agency before assigning respiratory protection factors in excess of those specified in Appendix A to 10 CFR §§ 20.1001 - 20.2401. The agency may authorize a licensee to use higher protection factors on receipt of an application that:
 - (A) describes the situation for which a need exists for higher protection factors, and
 - (B) demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

(c) The licensee shall use as emergency devices only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by NIOSH/MSHA.

(d) The licensee shall notify the agency, in writing, at least 30 days before the date that respiratory protection equipment is first used under the provisions of either Paragraph (a) or (b) of this Rule.

*History Note: Authority G.S. 104E-7(a)(2); 104E-12(a);
Eff. January 1, 1994;
Amended Eff. August 1, 1998.*

.1621 RESTRICTIONS ON THE USE OF RESPIRATORY PROTECTION EQUIPMENT

The agency may impose restrictions in addition to those in Rules .1619 and .1620 of this Section, and Appendix A to 10 CFR §§ 20.1001 - 20.2401 when the agency determines that such requirements are necessary to:

- (1) ensure that the respiratory protection program of the licensee is adequate to limit exposures of individuals to airborne radioactive materials to the levels prescribed in this Section; and
- (2) limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls when process or other engineering controls are appropriate to limit exposures of individuals to airborne radioactive materials to the levels prescribed in this Section.

History Note: Authority G.S. 104E-7(a)(2); 10 C.F.R. Chapter 1, Commission Notices, Policy

*Statements, Agreement States, 46 F.R. 7540;
Eff. January 1, 1994.*

.1622 SECURITY OF SOURCES OF RADIATION

(a) The licensee or registrant shall secure from unauthorized removal or access sources of radiation that are stored in controlled or unrestricted areas.

(b) The licensee or registrant shall control and maintain constant surveillance of sources of radiation that are in a controlled or unrestricted area and that are not in storage.

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

.1623 CAUTION SIGNS

(a) Unless otherwise authorized by the agency, the symbol prescribed by the rules of this Chapter shall use the colors magenta, or purple, or black on yellow background. The radiation symbol prescribed by the rules of this Chapter is the standard three-bladed design.

(1) The blades and interior circle shall be magenta, purple, or black; and

(2) The background shall be yellow.

(b) Notwithstanding the requirements of Paragraph (a) of this Rule, licensees and registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

(c) In addition to the contents of signs and labels prescribed in the rules of this Chapter, the licensee or registrant may provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

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

.1624 POSTING REQUIREMENTS

(a) The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words:

CAUTION
RADIATION AREA

(b) The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words:

CAUTION
HIGH RADIATION AREA

or the words:

DANGER
HIGH RADIATION AREA

(c) The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words:

GRAVE DANGER
VERY HIGH RADIATION AREA

(d) The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words:

CAUTION
AIRBORNE RADIOACTIVITY AREA

or the words:

DANGER
AIRBORNE RADIOACTIVITY AREA

(e) The licensee shall post each area or room in which there is used or stored an amount of licensed radioactive material exceeding 10 times the quantity of such material specified in Appendix C to 10 CFR §§ 20.1001 - 20.2401 with a conspicuous sign or signs bearing the radiation symbol and the words:

CAUTION
RADIOACTIVE MATERIAL(S)

or the words:

DANGER
RADIOACTIVE MATERIAL(S)

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

.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.

*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. May 1, 1995.

.1626 LABELING REQUIREMENTS AND EXEMPTIONS

(a) The licensee shall ensure that each container of licensed radioactive material bears a durable, clearly visible label bearing the radiation symbol and the words:

CAUTION
RADIOACTIVE MATERIAL

or the words:

DANGER
RADIOACTIVE MATERIAL

The label shall also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(b) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

(c) A licensee is not required to label:

- (1) containers holding licensed radioactive material in quantities less than the quantities listed in Appendix C to 10 CFR §§ 20.1001 - 20.2401;
- (2) containers holding licensed radioactive material in concentrations less than those specified in Table 3 of Appendix B to 10 CFR §§ 20.1001 - 20.2401;
- (3) containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this Section;
- (4) containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation,
- (5) containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record, for example, containers in locations such as water-filled canals, storage vaults, or hot cells, provided the record shall be retained as long as the containers are in use for the purpose indicated on the record; or
- (6) installed manufacturing or process equipment, such as piping and tanks.

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

.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:

- (1) is labeled as containing radioactive material; or

- (2) has evidence of potential contamination, 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.*

.1628 GENERAL REQUIREMENTS FOR WASTE DISPOSAL

- (a) A licensee shall dispose of licensed radioactive material only:
 - (1) by transfer to an authorized recipient as provided in Section .0300 of this Chapter;
 - (2) by decay in storage;
 - (3) by release in effluents within the limits in Rule .1611 of this Section; or
 - (4) as authorized by Rules .1629, .1630, .1631, or .1632 of this Section; or
 - (5) a land disposal facility licensed under Section .1200 of this Chapter or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state.
- (b) Except as provided in Section .1200 of this Chapter, no licensee shall receive radioactive waste from other persons for:
 - (1) treatment prior to disposal;
 - (2) treatment or disposal by incineration;
 - (3) decay in storage; or
 - (4) disposal.

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

.1629 METHOD FOR OBTAINING APPROVAL OF DISPOSAL PROCEDURES

A licensee or applicant for a license may apply to the agency for approval of proposed procedures, not otherwise authorized in this Section, to dispose of licensed radioactive material generated in the licensee's activities. Each application shall include:

- (1) a description of the waste containing licensed radioactive material to be disposed of, including the physical and chemical properties important to risk evaluation, and the proposed manner and conditions of waste disposal;
- (2) an analysis and evaluation of pertinent information on the nature of the environment;
- (3) the nature and location of other potentially affected licensed and unlicensed facilities; and
- (4) analyses and procedures to ensure that doses are maintained ALARA and within the dose limits

in this Section.

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

.1630 DISPOSAL BY RELEASE INTO SANITARY SEWERAGE

(a) A licensee may discharge licensed radioactive material into sanitary sewerage if each of the following conditions is satisfied:

- (1) The material is readily soluble in water or is biological material that is readily dispersible in water; and
- (2) The quantity of licensed or other radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table 3 of Appendix B to 10 CFR §§ 20.1001 - 20.2401; and
- (3) If more than one radionuclide is released, the following conditions shall also be satisfied:
 - (A) The licensee shall determine the fraction of the limit in Table 3 of Appendix B to 10 CFR §§ 20.1001 - 20.2401 represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table 3 of Appendix B to 10 CFR §§20.1001 - 20.2401; and
 - (B) The sum of the fractions for each radionuclide required by Part (a)(3)(A) of this Rule does not exceed unity; and
- (4) The total quantity of licensed and other radioactive material that the licensee releases into the sanitary sewerage system in a year does not exceed five curies (185 GBq) of hydrogen-3, one curie (37 GBq) of carbon-14, and one curie (37 GBq) of all other radioactive materials combined.

(b) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material is not subject to the limitations contained in Paragraph (a) of this Rule.

*History Note: Authority G.S. 104E-7(a)(2); 104E-7(a)(5);
Eff. January 1, 1994.*

.1631 TREATMENT OR DISPOSAL BY INCINERATION

A licensee may treat or dispose of licensed radioactive material by incineration only in the amounts and forms specified in Rule .1632 or as specifically approved by the agency pursuant to Rule .1629 of this Section.

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

.1632 DISPOSAL OF SPECIFIC WASTES

(a) A licensee may dispose of the following licensed radioactive material without regard to its radioactivity:

- (1) 0.05 microcurie (1.85 kBq), or less, of hydrogen-3, carbon-14 or iodine-125 per gram of medium used for liquid scintillation counting; and
- (2) 0.05 microcurie (1.85 kBq), or less, of hydrogen-3, carbon-14 or iodine-125 per gram of animal tissue, averaged over the weight of the entire animal.

(b) A licensee may not dispose of tissue pursuant to Subparagraph (a)(2) of this Rule in a manner that would permit its use either as food for humans or as animal feed.

(c) The licensee shall maintain records of disposals made pursuant to Subparagraph (a)(2) of this Rule

in accordance with Rule .1642 of this Section.

*History Note: Authority G.S. 104E-7(a)(2); 104E-7(a)(5); 104E-12(a);
Eff. January 1, 1994.*

.1633 TRANSFER FOR DISPOSAL AND MANIFESTS

(a) The requirements of this Rule and Appendix G to 10 CFR 20, incorporated by reference in Rule .0117 of this Chapter, are designed to:

- (1) control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in Appendix G to 10 CFR 20, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste disposal facility, as defined in Rule .1202 of this Chapter;
- (2) establish a manifest tracking system; and
- (3) supplement existing requirements concerning transfers and recordkeeping for those wastes.

(b) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility shall document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with this Rule and Appendix G to 10 CFR 20.

(c) Each shipment manifest shall include a certification by the waste generator as specified in Appendix G to 10 CFR 20.

(d) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in this Rule and Appendix G to 10 CFR 20.

(e) Reports and notifications required to be made to the nearest regional administrator by Appendix G to 10 CFR 20 shall, instead, be made to the agency.

*History Note: Authority G.S. 104E-7(a)(2),(a)(3); 104E-12(a);
Eff. January 1, 1994;
Amended Eff. April 1, 1999.*

.1634 COMPLIANCE WITH ENV. AND HEALTH PROTECTION REGULATIONS

Nothing in this Section relieves the licensee from complying with other applicable federal, state, and local regulations governing any other toxic or hazardous properties of materials that may be disposed of under this Section.

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

.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.

(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. April 1, 1999.*

.1636 RECORDS OF RADIATION PROTECTION PROGRAMS

- (a) Each licensee or registrant shall maintain records of the radiation protection program, including:
 - (1) The provisions of the program; and
 - (2) Audits and other reviews of program content and implementation.
- (b) The licensee or registrant shall retain the records required by Subparagraph (a)(1) of this Rule until the agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by Subparagraph (a)(2) of this Rule for three years after the record is made.

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

.1637 RECORDS OF SURVEYS

- (a) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by Rules .1613 and .1627(b) of this Section. The licensee or registrant shall retain these records for three years after the record is made.
- (b) The licensee or registrant shall retain each of the following records until the agency terminates each pertinent license or registration requiring the record:
 - (1) records of the results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents;
 - (2) records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;
 - (3) records showing the results of air sampling, surveys, and bioassays required pursuant to Rule .1620(a) of this Section; and
 - (4) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

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

.1638 DETERMINATION OF PRIOR OCCUPATIONAL DOSE

- (a) For each individual who may enter the licensee's or registrant's restricted or controlled area and is likely to receive, in a year, an occupational dose requiring monitoring pursuant to Rule .1614 of this Section, the licensee or registrant shall:
 - (1) determine the occupational radiation dose received during the current year; and
 - (2) attempt to obtain the records of lifetime cumulative occupational radiation dose.
- (b) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:
 - (1) the internal and external doses from all previous planned special exposures; and
 - (2) all doses in excess of the limits received during the lifetime of the individual, including doses received during accidents and emergencies.
- (c) In complying with the requirements of Paragraph (a) of this Rule, a licensee or registrant may:
 - (1) accept, as a record of the occupational dose that the individual received during the current

year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual may have received during the current year;

- (2) accept, as the record of lifetime cumulative radiation dose, an up-to-date agency form for recording occupational radiation dose history, or equivalent, signed by the individual and counter-signed by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer if the individual is not employed by the licensee or registrant; or
- (3) obtain reports of the individual's dose equivalent(s) by telephone, telegram, electronic media, or letter from the most recent employer for work involving radiation exposure, or the individual's current employer if the individual is not employed by the licensee or registrant. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(d) The licensee or registrant shall record the exposure history, as required by Paragraph (a) of this Rule, on the agency form for recording occupational radiation dose history, or other clear and legible record of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing the agency form for recording occupational radiation dose history. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on the agency form for recording occupational radiation dose history indicating the periods of time for which data are not available. Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed prior to January 1, 1994 under Section .0400 of this Chapter. Further, occupational exposure histories obtained and recorded before January 1, 1991, may not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

(e) If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

- (1) in establishing administrative controls under Rule .1604(f) of this Section for the current year, that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and
- (2) that the individual is not available for planned special exposures.

(f) The licensee or registrant shall retain the records on the agency form for recording occupational radiation dose history or equivalent until the agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing the agency form for recording occupational radiation dose history for three years after the record is made.

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

.1639 RECORDS OF PLANNED EXPOSURES

(a) For each use of the provisions of Rule .1608 of this Section for planned special exposures, the licensee or registrant shall maintain records that describe:

- (1) the exceptional circumstances requiring the use of a planned special exposure;
- (2) the name of the management official who authorized the planned special exposure and a copy of the signed authorization;
- (3) what actions were necessary;
- (4) why the actions were necessary;

- (5) how doses were maintained ALARA; and
 - (6) what individual and collective doses were expected to result, and the doses actually received in the planned special exposure.
- (b) The licensee or registrant shall retain the records until the agency terminates each pertinent license or registration requiring these records.

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

.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;
- (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.*

.1641 RECORDS OF DOSE TO INDIVIDUAL MEMBERS OF THE PUBLIC

(a) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public required by Rule .1611 of this Section. These records may include such things as survey results, monitoring results, calculations and other documents pertaining to the determination of doses to individual members of the public.

(b) The licensee or registrant shall retain the records required by Paragraph (a) of this Rule 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.*

.1642 RECORDS OF WASTE DISPOSAL

(a) Each licensee shall maintain records of the disposal of licensed radioactive materials made pursuant to Rules .1629, .1630, .1631, .1632 and .1633 of this Section, and disposal by burial in soil.

(b) The licensee shall retain the records required by Paragraph (a) of this Rule until the agency terminates each pertinent license requiring the record.

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

.1643 RECORDS OF TESTING ENTRY CONTROL DEVICES

(a) Each licensee or registrant shall maintain records of tests made pursuant to Subparagraph (a)(10) of Rule .1617 of this Section on entry control devices for very high radiation areas. These records shall include the date, time, and results of each such test of function.

(b) The licensee or registrant shall retain the records required by Paragraph (a) of this Rule for three years after the record is made.

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

.1644 FORM OF RECORDS

Each record required by this Section shall be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

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

.1645 REPORTS OF THEFT OR LOSS OF LICENSED RADIOACTIVE MATERIAL

(a) Each licensee shall report by telephone as follows:

- (1) immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C to 10 CFR §§ 20.1001 - 20.2401 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas; or
- (2) within 30 days after the occurrence of any lost, stolen, or missing licensed radioactive material becomes known to the licensee, all licensed radioactive material in a quantity greater than 10 times the quantity specified in Appendix C to 10 CFR §§ 20.1001 - 20.2401 that is still missing at this time.

(b) Telephone reports in Paragraph (a) of this Rule shall be made to the agency as specified in Rule .0111 of this Chapter.

(c) Each licensee required to make a report under Paragraph (a) of this Rule shall, within 30 days after making the telephone report, make a written report setting forth the following information:

- (1) a description of the licensed radioactive material involved, including kind, quantity, and chemical and physical form;
 - (2) a description of the circumstances under which the loss or theft occurred;
 - (3) a statement of disposition, or probable disposition, of the licensed radioactive material involved;
 - (4) exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;
 - (5) actions that have been taken, or will be taken, to recover the material; and
 - (6) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed radioactive material.
- (d) Written reports shall be addressed to the agency as specified in Rule .0111 of this Chapter.
- (e) Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.
- (f) The licensee shall prepare any report filed with the agency pursuant to this Rule so that names of individuals who may have received exposure to radiation are stated in a separate and detachable part of the report.

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

.1646 NOTIFICATION OF INCIDENTS

- (a) Notwithstanding any other requirements for notification, each licensee or registrant shall immediately report any event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:
- (1) an individual to receive:
 - (A) a total effective dose equivalent of 25 rems (0.25 Sv) or more; or
 - (B) an eye dose equivalent of 75 rems (0.75 Sv) or more; or
 - (C) a shallow-dose equivalent to the skin or extremities of 250 rads (2.5 Gy) or more; or
 - (2) the release of radioactive material, inside or outside of a restricted area, except locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational annual limit on intake; or
 - (3) a loss of one working week or more of the operation of any facilities affected; or
 - (4) damage to property in excess of \$200,000.
- (b) Each licensee or registrant shall, within 24 hours of discovery of the event, report any event involving loss of control of any source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:
- (1) an individual to receive, in a period of 24 hours:
 - (A) a total effective dose equivalent exceeding five rems (0.05 Sv);
 - (B) an eye dose equivalent exceeding 15 rems (0.15 Sv); or
 - (C) a shallow-dose equivalent to the skin or extremities exceeding 50 rems (0.5 Sv);
 - (2) the release of radioactive material, inside or outside of a restricted area, except locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational annual limit on intake;
 - (3) a loss of one day or more of the operation of any facilities affected; or
 - (4) damage to property in excess of \$2,000.
- (c) The licensee or registrant shall prepare any report filed with the agency pursuant to this Rule so that names of individuals who have received exposure to radiation or radioactive material are stated in a separate and detachable part of the report.
- (d) Reports made by licensees or registrants in response to the requirements of this Rule shall be

addressed to the agency as specified in Rule .0111 of this Chapter.

(e) The provisions of this Rule do not include doses that result from planned special exposures, that are within the limits for planned special exposures, and that are reported pursuant to Rule .1648 of this Section.

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

.1647 REPORTS OF RADIATION EXCEEDING THE LIMITS

(a) In addition to the notification required by Rule .1646 of this Section, each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

- (1) any incident for which notification is required by Rule .1646 of this Section;
- (2) doses in excess of any of the following:
 - (A) the occupational dose limits for adults in Rule .1604 of this Section;
 - (B) the occupational dose limits for a minor in Rule .1609 of this Section;
 - (C) the limits for an embryo/fetus of a declared pregnant woman in Rule .1610 of this Section;
 - (D) the limits for an individual member of the public in Rule .1611 of this Section;
 - (E) any applicable limit in the license; or
 - (F) The ALARA constraints for air emissions established in Rule .1603 of this Section;
- (3) levels of radiation or concentrations of radioactive material in:
 - (A) a restricted area in excess of any applicable limit in the license; or
 - (B) an unrestricted area in excess of 10 times any applicable limit set forth in this Section or in the license, whether or not involving exposure of any individual in excess of the limits in Rule .1611 of this Section.

(b) Each report required by Paragraph (a) of this Rule shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

- (1) estimates of each individual's dose;
- (2) the levels of radiation and concentrations of radioactive material involved;
- (3) the cause of the elevated exposures, dose rates, or concentrations; and
- (4) corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions.

(c) Each report filed pursuant to Paragraph (a) of this Rule shall include for each occupationally overexposed individual: the name, social security account number, and date of birth. With respect to the limit for the embryo/fetus required by Rule .1610 of this Section, the identifying information shall be that of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable part of the report.

(d) Reports made by licensees or registrants in response to the requirements of this Rule shall be addressed to the agency as specified in Rule .0111 of this Chapter.

(e) Any reports made by licensees or registrants in response to the requirements of this Rule shall also be provided to the exposed individual. The copy submitted to the exposed individual shall be transmitted at a time no later than the transmittal to the agency.

*History Note: Authority G.S. 104E-7(a)(2); 104E-12(a);
Eff. January 1, 1994;
Amended Eff. April 1, 1999; August 1, 1998.*

.1648 REPORTS OF PLANNED SPECIAL EXPOSURES

The licensee or registrant shall submit a written report to the agency within 30 days following any planned special exposure conducted in accordance with Rule .1608 of this Section, informing the agency

that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by Rule .1639 of this Section.

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

.1649 REPORTS OF INDIVIDUAL MONITORING

The agency may require by license condition, registration condition, or order pursuant to Rule .0108 of this Chapter, annual reports of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by Rule .1614 of this Section.

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

.1650 CLASSIFICATION/RADIOACTIVE WASTE FOR NEAR-SURFACE DISPOSAL

(a) The following are definitions of and special requirements applicable to the different classes of waste:

- (1) "Class A Waste" means radioactive waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste shall meet the minimum requirements set forth in Rule .1651(a) of this Section. If Class A waste also meets the stability requirements set forth in Rule .1651(b) of this Section, it is not necessary to segregate the waste for disposal.
- (2) "Class B Waste" means radioactive waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste shall meet both the minimum requirements and stability requirements set forth in Rule .1651 of this Section.
- (3) "Class C Waste" means radioactive waste that not only must meet more rigorous requirements on waste form to ensure stability, but also requires additional measures at the disposal facility to protect against inadvertent human intrusion. The physical form and characteristics of Class C waste shall meet both the minimum requirements and stability requirements set forth in Rule .1651 of this Section.

(b) If the waste contains only radionuclides listed in the table in Subparagraph (b)(5) of this Rule, the licensee shall determine the classification as follows:

- (1) If the concentration does not exceed 0.1 times the value in the table in Subparagraph (b)(5) of this Rule, the waste is Class A waste.
- (2) If the concentration exceeds 0.1 times the value in the table in Subparagraph (b)(5) of this Rule, the waste is Class C waste.
- (3) If the concentration exceeds the value in the table in Subparagraph (b)(5) of this Rule, the waste is not generally acceptable for near-surface disposal.
- (4) For wastes containing mixtures of radionuclides listed in the table in Subparagraph (b)(5) of this Rule, the licensee shall determine the concentration by the "sum of fractions rule" described in Paragraph (f) of this Rule.
- (5) The following is the table of long-lived radionuclides and concentrations for use in conjunction with waste classification rules of this Section:

Radionuclide	Concentration	
carbon 14	8	curies/cubic meter
carbon 14 in activated metal	80	curies/cubic meter
nickel 59 in activated metal	220	curies/cubic meter

niobium 94 in activated metal	0.2	curies/cubic meter
technetium 99	3	curies/cubic meter
iodine 129	0.08	curies/cubic meter
radium, and alpha emitting transuranic radionuclides with half-lives greater than five years	100	nanocuries/gram
plutonium 241	3,500	nanocuries/gram
curium 242	20,000	nanocuries/gram

(c) If the waste does not contain any of the radionuclides listed in the table in Subparagraph (b)(5) of this Rule, the licensee shall use the data for short-lived radionuclides and concentrations in the table in Subparagraph (c)(7) of this Rule to determine the classification as follows:

- (1) If the concentration does not exceed the value in column 1, the waste is Class A waste.
- (2) If the concentration exceeds the value in column 1, but does not exceed the value in column 2, the waste is Class B waste.
- (3) If the concentration exceeds the value in column 2, but does not exceed the value in column 3, the waste is Class C waste.
- (4) If the concentration exceeds the value in column 3, the waste is not generally acceptable for near-surface disposal.
- (5) For wastes containing mixtures of the radionuclides listed in the table in Subparagraph (c)(7) of this Rule, the total concentration shall be determined by the "sum of the fractions rule" described in Paragraph (f) of this Rule.
- (6) In determining the waste classifications in Subparagraphs (c)(1) through (5) of this Rule, the licensee may disregard any radionuclides not listed in the tables in Subparagraphs (b)(5) and (c)(7) of this Rule.
- (7) The following is the table of short-lived radionuclides for use in conjunction with the waste classification rules of this Section:

radionuclide	concentration in curies/cubic meter		
	column 1	column 2	column 3
total of all radionuclides with less than 5-year half-life	700	see (c)(8)	see (c)(8)
hydrogen 3	40	see (c)(8)	see (c)(8)
cobalt 60	700	see (c)(8)	see (c)(8)
nickel 63	3.5	70	700
nickel 63 in activated metal	35	700	7000
strontium 90	0.04	150	7000
cesium 137	1	44	4600

- (8) There are no limits established for the radionuclides noted by "see (c)(8)" in the table in Subparagraph (c)(7) of this Rule for Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation or transportation, handling, and disposal will limit the concentrations for these wastes. The licensee shall classify these wastes as Class B, unless the concentrations of other radionuclides in the table in Subparagraph (c)(7) of this Rule dictate classification as Class C waste independent of these radionuclides.
- (d) If waste contains a mixture of radionuclides, some of which are listed in the table in Subparagraph (b)(5) of this Rule and some of which are listed in the table in Subparagraph (c)(7) of this Rule, the

licensee shall determine the classification and suitability for near-surface disposal as follows:

- (1) In accordance with Paragraph (b) of this Rule, determine the class and suitability for near-surface disposal for only the radionuclides in the mixture which are listed in the table in Subparagraph (b)(5) of this Rule;
 - (2) In accordance with Paragraph (c) of this Rule, determine the class and suitability for near-surface disposal for only the radionuclides in the mixture which are listed in the table in Subparagraph (c)(7) of this Rule; and
 - (3) Classify the waste as the more restrictive of the two determinations in Subparagraphs (d)(1) and (d)(2) of this Rule where "not generally suitable for near-surface disposal" is the most restrictive and "Class A" is the least restrictive.
- (e) If waste contains none of the radionuclides listed in the tables in Subparagraphs (b)(5) and (c)(7) of this Rule, the licensee shall determine the waste to be Class A waste.
- (f) When required in Paragraphs (b) and (c) of this Rule, the licensee shall use the "sum of the fractions rule" described in Subparagraph (f)(1) of this Rule.
- (1) For determining the classification for waste that contains a mixture of radionuclides, the licensee shall determine the sum of the fractions by dividing the concentration of each radionuclide by the appropriate limit, where the appropriate limits shall all be taken from the same column of the same table, and by adding the resultant values. The sum of the fractions for the column must be less than 1.0, if the waste class is to be determined by that column.
 - (2) The following is an example calculation:
 - (A) A waste contains strontium-90 with a concentration of 50 curies per cubic meter and cesium-137 with a concentration of 22 curies per cubic meter.
 - (B) Since the concentrations of both exceed the values in column 1 of the table in Subparagraph (c)(7) of this Rule, they must be compared with the values in column 2.
 - (C) The strontium-90 fraction is $50/150$ or 0.33, the cesium-137 fraction is $22/44$ or 0.5, and the sum of the fractions is 0.83; therefore, since the sum is less than 1.0, the waste is Class B waste.
- (g) Provided that there is reasonable assurance that an indirect method can be correlated with actual measurements, the licensee may determine radionuclide concentrations by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured or use of radioactive material accountability records. The licensee may average a radionuclide concentration over the volume of the waste or over the weight of the waste in the case of radionuclides with nanocurie per gram limits specified in the table in Subparagraph (b)(5) of this Rule.

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

.1651 RADIOACTIVE WASTE CHARACTERISTICS

- (a) The following are minimum requirements for all classes of radioactive waste and are intended to facilitate handling and to provide protection of health and safety of personnel at the radioactive waste disposal site. The licensee shall:
- (1) package wastes in conformance with the conditions of the license issued to the site operator to which the waste will be shipped to the extent that such conditions are more restrictive or in addition to the requirements contained in this Rule;
 - (2) not package wastes for disposal in cardboard or fiberboard boxes;
 - (3) package liquid waste in sufficient absorbent material to absorb twice the volume of the liquid;
 - (4) limit the volume of freestanding liquid in solid wastes containing liquid to as little freestanding and non-corrosive liquid as is reasonably achievable, but in no case to more than one percent of the volume;
 - (5) limit wastes to those which are not readily capable of detonation or of explosive decomposition

- or reaction at normal pressures and temperatures, or of explosive reaction with water;
- (6) except for radioactive gaseous waste packaged in accordance with Subparagraph (a)(8) of this Rule, limit wastes to those which do not contain, or are not capable of generating quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste;
- (7) treat, prepare and package pyrophoric materials contained in waste in a manner to render them nonflammable;
- (8) package wastes in a gaseous form at an absolute pressure that does not exceed 1.5 atmospheres at 20 degrees C and limit the total activity to no more than 100 curies per container; and
- (9) treat wastes containing hazardous, biological, pathogenic, or infectious material to reduce the potential hazard from the non-radiological material to the maximum extent practicable.

(b) Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste. The licensee shall comply with the following requirements, which are intended to provide stability of waste, when the waste is either Class B or Class C waste.

- (1) The licensee shall ensure that the waste has structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.
- (2) Notwithstanding the provisions in Subparagraphs (a)(3) and (4) of this Rule, the licensee shall convert liquid wastes or wastes containing liquids into a form that contains as little freestanding and noncorrosive liquid as is reasonably achievable; but in no case more than one percent of the volume of the waste when the waste is in a disposable container designed to ensure stability; or 0.5 percent of the volume of the waste for waste processed to a stable form.
- (3) The licensee shall reduce void spaces within the waste and between the wastes and its package to the extent practicable.

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

.1652 LABELING

The licensee shall clearly label each package of waste to identify the waste as Class A, Class B or Class C waste as determined in accordance with the provisions of Rule .1650 of this Section.

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

.1653 RADIOLOGICAL REQUIREMENTS FOR LICENSE TERMINATION

(a) General provisions and scope:

- (1) The requirements in this Rule apply to the decommissioning of facilities licensed under the rules of this Chapter. For low-level radioactive waste disposal facilities licensed under Section .1200 of this Chapter, the requirements apply only to ancillary surface facilities that support radioactive waste disposal facilities.
- (2) The requirements in this Rule do not apply to sites which:
 - (A) have been decommissioned prior to the effective date of this Rule in accordance with

- criteria approved by the agency; or
- (B) have previously submitted and received agency approval for a license termination plan or for a decommissioning plan.
- (3) After a site has been decommissioned and the license terminated in accordance with the requirements set forth in this Rule, the agency may require additional cleanup only if, based on new information, the agency determines that the requirements of this Rule were not met and residual radioactivity remaining at the site could result in a significant threat to the public health and safety.
- (4) When calculating Total Effective Dose Equivalent (TEDE) to the average member of the critical group, the licensee shall determine the peak annual TEDE expected within the first 1,000 years after decommissioning.
- (b) Radiological criteria for unrestricted use of a site shall be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radioactivity results in a TEDE to an average member of the critical group that does not exceed 25 millirem (0.25 millisievert) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels, which are ALARA, may take into account consideration of detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.
- (c) A site shall be considered acceptable for license termination under restricted conditions if:
- (1) the licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of Paragraph (b) of this Rule would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA may take into account consideration of detriments, such as traffic accidents, expected to result from decontamination and waste disposal;
- (2) the licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background radioactivity, to the average member of the critical group, will not exceed 25 millirem (0.25 millisievert) per year;
- (3) the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms to meet the requirements of Subparagraph (c)(3) of this Rule are described in Rule .0354 of this Chapter.
- (4) the licensee has submitted to the agency a decommissioning plan or license termination plan, as described in Rule .0339 of this Chapter, indicating the licensee's intent to decommission in accordance with the requirements of this Chapter, and specifying that the licensee intends to decommission by restricting use of the site;
- (5) the licensee has documented in the license termination plan or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice:
- (A) licensees proposing to decommission by restricting use of the site shall have sought advice from such affected parties regarding the following matters concerning the proposed decommissioning:
- (i) whether provisions for institutional controls proposed by the licensee will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background radioactivity to the average member of the critical group will not exceed 25 millirem (0.25 millisievert) TEDE per year, will be enforceable and will not impose undue burdens on the community or other affected parties; and

- (ii) whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.
 - (B) the licensee has provided for:
 - (i) participation by representatives of a broad cross-section of community interests who may be affected by the decommissioning;
 - (ii) an opportunity for a comprehensive, collective discussion of the issues by the participants represented; and
 - (iii) a publicly available summary of the results of all such discussions, and the extent of agreement and disagreement among the participants on the issues.
- (6) residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background radioactivity to the average member of the critical group is as low as reasonably achievable and would not exceed either:
 - (A) 100 millirem (1 millisievert) per year; or
 - (B) 500 millirem (5 millisievert) per year provided the licensee:
 - (i) demonstrates that further reductions in residual radioactivity necessary to comply with the 100 millirem per year (1 millisievert per year) value described in Part (c)(6)(A) of this Rule, are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;
 - (ii) makes provisions for durable institutional controls; or
 - (iii) provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every five years to assure that the institutional controls remain in place as necessary to meet the requirements of Subparagraph (c)(2) of this Rule and to assume and carry out responsibilities for any necessary control and maintenance of those controls.
- (d) Alternate criteria for license termination:
 - (1) The agency may terminate a license using alternate criteria greater than the dose requirements of Paragraph (b), Subparagraph (c)(2), and Subpart (c)(5)(A)(i) of this Rule, if the licensee:
 - (A) provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than 100 millirem TEDE per year (1 millisievert per year) limit described in Rule .1611 of this Section, by submitting an analysis of possible sources of exposure;
 - (B) has employed, to the extent practical, restrictions on site use according to the provisions of Paragraph (c) of this Rule in minimizing exposures at the site;
 - (C) reduces doses to ALARA levels, taking into consideration detriments such as traffic accidents expected to potentially result from decontamination and waste disposal;
 - (D) has submitted a decommissioning plan or license termination plan to the agency indicating the licensee's intent to decommission in accordance with the requirements of this Chapter, and specifying that the licensee proposes to decommission by use of alternate criteria;
 - (E) has documented in the decommissioning plan or license termination plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed; and
 - (F) in seeking such advice, the licensee has provided for:
 - (i) participation by representatives of a broad-cross section of community interests who may be affected by the decommissioning;
 - (ii) an opportunity for a comprehensive, collective discussion of the issues by the participants represented; and

- (iii) a publicly available summary of the results of such discussions, including a description of the extent of agreement and disagreement among the participants on the issues.
- (2) The use of alternate criteria to terminate a license requires the consideration of any comments provided by any other interested state agencies and any public comments submitted pursuant to Paragraph (e) of this Rule.
- (e) Upon the receipt of a license termination plan or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to Paragraphs (c) and (d) of this Rule, or whenever the agency deems such notice to be in the public interest, the agency shall notify and solicit comments from:
 - (1) local governments in the vicinity of the site, appropriate state agencies, the U.S. Environmental Protection Agency, and any Indian Nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and
 - (2) publish a notice in a forum, such as local newspapers, letters to state or local organizations or other appropriate forum that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

*History Note: Authority G.S. 104E-7(a)(2); 104E-10(b);
Effective April 1, 1999.*