TITLE 180 CONTROL OF RADIATION

CHAPTER 3 LICENSING OF RADIOACTIVE MATERIAL

3-001 Scope and Authority....1
3-002 Definitions....1

EXEMPTIONS

3-003 Source Material....2
3-004 Radioactive Material Other Than Source Material....4
Licenses....10
3-005 Types of Licenses....10
3-006 Radioactive Drug: Capsules Containing Carbon-14 Urea for 'In-Vivo' Diagnostic Use for Humans.... 10

GENERAL LICENSES

3-007 General Licenses – Source Material....11
3-008 General Licenses – Radioactive Material Other Than Source Material....13
3-009 Reserved....27

SPECIFIC LICENSES

3-010 Filing Application for Specific Licenses....27
3-011 General Requirements for the Issuance of Specific Licenses....31
3-012 Reserved....33
3-013 Special Requirements for Specific Licenses of Broad Scope....33
3-014 Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices which Contain Radioactive Material....36
3-015 Special Requirements for Issuance of Specific Licenses for Source Material Milling 56
3-016 Issuance of Specific Licenses....58
3-017 Specific Terms and Conditions of License....59
3-018 Financial Assurance and Recordkeeping for Decommissioning....60
3-019 Expiration and Termination of Licenses and Decommissioning of Sites and Separate
Building or Outdoor Areas....65
3-020 Renewal of Licenses....69
3-021 Amendment of Licenses at Request of Licensee....70
3-022 Department Action on Applications to Renew and Amend....70
3-023 Reserved....70
3-024 Reserved....70
3-025 Transfer of Material....70
3-026 Reporting Requirements....71
3-027 Modification and Revocation of Licenses....73
3-028 Reciprocal Recognition of Licenses....74
3-029 Reserved....76

3-030 Records 76

APPENDICES

Appendix 3-A Exempt Concentrations 79
Appendix 3-B Exempt Quantities 85
Appendix 3-C Limits for Broad Licenses 180 NAC 3-013 91
Radioactive Material Col. I curies Col. II curies 91
Appendix 3-D Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning 96
Appendix 3-E Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release 98
Appendix 3-F Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning 101

FORMS

Form NRH 5 Application for Radioactive Material License
Form NRH-11 Certificate – Use of Depleted Uranium Under General License
Form NRH-17 Certificate – In Vitro Testing With Radioactive Material General License
Form NRH-60 Certificate of Disposition of Materials
Form NRH 653, A & B Transfers of Industrial Devices Report

ATTACHMENT

Attachment 3 – 11 U.S. C. 101(2) and (15)

Copies of the Code of Federal Regulations (CFR) cited in this Chapter are located at:
http://www.gpoaccess.gov/cfr/index.html

`

TITLE 180 CONTROL OF RADIATION

CHAPTER 3 LICENSING OF RADIOACTIVE MATERIAL

3-001 SCOPE AND AUTHORITY

3-001.01 180 NAC 3 provides for the licensing of radioactive material. No person will manufacture, produce, receive, possess, use, transfer, own, dispose or acquire radioactive material except as authorized in a specific or general license issued pursuant to 180 NAC 3 or as otherwise provided in 180 NAC 3, 5, 7, 9, 12, 13 or 19. The regulations are authorized by and implement the Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 71-3520.

3-001.02 In addition to the requirements of 180 NAC 3, all licensees are subject to the requirements of 180 NAC 1, 4, 10, 13, 15, 17, and 18. Licensees engaged in industrial radiographic operations are subject to the requirements of 180 NAC 5, licensees using sealed and unsealed sources in the healing arts are subject to the requirements of 180 NAC 7, licensees engaged in the management of radioactive waste are subject to the requirements of 180 NAC 12, licensees engaged in well logging and subsurface tracer studies are subject to the requirements of 180 NAC 14, and licensees using sealed sources containing radioactive materials in irradiators are subject to the requirements of 180 NAC 19.

3-001.03 10 Code of Federal Regulations (CFR), as published on January 1, 2005 and referred throughout this Chapter are herein incorporated by reference and available for viewing at the Nebraska Department of Health and Human Services,~~,~~ Radiological Health, 301 Centennial Mall South, 3rd Floor, Lincoln, Nebraska 68509.

3-002 DEFINITIONS: As used in 180 NAC 3.

Alert means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

Consortium means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.

Site-area emergency means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

Principal activities means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no license material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

Site area emergency means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

Technologically Enhanced Naturally Occurring Radioactive Material (TENORM) means naturally occurring radioactive material whose radionuclide concentration are increased by or as a result of past or present human practices. TENORM does not include background radiation or the natural radioactivity of rocks or soils.

EXEMPTIONS

3-003 SOURCE MATERIAL

3-003.01 Any person is exempt from 180 NAC 3 to the extent that the person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 % (0.05 %) of the mixture, compound, solution, or alloy.

3-003.02 Any person is exempt from 180 NAC 3 to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, the person must not refine or process such ore.

3-003.03 Any person is exempt from 180 NAC 3 to the extent that the 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 2 grams of thorium,
   f. rare earth metals and compounds, mixtures, and products containing not than 0.25% by weight thorium, uranium, or any combination of these, or

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% by weight source material,
b. glassware, containing not more than 10% by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass, or ceramic used in construction,
c. glass enamel or glass enamel frit containing not more than 10% 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,[1] or
d. piezoelectric ceramic containing not more than 2% by weight source material;

3. Photographic film, negatives, and prints containing uranium or thorium;

4. Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4% by weight and that the exemption contained in this subpart does not authorize the chemical, physical, or metallurgical treatment or processing of any such 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 such counterweights, provided that:

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: "DEPLETED URANIUM",[2]
c. each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED",[3] and

[1]On July 25, 1983, the exemption of glass enamel or glass enamel frit was suspended. The exemption was eliminated on September 11, 1984.

[2]The requirements specified in 180 NAC 3-003.03, items 5.b. and 5.c. need not be met by counter weights manufactured prior to December 31, 1969; provided, that such counter weights are impressed with the legend, "CAUTION, RADIOACTIVE MATERIAL - URANIUM", as previously required by Title 180.

[3]Ibid. p. 3

d. the exemption contained in this division does not authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering;

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 of minimum wall thickness of one-eighth inch (3.2mm).

7. Thorium contained in finished optical lenses, provided that each lens does not contain more than 30% by weight of thorium, and that the exemption does not authorize either:

   a. the shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such 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 eyepieces 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 185 Bq (0.005 microcurie) of uranium; or

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), and
   b. the thorium content in the nickel-thoria alloy does not exceed 4% by weight.

3-003.04 The exemptions in 180 NAC 3-003.03 do not authorize the manufacture of any of the products described.

3-004 RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL

3-004.01 Exempt Concentrations.

1. Except as provided in 3-004.01, item ~~2 and 3~~ 3 and 4, any person is exempt from ~~this~~ 180 NAC 3 to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in 180 NAC 3, Appendix 3-A.

2. 180 NAC 3-004.01 must not be deemed to authorize the import of radioactive material or products containing radioactive material.
3. A manufacturer, processor, or producer of a product or material~~ in an Agreement State~~ is exempt from the requirements for a license in 180 NAC 3-004, 3-005, 3-006, 3-008, 3-013, 3-014, 3-016 through 3-024, 180 NAC 5, 7, 14 and 19 to the extent that they transfer~~s~~ radioactive material contained in a product or material in concentrations not in excess of those specified in 180 NAC 3, Appendix 3-~~1~~A and introduced into the product or material by a licensee holding a specific license issued by the ~~Department, an Agreement State, or the~~ U.S. Nuclear Regulatory Commission expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.
4. No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 180 NAC 3-004.01, item 1 or equivalent regulations of the U.S. Nuclear Regulatory Commission, or any Agreement State, except in accordance with a specific license issued pursuant to~~ 180 NAC 3-014.01~~ 10 CFR 32.11.~~ or the general license provided in 180 NAC 3-028~~.

3-004.02 Exempt Quantities.

1. Except as provided in 180 NAC 3-004.02 , items ~~2 and 3.~~ 3 through 5, any person is exempt from Title 180 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 180 NAC 3, Appendix 3-B.
2. Any person who possesses radioactive material received or acquired, prior to September 25, 1971, in accordance with the general license provided in 180 NAC 3-008 or similar general license of the U.S. Nuclear Regulatory Commission or another Agreement State is exempt from the requirements for a license set forth in Title 180 if that person possesses, uses, or transfers such radioactive material.
~~2.~~3. 180 NAC 3-004.02 does not authorize the production, packaging, repackaging, or transfer of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.
~~3~~4. No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in 180 NAC 3, Appendix 3-B knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under 180 NAC 3-004.02 or equivalent regulations of the U.S. Nuclear Regulatory Commission, or any Agreement State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.18 ~~or by the Department pursuant to 180 NAC 3-014.02~~ which license states that the radioactive material may be transferred by the licensee to persons exempt

under 180 NAC 3-004.02 or the equivalent regulations of the U.S. Nuclear Regulatory Commission, or any Agreement State.

5. No person may, for purposes of producing an increase radiation level combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in 180 NAC 3, Appendix 3B, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulation in 180 NAC 3.

3-004.03 Exempt Items.

1. Certain Items Containing Radioactive Material.

a. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, or persons who initially transfer for sale or for distribution the following products containing radioactive material any person is exempt from Title 180 to the extent that s/he receives, possesses, uses, transfers, owns, or acquires the following products:

~~a.~~(1) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rate:

(~~1~~a) 925 MBq (25 millicuries) of tritium per timepiece.
(b~~2~~) 185 MBq (5 millicuries) of tritium per hand.
(c~~3~~) 555 MBq (15 millicuries) of tritium per dial (The Department considers bezels when used to be part of the dial).
(d~~4~~) 3.7 MBq (100 microcuries) of promethium-147 per watch or 7.4 MBq (200 microcuries) of promethium-147 per any other timepiece.
(e~~5~~) 0.74 MBq (20 microcuries) of promethium-147 per watch hand or 1.48 MBq (40 microcuries) of promethium-147 per other timepiece hand.
(f) 2.22 MBq (60 microcuries) of promethium-147 per watch dial or 4.44 MBq (120 microcuries) of promethium-147 per other timepiece dial (bezels when used will be considered as part of the dial).
(~~7~~g) ~~1.11 kBq (0.03 microcurie) of radium per hand.(8)~~ 0.037 megabecquerel (1 micorcuries)~~3.33 kBq (0.09 microcurie~~) of radium per timepiece in intact timepieces manufactured prior to August 22, 1981. ~~dial (when used bezels will be considered as part of the dial).~~
(h~~9~~) The radiation dose rate from hands and dials containing promethium-147 will not exceed the following, when measured through 50 milligrams per square centimeter of absorber:

(~~a~~i) For wrist watches, 1 μGy (0.1 millirad) per hour at 10 centimeters from any surface.

(ii~~b~~) For pocket watches, 1 μGy (0.1 millirad) per hour at 1 centimeter from any surface.

(iii~~c~~) For any other timepiece, 2 μGy (0.2 millirad) per hour at 10 centimeters from any surface.

~~(10) 37 kBq (one microcurie) of radium-226 per timepiece in timepieces acquired prior to August 22, 1982.~~

~~b~~(2). ~~Lock illuminators containing not more than 555 MBq (15 millicuries) of tritium or not more than 74 MBq (2 millicuries) of promethium-147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium-147 will not exceed 10 μGy (1 millirad) per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.~~Reserved.

~~c~~(3). Precision balances containing not more than 37 MBq (1 millicurie) of tritium per balance or not more than 18.5 MBq (0.5 millicurie) of tritium per balance part manufactured before December 17, 2007..

~~d.~~(4) ~~Automobile shift quadrants containing not more than 925 MBq (25 millicuries) of tritium.~~Reserved.

~~e~~(5). Marine compasses containing not more than 27.8 GBq (750 millicuries) of tritium gas and other marine navigational instruments containing not more than 9.25 GBq (250 millicuries) of tritium gas manufactured before December 17, 2007.

~~f~~(6). ~~Thermostat dials and pointers containing not more than 925 MBq (25 millicuries) of tritium per thermostat.~~ Reserved

~~g~~(7). Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of radioactive material:

(~~1~~a) 5.55 GBq (150 millicuries) of tritium per microwave receiver protector tube or 370 MBq (10 millicuries) of tritium per any other electron tube.

(~~2~~b) 37 kBq (1 microcurie) of cobalt-60.

(~~3~~c) 185 kBq (5 microcuries) of nickel-63.

(~~4~~e) 1.11 MBq (30 microcuries) of krypton-85.

(~~5~~f) 185 kBq (5 microcuries) of cesium-137.

(~~6~~g) 1.11 MBq (30 microcuries) of promethium-147.

And provide further, that the levels of radiation from each electron tube containing radioactive material will not exceed 10 μGy (1 millirad) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.[4]

[4]For purposes of this division, "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~~(8). Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material provided that:

(~~1~~a) Each source contains no more than one exempt quantity set forth in 180 NAC 3, Appendix 3-B, and

(~~2~~b) Each instrument contains no more than 10 exempt quantities. An instrument's source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in 180 NAC 3, Appendix 3-B provided that the sum of such fractions does not exceed unity.

(~~3~~c) For americium-241, 1.85 kBq (0.05 microcurie) is considered an exempt quantity under 180 NAC 3-004.03, item 1.h.

~~i.~~ ~~Spark gap irradiators containing not more than 37 kBq (1 microcurie) of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons (11.4 liters) per hour.~~ Ionization chamber smoke detectors containing not more than 1 micocurie (μCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires..

b. Any person who desires to apply radioactive material to, or to incorporate radioactive material into, the products exempted in 180 NAC 3-004.03, item 1.a. or who desires to initially transfer for sale or distribution such products containing radioactive material, should apply for a specific license pursuant to 10 CFR 32.14, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to 180 NAC 3-004.03, item 1.a.

2. Self-luminous products containing radioactive material.

a. Tritium, krypton-85, or promethium-147. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from Title 180 to the extent that such 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 § 32.22 of 10 CFR 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in 180 NAC 3-004.03, item 2 does not apply to tritium,

krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.

b. Radium-226. Any person is exempt from Title 180 to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 3.7 kBq (0.1 microcuries) of radium-226 which were acquired prior to August 22, 1982.

c. Any person who desires to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, or to initially transfer such products for use in accordance with 180 NAC 3-004.03, item 2.a., should apply for a license in accordance with 10 CFR 32.22, which license states that the product may be initially transferred by the licensee to persons exempt from 180 NAC 3-004.03, item 2.a. C.4c.iii(1) or equivalent regulations of an Agreement State.

3. Gas and aerosol detectors containing radioactive material.

a. Except for persons who manufacture, process, produce or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from Title 180 to the extent that such 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 and provided that detectors containing radioactive material must have been manufactured, processed, producedimported, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.26, or an Agreement State, pursuant to180 NAC 3-014.03, which authorizes the initial transfer of the product for use under 180 NAC 3-004.0310 CRF 32.26. This exemption also covers gas and aerosol detectors manufactured or distruted before November 30, 2007 in accordance with a specific license issued by a State under comparable provision to 10 CFR 32.26 authorizing distribution detectors to persons who are exempt from regulatory requirements.This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by a State under comparable provision to 10 CFR 32.26 authorizing distribution detectors to persons exempt from regulatory requirements.

b. Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State are considered exempt under 180 NAC 3-004.03, item 1., provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of 180 NAC 3-014.03.

b. Any person who desires to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer

such products for use in accordance with -180 NAC 3-004.03, item 3.a. should apply for a license in accordance with 10 CFR 32.26, which license states that the product may be initially transferred by the licensee to persons exempt from 180 NAC 3-014.03, item 3.a. or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State.

4. Persons who receive, possess, use, process, transfer, distribute, or dispose of TENORM are exempt from the requirements of 180 NAC 3 with respect to any combination of radium-226 and radium-228 if the material contain, or are contaminated at, concentrations less than 5 pCi/gram (185 becquerel per kilogram) excluding natural background. The progeny of the exempt TENORM radium-226 and radium228 are also exempt.

~~4. Resins Containing Scandium-46 and Designed for Sand Consolidation in Oil Wells. Any person is exempt from Title 180 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. Such resins must have been manufactured or initially transferred for sale or distribution, in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or must have been manufactured in accordance with the specifications contained in a specific license issued by the Department or any Agreement State to the manufacturer of such resins pursuant to licensing requirements equivalent to those in §10 CFR 32.16 and 32.17 of the regulations of the U.S. Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing scandium-46~~

LICENSES

3-005 TYPES OF LICENSES: Licenses for radioactive materials are of two types: general and specific:

3-005.01 General licenses provided in 180 NAC 3 are effective without the filing of applications with the Department or the issuance of licensing documents to the particular persons. However, registration or certification with the Department may be required by the particular general license. The general licensee is subject to all other applicable portions of Title 180 and any limitations based on the type and quantity of radioactive material of the general license.

3-005.02 Specific licenses require the submission of an application to the Department and the issuance of a licensing document by the Department. The licensee is subject to all applicable portions of Title 180 as well as any limitations based on quantities and types of radioactive materials, proposed use and upon the training and experience of the user(s) specified in the licensing document.

3-006 RADIOACTIVE DRUG: CAPSULES CONTAINING CARBON-14 UREA FOR “IN-VIVO” DIAGNOSTIC USE FOR HUMANS

3-006.01 Except as provided in 180 NAC 3-006.02, any person is exempt from the requirements for a license set forth in the Act and from the regulations in 180 NAC 3 and 7 provided that such person receives, possesses, uses, transfers, owns or acquires capsules containing 37 kBq (1μCi) carbon-14 urea (allowing for nominal variation that

may occur during the manufacturing process) each for "in vivo" diagnostic use for humans.

3-006.02 Any person who desires to use the capsules for research involving human subjects must apply for and receive a specific license pursuant to 180 NAC 7.

3-006.03 Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules must apply for and receive a specific license from the Nuclear Regulatory Commission pursuant to 10 CFR 32.21.

3-006.04 Nothing in 180 NAC 3-006 relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

GENERAL LICENSES

3-007 GENERAL LICENSES - SOURCE MATERIAL

3-007.01 A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions and Federal, State and local government agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any one time for research, development, educational, commercial or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.

3-007.02 Persons who receive, possess, use, or transfer source material pursuant to the general license issued in 180 NAC 3-007.01 are exempt from the provisions of 180 NAC 4 and 10 to the extent that such receipt, possession, use, or transfer is within the terms of such general license; provided, however, that this exemption does not apply to any such person who is also in possession of source material under a specific license issued pursuant to 180 NAC 3.

3-007.03 A general license is hereby 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.

3-007.04 Depleted Uranium In Industrial Products and Devices.

1. A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 180 NAC 3-007.04 items 2 through 5, 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.

2. The general license in 180 NAC 3-007.04, item 1 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 180 NAC 3-014.13 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.

3. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 180 NAC 3-007.04, item 1 must:

   a. File Department Form NRH-11 "Certificate - Use of Depleted Uranium Under General License," with the Department. The form must be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant must furnish on Department Form NRH-11 the following information and such other information as may be required by that form:

      (1) Name and address of the general licensee;
      (2) A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 180 NAC 3-007.04, item 1 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
      (3) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in 180 NAC 3-007.04, item 3.a.(2).

   b. Report in writing to the Department any changes in information furnished by him/her in Department Form NRH-11 "Certificate - Use of Depleted Uranium Under General License." The report must 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 180 NAC 3-007.04, item 1 must:

   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 180 NAC 3-025 and 4-039. In the case where the transferee receives the depleted uranium pursuant to

the general license established by 180 NAC 3-007.04, item 1, the transferor must furnish the transferee a copy of these regulations and a copy of Department Form NRH-11. 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's regulation equivalent to 180 NAC 3-007.04, item 1, the transferor must furnish the transferee a copy of Title 180 and a copy of Department Form NRH-11 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 Title 180.

d. Within 30 days of any transfer, report in writing to the Department the name and address of the person receiving the depleted uranium pursuant to such transfer.

5. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 180 NAC 3-007.04, item 1 is exempt from the requirements of 180 NAC 4 and 10 with respect to the depleted uranium covered by that general license.

3-007.05 Persons who receive, possess, use, or transfer source material pursuant to the general license in 180 NAC 3-007.01 are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Department in a specific license.

3-008 GENERAL LICENSES - RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL[5]

3-008.01 Certain Devices and Equipment: A general license is hereby 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 10 CFR 31.3. This general license is subject to the provisions of 180 NAC 1-004 through 009, 180 NAC 3-004.01, item 2, 180 NAC 3-017, 3-025, and 3-026, 3-030, 180 NAC 4,[6] and 180 NAC 10, 13, 17 and 18.

1. Static Elimination Device. Devices designed for use as static eliminators which contain, as sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 microcuries) of polonium-210 per device.

[5]Note: Different general licenses are issued in 180 NAC 3-008, each of which has its own specific conditions and requirements.

[6]Attention is directed particularly to the provisions of 180 NAC 4 which relate to the labeling of containers.

2. Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 microcuries) of polonium-210 per device or a total of not more than 1.85 GBq (50 millicuries) of hydrogen-3 (tritium) per device.

3. A general license is hereby issued to receive title to and own special nuclear material without regard to quantity. Notwithstanding any other provision of 180 NAC 3, a general licensee under this 180 NAC 3-008 is not authorized to acquire, deliver, receive, possess, use, transfer, import, or export special nuclear material, except as authorized in a specific license.

3-008.02 Reserved

3-008.03 Reserved

3-008.04 Certain Measuring, Gauging and Controlling Devices[7]

1. A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of 180 NAC 3-008.04, items, 2, 3 and 4, radioactive material, excluding special nuclear 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.

2. The general license in 180 NAC 3-008.04, item 1 applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specification contained in a specific license issued under 180 NAC 3-014.04; or an equivalent specific license issued by the U. S. Nuclear Regulatory Commission or an Agreement State with provisions comparable to 180 NAC 3.014.04.

   The devices must have been received from one of the specific licensees described in this paragraph or through a transfer made under 180 NAC 3-008.04, item 3.i.

3. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in 180 NAC 3-008.04, item 1 must:

[7]Persons possessing radioactive material in devices under 180 NAC 3-008.04 before January 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of 180 NAC 3-008.04 in effect on January 14, 1975.

a. 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 comply with all instructions and precautions provided by such labels;

b. 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, however,

(1) Devices containing only krypton need not be tested for leakage of radioactive material, and
(2) Devices containing only tritium or not more than 3.7 MBq (100 microcuries) of other beta and/or gamma emitting material or 0.37 MBq (10 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;

c. Assure that the tests required by 180 NAC 3-008.04, item 3.b. and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(1) In accordance with the instructions provided by the labels; or
(2) By a person holding an applicable specific license from the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform such activities;

d. Maintain records showing compliance with the requirements of 180 NAC 3-008.04, items 3.b. and 3.c. The records must show the results of the tests. The records also must show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. The licensee must retain these records as follows:

(1) Each record of tests for leakage of radioactive material required by 180 NAC 3-008.04, item 3.b. must be maintained until the sealed source is transferred or disposed of.
(2) Each record of tests of the on/off mechanism and indicator required by 180 NAC 3-008.04, item 3.b. must be retained for three years after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed of.
(3) Each record which is required by 180 NAC 3-008.04, item 3.c. must be retained for a period of three years from the date of the recorded event or until the device is transferred or disposed of;

e. Immediately suspend operation of the device if there is 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 185 becquerel (0.005 microcurie) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued by this Department, the U.S. Nuclear Regulatory Commission or by an Agreement State. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 185 becqueral (0.005 microcurie) or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Department within 30 days. Under these circumstances, the criteria set out in 180 NAC 4-016, "Radiological Criteria for Unrestricted Use," may be applicable, as determined by the Department on a case-by-case basis;

f. Not abandon the device containing radioactive material;

g. Not export the device containing ~~byproduct~~radioactive material except in accordance with 10 CFR 110.

h. Transfer or Disposal of Device Containing Radioactive Material

(1) Transfer or dispose of the device containing radioactive material only by export as provided by 180 NAC 3-008.04 item 3.g., by transfer to another general licensee as authorized in paragraph 180 NAC 3-008.04, item 3. i., or to a person authorized to receive the device by a specific license issued under 180 NAC 3, or 180 NAC 12 that authorized waste collection, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, or as otherwise approved under 180 NAC 3-008.04, item 3. h.

(2) Furnish a report to the Department within 30 days after the transfer of a device to a specific licensee or export. The report must contain:

(a) The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;
(b) The name, address, and license number of the person receiving the device (license number not applicable if exported); and

(c) The date of the transfer.

(3) Obtain written Department approval before transferring the device to any other specific licensee not specifically identified in 180 NAC 3-008.04 item 3.h.(1). However a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

(a) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;
(b) Removes, alters, covers, or clearly and unambiguously augments the existing label otherwise required by 180 NAC 3-008.04, item 3.a. so that the device is labeled in compliance with 180 NAC 4-036; however the manufacturer, model number, and serial number must be retained;
(c) Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and
(d) Reports the transfer under paragraph 180 NAC 3-008.04, item 3.h.(2).

i. Transfer the device to another general licensee only if:

(1) The device remains in use at a particular location. In such case the transferor must give the transferee a copy of 180 NAC 3-008.01, 3-030, 4-057, and 4-058, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor must report to the Department:

(a) The manufacturer's (or initial transferor's) name;
(b) The model number and the serial number of the device transferred;
(c) The transferee's name and mailing address for the location of use; and
(d) The name, title, and phone number of the responsible individual identified by the transferee in accordance with 180 NAC 3-008.04, item 3., l. to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(2) The device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

j. Comply with the provisions of 180 NAC 4-057 and 4-058 for reporting radiation incidents, theft, or loss of licensed material, but will be exempt from the other reporting requirements of 180 NAC 4 and 10.

k. Respond to written requests from the Department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it must, within the same time period, request a longer period to supply information by submitting a letter to the Radioactive Material Program Manager, Nebraska Department of Health and Human Services, 301 Centennial Mall South, P.O. Box 95026, Lincoln, Nebraska 68509-5026 and provide written justification as to why it cannot comply.

l. Appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, must ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

m. Register general license devices.

(1) Register, in accordance with 180 NAC 3-008.04, item 3., m., (2) and (3), devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, 3.7 MBq (0.1 millicurie) of radium-226,or 37 MBq (1 mCi) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described in 180 NAC 3-008.04, item 3., m., (3), d., represents a separate general licensee and requires a separate registration and fee.

(2) If in possession of a device meeting the criteria of 180 NAC 3-008.04, item 3., m., (1), must register these devices annually with the Department and must pay the fee required by 180 NAC 18. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Department. The registration information must be submitted to the Department within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices that meet the criteria of 180 NAC 3-008.04, item 3 m. (1) is subject to the bankruptcy notification requirement in 180 NAC 3-017.05.

(3) In registering devices, the general licensee must furnish the following information and any other information specifically

requested by the Department:

(a) Name and mailing address of the general licensee.
(b) Information about each device: the manufacturer (or initial transferor), model number, serial number, the radionuclide and activity (as indicated on the label).
(c) Name, title, and telephone number of the responsible person designated as a representative of the general licensee in 180 NAC 3-008.04, item 3. l.
(d) Address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage.
(e) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.
(f) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

(4) Persons generally licensed by an Agreement State or the NRC, with respect to devices meeting the criteria in paragraph 180 NAC 3-008.04, item 3., m. (1) are not subject to registration requirements if the devices are used in areas subject to Department jurisdiction for a period less than 180 days in any calendar year. The Department will not request registration information from such licensees.

n. Report changes to the mailing address for the location of use (including change in name of general licensee) to the Radioactive Materials Program Manager, Nebraska Department of Health and Human Services, 301 Centennial Mall South, P.O. Box 95026, Lincoln, NE 68509-5026 within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.

o. Not hold unused devices for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by 180 NAC 3-008.04, item 3. b. need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

4. The general license in 180 NAC 3-008.04, item 1. does not authorize the manufacture or import of devices containing radioactive material.

5. The general license provided in 180 NAC 3-008.04, item 1. is subject to the provisions of 180 NAC 1-004 through 1-009, 180 NAC 3-017, 3-025, 3-027, and 180 NAC 13 .

3-008.05 Luminous Safety Devices for Aircraft

1. A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

   a. Each device contains not more than 370 GBq (l0 curies) of tritium or 11.1 GBq (300 millicuries) of promethium-147; and
   b. Each device has been manufactured, assembled or initially transferred 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 Department or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in 10 CFR 30.33 and 32.53.

2. Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 180 NAC 3-008.05, item 1. are exempt from the requirements of 180 NAC 4 and 10 except that they must comply with the provisions of 180 NAC 4-057 and 4-058.

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

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

5. This general license is subject to the provisions of 180 NAC 1-004 through 1-009, 180 NAC 3-017, 3-025, 3-027, and 13.

6. This general license does not authorize the export of luminous safety devices containing tritium or promethium-147.

3-008.06 Ownership of Radioactive Material: A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of 180 NAC 3, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

3-008.07 Calibration and Reference Sources

1. A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of 180 NAC 3-008.07, items 4. and 5., americium-241 in the form of calibration or reference sources:

   a. Any person who holds a specific license issued by the Department which authorizes the licensee to receive, possess, use, and transfer radioactive material; and
   b. Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes the licensee to receive, possess, use, and transfer special nuclear material.

2. A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of 180 NAC 3-008.07, items 4. and 5. to any person who holds a specific license issued by the Department which authorizes the licensee to receive, possess, use, and transfer radioactive material.

7. A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of 180 NAC 3-008.07, items 4 and 5 to any person who holds a specific license issued by the Department which authorizes the licensee to receive, possess, use, and transfer radioactive material.

8. The general licenses in 180 NAC 3-008.07, items 1. through 3. 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 10 CFR 30.33, in accordance with the specifications contained in a specific license issued to the manufacturer by the Department, or any Agreement State pursuant to licensing requirements equivalent to those contained in 10 CFR 30.33.

9. The general licenses provided in 180 NAC 3-008.07, items 1. through 3. are subject to the provisions of 180 NAC 1-004 through 1-009, 180 NAC 3-017, 3-025, 3-027, 180 NAC 4, 10, and 13. In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses must:

   a. Not possess at any one time, at any one location of storage or use, more than 185 kBq (5 microcuries) of americium-241, 185 kBq (5 microcuries) of plutonium, and 185 kBq (5 microcuries) of radium-226 in such sources;

   b. Not receive, possess, use, or transfer such 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.

(1) 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 (RADIUM-226) (AMERICIUM-241). (PLUTONIUM)[8] DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer or importer

c. Not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Department, the U.S. Nuclear Regulatory Commission, or any other Agreement State to receive the source;

d. Store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

e. Not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

6. These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

3-008.08 Reserved

3-008.09 General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing

1. A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 180 NAC 3-008.09, items 2. through 6., the following radioactive materials in prepackaged units for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

[8]Showing only the name of the appropriate material.

a. Iodine-125, iodine-131, selenium-75, cobalt-57, and carbon-14 in units not exceeding 370 kBq (10 microcuries) each.
b. Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 microcuries) each.
c. Iron-59, in units not exceeding 740 kBq (20 microcuries) each.
d. Mock Iodine-125 reference or calibration sources, in units not exceeding 1.85 kBq (0.05 microcurie) of iodine-129 and 1.85 Bq (0.005 microcurie) of americium-241 each.
e. Colbalt-57, in units not exceeding 0.37MBq (01 microcuries each).

2. No person receives, acquires, possesses, uses or transfers radioactive material pursuant to the general license established by 180 NAC 3-008.09, item 1. until s/he has filed Department Form NRH-17, "Certificate - In Vitro Testing with Radioactive Material Under General License", with the Department and received from the Department a validated copy of Department Form NRH-17 with certification number assigned. The physician, veterinarian, clinical laboratory or hospital must furnish on Department Form NRH-17 the following information and such other information as may be required by that form:

a. Name and address of the physician, veterinarian, clinical laboratory or hospital;
b. The location of use; and
A statement that the physician, veterinarian in the practice of veterinary medicine, 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 180 NAC 3-008.09, item 1. and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

3. A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 180 NAC 3-008.09, item 1. must comply with the following:

a. The general licensee must not possess at any one time, pursuant to the general license in 180 NAC 3-008.09, item 1. at any one location of storage or use a total amount of iodine-125, iodine-131, iron-59, cobalt-57 and/or selenium-75 in excess of 7.4 MBq (200 microcuries).

b. The general licensee must store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

c. The general licensee must use the radioactive material only for the uses authorized by 180 NAC 3-008.09, item 1.

d. The general licensee must not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Department, the U.S. Nuclear Regulatory Commission, or any Agreement State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

e. The general licensee must dispose of the Mock Iodine-125 reference or calibration sources described in 180 NAC 3-008.09, item 1.d. as required by 180 NAC 4-039 and 4-044.

4. The general licensee must not receive, acquire, possess, or use radioactive material pursuant to 180 NAC 3-008.09, item 1.:

a. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 180 NAC 3-014.08 or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, or any Agreement State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under 180 NAC 3-008.09 or its' equivalent, and

b. Unless the following statement, or 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 is received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, 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 of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of Manufacturer

5. The physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital possessing or using radioactive material under the general license of 180 NAC 3-008.09, item 1. must report in writing to the Department, any changes in the information furnished by him/her in the "Certificate - In Vitro Testing with Radioactive Material Under General

License", Department Form NRH-17. The report must be furnished within 30 days after the effective date of such change.

6. Any person using radioactive material pursuant to the general license of 180 NAC 3-008.09, item 1 is exempt from the requirements of 180 NAC 4 and 10 with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 180 NAC 3-008.09 item 1.d. must comply with the provisions of 180 NAC 4-039, 4-057, and 4-058.

3-008.10 Ice Detection Devices

1. A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 1.85 MBq (50 microcuries) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Department or any Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in 10 CFR 32.61.

2. Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in 180 NAC 3-008.10, item 1,

   a. Must 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 to manufacture or service such devices; or must dispose of the device pursuant to the provisions of 180 NAC 4-039;
   b. Must assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and
   c. Are exempt from the requirements of 180 NAC 4 and 10 except that such persons must comply with the provisions of 180 NAC 4-039, 4-057, and 4-058.

3. This general license does not authorize the manufacture, assembly, disassembly, repair or import of strontium-90 in ice detection devices.

4. This general license is subject to the provisions of 180 NAC 1-004 through 1-009, 180 NAC 3-017, 180 NAC 3-025, 180 NAC 3-027, and 180 NAC 13.

3-008.11 General license for certain items and self-luminous products containing radium-226.

3-008.11.01A A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of 180 NAC 3-008.11.01B, 3-008.11.01 C and 3-008.11.01D, radium-226 contained in the following products manufactured prior to November 30, 2007:

1. Antiquities originally intended for use by the general public. For the purposes of this paragraph, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.
2. Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.
3. Luminous items installed in air, marine, or land vehicles.
4. All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.
5. Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. For the purposes of this paragraph, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the U.S. Nuclear Regulatory Commission.

3-008.11.01B Persons who acquire, receive, possess, use, or transfer radioactive material under the general license issued in 180 NAC 3-08.11.01A are exempt from the provisions of 180 NAC 4, 10 , 3-026 and 3-030, to the extent that the receipt, possession, use, or transfer of radioactive material is within the terms of the general license; provided, however, that this exemption must not be deemed to apply to any such person specifically licensed under 180 NAC 3.

3-008.11.01C Any person who acquires, receives, possesses, uses, or transfers radioactive material in accordance with the general license in 180 NAC 3-008.11.01A:

1. Will notify the Department should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director of Public Health of the Nebraska Department of Health and Human Services, P.O. Box 95026, Lincoln, NE 68509 within 30 days.

2. Will not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to 180 NAC 4-039 or by transfer to a person authorized by a specific

license to receive the radium-226 in the product or as otherwise approved by the U.S. Nuclear Regulatory Commission.

3. Will not export products containing radium-226 except in accordance with 10 CFR § 110.

4. Will dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under 180 NAC 3, or equivalent regulations of this Department or an Agreement State, or U.S. Nuclear Regulatory Commission.

5 Will respond to written requests from the Department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it must, within that same time period, request a longer period to supply the information by providing the Director of Public Health of the Nebraska Department of Health and Human Services, by an appropriate method listed in 180 NAC 1-012, a written justification for the request.

3-008.11.01D The general license in 180 NAC 3-008.11.01A does not authorize the manufacture, assembly, disassembly,repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

3-009 RESERVED

SPECIFIC LICENSES

3-010 FILING APPLICATION FOR SPECIFIC LICENSES

3-010.01 Applications for specific licenses must be filed on form NRH-7 (medical) for all medical licenses and form NRH-5 for all other licenses.

3-010.02 The Department may at any time after the filing of the original application require further statements in order to enable the Department to determine whether the application should be granted or denied or whether a license should be modified or revoked.

3-010.03 Each application must be signed by the applicant or licensee or a person duly authorized to act for and on his/her behalf.

3-010.04 An application for a license may include a request for a license authorizing one or more activities.

3-010.05 ~~In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Department provided such references are clear and specific.~~RESERVED

3-010.06 Applications and documents submitted to the Department may be made available for public inspection except that the Department may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

3-010.07 As provided by 180 NAC 3-018 certain applications for specific licenses filed under 180 NAC 3, 5, and 7, must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning.

3-010.08 An application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source must either:

1. Identify the source or device by manufacturer and model number as registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State~~;~~, or for source or a device containing radium-226 or accelerator-produced radioactive material with the U.S. Nuclear Regulatory Commission or an State under provisions comparable to 10 CFR § 32.210.

2. Contain the information identified in 10 CFR 32.210(c);~~.~~ or

3. For sources or devices containing naturally occurring or accelerator-produced radioactive material manufactured prior to November 30, 2007 that are not registered with the U.S. Nuclear Regulatory Commission under 10 CFR § 32.210 or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in 10 CRF § 32.210(c), the applicant must provide:

   a. All available information identified in 10 CFR § 32.210(c) concerning the source, and, if applicable, the device; and

   b. Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

3-010.09 Emergency Plans

1. Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 180 NAC 3, Appendix 3-E "Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release" must contain either:

a. An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or
b. An emergency plan for responding to a release of radioactive material.

2. One or more of the following factors may be used to support an evaluation submitted under 180 NAC 3-010.09, item 1:

a. The radioactive material is physically separated so that only a portion could be involved in an accident;
b. All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;
c. The release fraction in the respirable size range would be lower than the release fraction shown in 180 NAC 3, Appendix 3-E due to the chemical or physical form of the material;
d. The solubility of the radioactive material would reduce the dose received;
e. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in 180 NAC 3, Appendix 3-E;
f. Operating restrictions or procedures would prevent a release fraction as large as that shown in 180 NAC 3, or
g. Other factors appropriate for the specific facility.

3. An emergency plan for responding to a release of radioactive material submitted under 180 NAC 3-010.09 must include the following information:

a. Facility description: A brief description of the licensee's facility and area near the site.
b. Types of accidents: An identification of each type of radioactive materials accident for which protective actions may be needed.
c. Classification of accidents: A classification system for classifying accidents as alerts or site area emergencies.
d. Detection of accidents: Identification of the means of detecting each type of accident in a timely manner.
e. Mitigation of consequences: A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.
f. Assessment of releases: A brief description of the methods and equipment to assess releases of radioactive materials.
g. Responsibilities: A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the Department; also responsibilities for developing, maintaining, and updating the plan.
h. Notification and coordination: A commitment to and a brief description of the means to promptly notify offsite response organizations and

request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must to be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee must also commit to notify the Department immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.[9]

i. Information to be communicated: A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the Department.

j. Training: A 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. The training must familiarize personnel with site-specific emergency procedures. Also, the training must 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.

k. Safe shutdown: A brief description of the means of restoring the facility to a safe condition after an accident.

l. Exercises: Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee must invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios must not be known to most exercise participants. The licensee must critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

m. Hazardous chemicals: A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, P. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

[9]These reporting requirements do not supersede or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, P. L. 99-499 or other state or federal reporting requirements.

4. The licensee must allow the offsite 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 Department. The licensee must provide any comments received within the 60 days to the Department with the emergency plan.

3-010.11 An application from a medical facility, or educational institution, to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under 180 NAC 7 or equivalent Agreement State or U.S. NRC requirements must include:

1.. A request for authorization for the production of PET radionuclides or evidence of an existing license issued under 180 NAC 3, U.S. NRC or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

2. Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 180 NAC 3-014.10, item 1,b,

3. Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in 180 NAC 3-014.10, item 2.b.

4 Information identified in 180 NAC 3-014.10, item 1.c. on the PET drugs to be noncommercially transferred to members of its consortium.

3-011 GENERAL REQUIREMENTS FOR THE ISSUANCE OF SPECIFIC LICENSES: A license application will be approved if the Department 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 Title 180 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 minimize danger to the public health and safety 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 180 NAC 3-013, 180 NAC 3-014, or 180 NAC 3-015, 180 NAC 5, 180 NAC 7, 180 NAC 12, 180 NAC 14 or 180 NAC 19.

3-011.01 Environmental Report, Commencement of Construction: In the case of an application for a license to receive and possess radioactive material for commercial waste management, source material milling, or for the conduct of any other activity which the Department determines will significantly affect the quality of the environment, the Department, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental,

economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion is grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of the environmental values.

3-011.02 Financial Surety Arrangements for Site Reclamation

1. Pursuant to Radiation Control Act §71-3508.04, Reissued Revised Statues of Nebraska 1943, as amended and as otherwise provided, financial surety arrangements for site reclamation which may consist of surety bonds, cash deposits, certificates of deposit, deposits of government securities, letters or lines of credit, or any combination of the above for the categories of licensees listed in 180 NAC 3-011.02 must be established to ensure the protection of the public health and safety in the event of abandonment, default, or other inability of the licensee to meet the requirements of the Act.

    a. The amount of funds to be ensured by such surety arrangements must be based on Department approved cost estimates equal to meet the requirements of 180 NAC 3-011.02, item 1.
    b. Self insurance, or any arrangement which essentially constitutes self insurance, will not satisfy the surety requirement since this provides no additional assurance other than that which already exists through license requirements.

2. The arrangements required in 180 NAC 3-011.02, item 1. must be established prior to issuance of the license to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the facility, except as provided in 180 NAC 3-011.02, item 3.

3. If application is made to amend an existing license to fall within the purview of 180 NAC 3-011.06 then the financial surety arrangements for site reclamation must be established prior to the issuance of the amendment.

4. The following specific licensees are required to make financial surety arrangements:

    a. Major processors;
    b. Waste management licensees, except the commercial disposal of low-level radioactive waste in a disposal facility, designated by the Central Interstate Low-Level Radioactive Waste Compact Commission;

c. Former U.S. Atomic Energy Commission or U.S. Nuclear Regulatory Commission licensed facilities;
d. Source material milling operations; and
e. All others except persons exempt pursuant to 180 NAC 3-011.02, item 5.

5. The following persons are exempt from the requirements of 180 NAC 3-011.02, item 1. because they are exempt from licensure:

a. All State, local, or other government agencies unless they are subject to 180 NAC 3-011.02, item 4.b. or 4.d.,
b. Persons authorized to possess no more than 1,000 times the quantity specified in 180 NAC 3, Appendix 3-B or combination of radioactive material listed therein as given in 180 NAC 3, Appendix 3-B, Note 1.;
c. Persons authorized to possess hydrogen-3 contained as hydrogen gas in a sealed source; or
d. Persons authorized to possess radioactive noble gases in sealed sources with no radioactive daughter product with half-life greater than 30 days.

6. Long-term Care Requirements: Pursuant to Radiation Control Act §71-3508.04, Reissued Revised Statues of Nebraska, 1943, as amended and as otherwise provided, a long-term care fund must be established by the following specific licensees prior to the issuance of the license or prior to the termination of the license if the applicant chooses at the time of the licensure to provide a surety in lieu of a long-term care fund:

a. Waste management licensees.
b. Source material milling and mill tailings licensees.

3-012 RESERVED

3-013 SPECIAL REQUIREMENTS FOR SPECIFIC LICENSES OF BROAD SCOPE: 180 NAC 3-013 prescribes requirements for the issuance of specific licenses of broad scope for radioactive material ("broad licenses") and certain regulations governing holders of such licenses:

3-013.01 The different types of broad licenses are set forth below:

1. A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range, and the limits are based on types of radioactive materials, proposed use and upon the training and experience of the user(s).

2. A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in 180 NAC 3, Appendix 3-C for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Column I of 180 NAC 3, Appendix 3-C, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 180 NAC 3, Appendix 3-C, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license must not exceed unity.

3. A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in 180 NAC 3, Appendix 3-C for any authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in 180 NAC 3, Appendix 3-C, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in 180 NAC 3, Appendix 3-C, Column II for that radionuclide. The sum of the ratios for all radionuclides possessed under the license must not exceed unity.

<u>3-013.02 An application for a Type A specific license of broad scope will be approved if:</u>

1. The applicant satisfies the general requirements specified in 180 NAC 3-011;
2. The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and
3. 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 in training and experience in radiation protection consistent with the requirements of training specified in 180 NAC 15-015.01, item 1, and who is available for advice and assistance on radiation safety matters; and
    c. Authorized users designated by the Radiation Safety Committee must have formal training and experience in the safe handling of radioactive material consistent with the requirements of training specified in 180 NAC 15-015.01, item 2.; and
    d. The establishment of appropriate administrative procedures to assure:

(1) Control of procurement and use of radioactive material;
(2) 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
(3) Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 180 NAC 3-013.02, item 3.d.(2). prior to use of the radioactive material.

3-013.03 An application for a Type B specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in 180 NAC 3-011; 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 appointment of a radiation safety officer who is qualified by training and experience in radiation protection consistent with the requirements of training specified in 180 NAC 15-015.01, item 1 and who is available for advice and assistance on radiation safety matters,
b. Authorized users must have formal training and experience in the safe handling of radioactive material consistent with the requirements of training specified in 180 NAC 15-015.01, item 2; and
c. The establishment of appropriate administrative procedures to assure:

(1) Control of procurement and use of radioactive material,
(2) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures, and
(3) Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with 180 NAC 3-013.03, item 2.c. prior to use of the radioactive material.

3-013.04 An application for a Type C specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in 180 NAC 3-011;
2. The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

a. A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering, and
b. At least 40 hours of formal training and 160 hours experience in the safe handling of radioactive material, and in the characteristics of ionizing

radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

3. The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

3-013.05 Specific licenses of broad scope are subject to, based on quantities and types of radioactive materials, proposed use and upon the training and experience of the user(s), to the following conditions:

1. Unless specifically authorized, persons licensed pursuant to 180 NAC 3-013 must not:

   a. Conduct tracer studies in the environment involving direct release of radioactive material;
   b. Receive, acquire, own, possess, use or transfer devices containing 3.7 PBq (100,000 curies) or more of radioactive material in sealed sources used for irradiation of materials;
   c. Conduct activities for which a specific license issued by the Department under 180 NAC 3-014, 3-015 or 180 NAC 7, and 12 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.

2. Each Type A specific license of broad scope issued under this 180 NAC 3-013.05 is 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.

3. Each Type B specific license of broad scope issued under 180 NAC 3-013.05 is 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 officer.

4. Each Type C specific license of broad scope issued under this 180 NAC 3-013.05, item 4 is subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of 180 NAC 3-013.04.

3-014 SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO MANUFACTURE, ASSEMBLE, REPAIR, OR DISTRIBUTE COMMODITIES, PRODUCTS, OR DEVICES WHICH CONTAIN RADIOACTIVE MATERIAL

3-014.01 ~~Licensing the Introduction of Radioactive Material Into Products In Exempt Concentrations~~Reserved

~~1. In addition to the requirements set forth in 180 NAC 3-011, 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 180 NAC 3-004.01, item 1 will be issued if:~~

~~a. 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~~

~~b. The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in 180 NAC 3, Appendix 3-A, that reconcentration of the radioactive material in concentrations exceeding those in Appendix 3-A of 180 NAC 3 is not likely, that use of lower concentrations is not feasible, and 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.~~

~~2.Each person licensed under 180 NAC 3-014.01 must file an annual report with the Department which identifies the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; 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; the type and quantity of radionuclide introduced into each such product or material; and 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 180 NAC 3-014.01 during the reporting period, the report must so indicate. The report must cover the year ending June 30, and must be filed within 30 days thereafter.~~

~~3. The Radiation Safety Officer and/or authorized user must have training and experience requirements consistent with training specified in 180 NAC 15-018.01.~~

3-014.02 Prohibiition of introduction. No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 180 NAC 3.004.01 or equivalent regulation of an Agreement State or U.S. Nuclear Regulatory Commission, except in accordance with a license issued under 10 CFR32.11.~~Reserved~~

3-014.03 Licensing the Incorporation of Naturally Occurring Accelerator-Produced Radioactive Material Into Gas and Aerosol Detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under 180 NAC 3-004.03, item 3 will be approved if the application satisfies the requirements of 10 CFR 32.26 . The maximum quantity of radium-226 in each device must not exceed 3.7 kBq (0.1 microcurie).

3-014.04 Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under 180 NAC 3-008.04

1. An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 180 NAC 3-008.04 or equivalent regulations of the U.S. Nuclear Regulatory Commission, or an Agreement State will be approved if:

   a. The applicant satisfies the general requirements of 180 NAC 3-011;
   b. 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:

      (1) The device can be safely operated by persons not having training in radiological protection;
      (2) 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 one year a dose in excess of 10% of the annual limits specified in 180 NAC 4-005.01; and
      (3) 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:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	150 mSv (15 rems)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	2 Sv (200 rems)
Other organs	500 mSv (50 rems)

   c. Each device bears a durable, legible, clearly visible label or labels approved by the Department, which contain in a clearly identified and separate statement:

(1) 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;

(2) 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

(3) The information called for in the following statement, as appropriate in the same or substantially similar form:

The receipt, possession, use, and transfer of this device Model _____[10], Serial No. _____[10], are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a state with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label must be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

_____
Name of Manufacturer or Distributor[10]

d. Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the radionuclide and quantity, the words, "`Caution-Radioactive Material," the radiation symbol described in 180 NAC 4-033.01, and the name of the manufacturer or initial distributor.

e. Each device meeting the criteria of 180 NAC 3-008.04, item 3. m. (1), bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in 180 NAC 4-033.01.

2. 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, the applicant must include in the application sufficient information to

[10]The model, serial number, and name of manufacturer or distributor may be omitted from this label provided the information is elsewhere specified and labeling affixed to the device.

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 Department will consider information which includes, but is not limited to:

a. Primary containment or source capsule;
b. Protection of primary containment;
c. Method of sealing containment;
d. Containment construction materials;
e. Form of contained radioactive material;
f. Maximum temperature withstood during prototype tests;
g. Maximum pressure withstood during prototype tests;
h. Maximum quantity of contained radioactive material;
i. Radiotoxicity of contained radioactive material; and
j. Operating experience with identical devices or similarly designed and constructed devices.

3. In the event the applicant desires that the general licensee under 180 NAC 3-008.04, or under equivalent regulations of 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, the applicant must include in his/her application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information must demonstrate that performance of 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, is unlikely to cause that individual to receive a dose in excess of 10% of the annual limits specified in 180 NAC 4-005.01.

4. Conditions of transferring a device for use under a general license in 180 NAC 3-008.04.

a. If a device containing radioactive material is to be transferred for use under the general license in 180 NAC 3-008.04, each person that is licensed under 180 NAC 3-014.04 must provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(1) A copy of the general license contained in 180 NAC 3-008.04,

item 3. b. through d. or item 3.m. do not apply to the particular device, those paragraphs may be omitted.

(2) A copy of 180 NAC 3-008.01, 180 NAC 3-030, 180 NAC 4-057 and 4-058;

(3) A list of the services that can only be performed by a specific licensee;

(4) Information on acceptable disposal options including estimated costs of disposal; and

(5) An indication that the Department's policy is to issue high civil penalties for improper disposal.

b. If radioactive material is to be transferred in a device for use under an equivalent general license of the U.S. Nuclear Regulatory Commission or an Agreement State, each person that is licensed under 180 NAC 3-014.04 provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(1) A copy of the 180 NAC 3-008.01, 180 NAC 3-008.04, 180 NAC 4-057 and 058 or a copy of equivalent U.S. Nuclear Regulatory Commission or Agreement State's regulations. If a copy of the U.S. Nuclear Regulatory Commission regulations is provided to a prospective general licensee in lieu of the Department's or Agreement State's regulations, it must be accompanied by a note explaining that use of the device is regulated by the U. S. Nuclear Regulatory Commission or an Agreement State; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted.

(2) A list of the services that can only be performed by a specific licensee;

(3) Information on acceptable disposal options including estimated costs of disposal; and

(4) The name or title, address, and phone number of the contact at the Department, U.S. Nuclear Regulatory Commission or Agreement State from which additional information may be obtained.

c. An alternative approach to informing customers may be proposed by the licensee for approval by the Department.

d. Each device that is transferred after April 12, 2003 must meet the labeling requirements in 180 NAC 3-014.04, item 1.c. through d.

e. If a notification of bankruptcy has been made under 180 NAC 3-017.05 or the license is to be terminated, each person licensed under 180 NAC 3-014.04 must provide, upon request, to the Department, the U.S. Nuclear Regulatory Commission and to any appropriate Agreement State, records of final disposition required under 180 NAC 3-014.04,

item 5. c.

5. Material transfer reports and records. Each person under 180 NAC 3-014.04 to initially transfer devices to generally licensed persons must comply with the requirements of 180 NAC 3-014.04, item 5.

a. The person must report all transfers of devices to persons for use under the general license in 180 NAC 3-008.04 and all receipts of devices from persons licensed under 180 NAC 3-008.04 to the Radioactive Material Program Manager, Nebraska Department of Health and Human Services, Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, Nebraska 68509-5026. The report must be submitted on a quarterly basis on the NRH Form 653, “Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

(1) The required information for transfers to general licensees includes:

(a) The identity of each general licensee by name and mailing location of use, an alternate address for the general licensee must be submitted along with information on the actual location of use.
(b) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;
(c) The date of transfer;
(d) The type, model number, and serial number of the device transferred; and
(e) The quantity and type of radioactive material contained in the device.

(2) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).
(3) For devices received from a 180 NAC 3-008.04 general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.
(4) If the licensee makes changes to a device possessed by a 180 NAC 3-008.04 general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information

on the device label.

(5) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(6) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(7) If no transfers have been made to or from persons generally licensed under 180 NAC 3-008.04 during the reporting period, the report must so indicate.

b. The person must report all transfers of devices to persons for use under a general license in an U.S. Nuclear Regulatory Commission or Agreement State's regulations that are equivalent to 180 NAC 3-008.04 and all receipts of devices from general licensees in the U.S. Nuclear Regulatory Commission or Agreement State's jurisdiction to the U.S. Nuclear Regulatory Commission or responsible Agreement State agency. The report must be submitted on the Department's Form 653, "Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

(1) The required information for transfers to general licensees includes:

(a) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee must be submitted along with information on the actual location of use.

(b) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(c) The date of transfer;

(d) The type, model number, and serial number of the device transferred; and

(e) The quantity and type of radioactive material contained in the device.

(2) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(3) For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the

manufacturer or initial transferor.

(4) If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(5) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(6) The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

(7) If no transfers have been made to or from the U.S. Nuclear Regulatory Commission or a particular Agreement State during the reporting period, this information must be reported to the U.S. Nuclear Regulatory Commission or responsible Agreement State agency upon request of the Department.

c. The person must maintain all information concerning transfers and receipts of devices that supports the reports required by this 180 NAC 3-014.04, Item 5. Records required by 180 NAC 3-014.04, item 5 must be maintained for a period of 3 years following the date of the recorded event.

3-014.05 Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use 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 180 NAC 3-008.05 will be approved subject to the following conditions:

1. The applicant satisfies the general requirements specified in 180 NAC 3-011, and
2. The applicant satisfies the requirements of 10 CFR 30.33, 32.53 through 32.56 and 32.101.
3. The Radiation Safety Officer and/or authorized user must have training and experience requirements consistent with training specified in 180 NAC 15-018.01.

3-014.06 Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under 180 NAC 3-008.07. An application for a specific license to manufacture or initially transfer calibration and reference sources containing americium-241, plutonium or radium-226 for distributions to persons generally licensed under 180 NAC 3-008.07 will be approved subject to the following conditions:

1. The applicant satisfies the general requirement of 180 NAC 3-011, and
2. The applicant satisfies the requirements of 10 CFR 30.33, 32.57 through 32.59, 32.102, and 70.39, and

3. The Radiation Safety Officer and/or authorized user must have training and experience requirements consistent with training specified in 180 NAC 15-018.01.

3-014.07 Reserved

3-014.08 Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 180 NAC 3-008.09 will be approved if:

1. The applicant satisfies the general requirements specified in 180 NAC 3-011.
2. The radioactive material is to be prepared for distribution in prepackaged units of:

   a. Iodine-125 in units not exceeding 370 kBq (10 microcuries) each.
   b. Iodine-131 in units not exceeding 370 kBq (10 microcuries) each.
   c. Carbon-14 in units not exceeding 370 kBq (10 microcuries) each.
   d. Hydrogen-3 (tritium) in units not exceeding 1.85 MBq (50 microcuries) each.
   e. Iron-59 in units not exceeding 740 kBq (20 microcuries) each.
   f. Cobalt-57 in units not exceeding 370 kBq (10 microcuries) each.
   g. Selenium-75 in units not exceeding 370 kBq (10 microcuries) each.
   h. Mock Iodine-125 in units not exceeding 1.85 kBq (0.05 microcurie) of iodine-129 and 185 Bq (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 370 kBq (10 microcuries) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 1.85 MBq (50 microcuries) of hydrogen-3 (tritium); 740 kBq (20 microcuries) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kBq (0.05 microcurie) of iodine-129 and 185 Bq (0.005 microcurie) of americium-241 each or colbalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries); and

   b. Displaying the radiation caution symbol described in 180 NAC 4-033.01 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, veterinarians in the practice of veterinary medicine, 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 of 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 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 180 NAC 4-039.

6. The Radiation Safety Officer and/or authorized user must have training and experience requirements consistent with training specified in 180 NAC 15-019.01.

3-014.09 Licensing the Manufacture and Distribution of Ice Detection Devices Containing Strontium 90. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under 180 NAC 3-008.10 will be approved subject to the following conditions: The applicant satisfies the general requirements of 180 NAC 3-011, the criteria of 10 CFR 30.33, 32.61, 32.62, and 32.103. The Radiation Safety Officer and/or authorized user must have training and experience requirements consistent with training specified in 180 NAC 15-018.01.

3-014.10 Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Radioactive Material for Medical Use Under 180 NAC 7.

1. An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to 180 NAC 7, will be approved if:

   a. The applicant satisfies the general requirements specified in 180 NAC 3-011;

   b. The applicant submits evidence that the applicant is at least one of the following:

      (1) Registered ~~or licensed~~ with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a) ~~manufacturer~~;

(2) Registered or licensed with a state agency as a drug manufacturer;
(3) Licensed according to 175 NAC 8, Pharmacies; or
(4) Operating as a nuclear pharmacy within a Federal medical institution; or
(5) A Positron Emission Tomography (PET) drug production facility registered with the Department.

c. The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

d. The applicant satisfies the following labeling requirements:

(1) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL”; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.
(2) A label is affixed to each syringe, vial or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL” and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

2. A licensee described by 180 NAC 3-014.10, item 1.b.(3) or 1.b.(4).

a. May prepare radioactive drugs for medical use, as defined in 180 NAC 7-002, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 180 NAC 3-014.10, item 1.b. and d, or an individual under the supervision of an authorized nuclear pharmacist as specified in 180 NAC 7-018.

b. May allow a pharmacist to work as an authorized nuclear pharmacist if:

(1) This individual qualifies as an authorized nuclear pharmacist as defined in 180 NAC 7-002;
(2) This individual meets the requirements specified in 180 NAC 7-024.02 and 7-027 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

(3) This individual is designated as an authorized nuclear pharmacist in accordance with 180 NAC 3-014.10, item 2.c.

c. The actions authorized in 180 NAC 3-014.10, items 2.a. and b. are permitted in spite of more restrictive language in license conditions.

d. May designate a pharmacist (as defined in 180 NAC 1~~7~~-002) as an authorized nuclear pharmacist if the individual is identified as of the effective date of these regulations , as an "authorized user" on a nuclear pharmacy license issued by the Department under 180 NAC 3. if

(1) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

(2) The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the U.S. Nuclear Regulatory Commission.

e. Must provide to the Department a copy of each individual's:

(1) ~~a copy of each individual's c~~Certification by a specialty board whose certification process has been recognized by ~~the Board of Pharmaceutical Specialties,~~ the Department, U.S. Nuclear Regulatory Commission, or any Agreement State as specified in 7-024.01 with the written attestation signed by a preceptor as required by 7-024.03; or

(2) The Department, the U.S. Nuclear Regulatory Commission, or any Agreement State license, or

(3) U.S. Nuclear Regulatory Commision master materials licensee permit, or

(4) ~~t~~The permit issued by a licensee or U.S. Nuclear Regulatory Commission master material permittee of broad scope, or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or

(5) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the U.S. Nuclear Regulatory Commission; and

(6) ~~and a copy of the s~~State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to 180 NAC 3-014.10, item 2.b.(1) and (3), the individual to work as an authorized nuclear pharmacist.

3. A licensee must possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee must have procedures for use of the instrumentation. The licensee must measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in

dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee must:

a. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and
b. Check each instrument for constancy and proper operation at the beginning of each day of use.

4. Nothing in 180 NAC 3-014.10 relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

3-014.11 Reserved

3-014.12. Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 180 NAC 7 for use as a calibration, transmission or reference source or for the uses listed in 180 NAC 7-055, 7-065, 7-067 and 7-0~~67~~85 will be approved if:

1. The applicant satisfies the general requirements in 180 NAC 3-011.
2. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

a. The radioactive material contained, its chemical and physical form, and amount,
b. Details of design and construction of the source or device,
c. Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,
d. For devices containing radioactive material, the radiation profile of a prototype device,
e. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,
f. Procedures and standards for calibrating sources and devices,
g. Legend and methods for labeling sources and devices as to their radioactive content, and
h. Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label.

3. The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the Department has approved distribution of the (name of the source or device) to persons licensed to use radioactive material identified in 180 NAC 7-032, 7-055, 7-065 and 7-067 as appropriate, and to persons who hold an equivalent license issued by the U.S. Nuclear Regulatory Commission or an Agreement State.

4. In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, the applicant must include in his/her application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

5. In determining the acceptable interval for test of leakage of radioactive material, the Department will consider information that includes, but is not limited to:

   a. Primary containment or source capsule;
   b. Protection of primary containment;
   c. Method of sealing containment;
   d. Containment construction materials;
   e. Form of contained radioactive material;
   f. Maximum temperature withstood during prototype tests;
   g. Maximum pressure withstood during prototype tests;
   h. Maximum quantity of contained radioactive material;
   i. Radiotoxicity of contained radioactive material; and
   j. Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

6. The Radiation Safety Officer and/or authorized user must have training and experience requirements consistent with training specified in 180 NAC 15-018.01.

<u>3-014.13 Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications</u>

1. An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 180 NAC 3-007.04 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

   a. The applicant satisfies the general requirements specified in 180 NAC 3-011;

b. 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 year a radiation dose in excess of 10% of the annual limits specified in 180 NAC 4-005.01; and

c. 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.

2. In the case of an industrial product or device whose unique benefits are questionable, the Department will approve an application for a specific license under 180 NAC 3-014.13 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.

3. The Department may deny any application for a specific license under 180 NAC 3-014.13 if the end use or uses of the industrial product or device cannot be reasonably foreseen.

4. Each person licensed pursuant to 180 NAC 3-014.13 item 1 must:

a. 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;

b. 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;

c. 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";

d. Furnish:

(1) A copy of the general license contained in 180 NAC 3-007.04 and a copy of Department Form NRH-11 to each person to whom the

licensee transfers depleted uranium in a product or device for use pursuant to the general license contained in 180 NAC 3-007.04; or

(2) A copy of the general license contained in the U.S. Nuclear Regulatory Commission or Agreement State's regulation equivalent to 180 NAC 3-007.04 and a copy of the U.S. Nuclear Regulatory Commission or Agreement State's certificate; or alternatively, furnish a copy of the general license contained in 180 NAC 3-007.04 and a copy of Department Form NRH-11 to each person to whom the licensee transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in 180 NAC 3-007.04;

e. Report to the Department all transfers of industrial products or devices to persons for use under the general license in180 NAC 3-007.04. Such report must identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Department and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report must be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under 180 NAC 3-007.04 during the reporting period, the report must so indicate;

f. File a report which identifies each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report must be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person. The licensee must report:

(1) To the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in 10 CFR 40.25;

(2) To the responsible State agency all transfers of devices manufactured and distributed pursuant to 180 NAC 3-014.13 for use under a general license in that State's regulations equivalent to180 NAC 3-007.04;

(3) To U.S. Nuclear Regulatory Commission if no transfers have been made by the licensees during the reporting period;

(4) To the responsible Agreement State Agency, upon the request of the Department, if no transfers have been made to general licensees within a particular Agreement State during the reporting period; and

5. Keep records showing the name, address, and point of contact for each general licensee to whom the licensee transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 180 NAC 3-008.04 or equivalent regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State. The records must be maintained for a period of two years and must show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements.

6. The Radiation Safety Officer and/or authorized user must have training and experience consistent with the requirements of training specified in 180 NAC 15-018.01.

3-014.14 Serialization of Nationally Tracked Sources. Each licensee who manufactures a nationally tracked source after February 6, 2007, must assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

3-014.15 Acceptance Sampling Procedures Under Certain Specific Licenses.

1. A random sample shall be taken from each inspection lot of devices licensed under 10 CFR 32.14, 180 NAC 3-014.05, or 3-014.09 for which testing is required in accordance with the appropriate Sampling Table in 180 NAC 3-014.15 determined by the designated Lot Tolerance Percent Defective. If the number of defectives in the sample does not exceed the acceptance number in the appropriate Sampling Table 180 NAC 3-014.15, the lot will be accepted. If the number of defectives in the sample exceeds the acceptance number in the appropriate Sampling Table 180 NAC 3-014.15, the entire inspection lot will be rejected.

2. Single sampling tables for Lot Tolerance Percent Defective:
   a. Lot Tolerance Percent Defective 0.5 percent:

Lot Size	Sample Size	Acceptance No.
1 to 180	All	0
181 to 210	180	0
211 to 250	210	0
251 to 300	240	0
301 to 400	275	0
401 to 500	300	0

501 to 600	320	0
601 to 800	350	0
801 to 1,000	365	0
1,001 to 2,000	410	0
2,001 to 3,000	430	0
3,001 to 4,000	440	0
4,001 to 5,000	445	0
5,001 to 7,000	450	0
7,001 to 10,000	455	0
10,001 to 20,000	460	0
20,001 to 50,000	775	1
50,001 to 100,000	780	1

b. Lot Tolerance Percent Defective 1.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 120	All	0
121 to 150	120	0
151 to 200	140	0
201 to 300	165	0
300 to 400	175	0
401 to 500	180	0
501 to 600	190	0
601 to 800	200	0
801 to 1,000	205	0
1,000 to 3,000	220	0
3,001 to 5,000	225	0
5,001 to 10,000	230	0
10,001 to 100,000	390	1

c. Lot Tolerance Percent Defective 2.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 75	All	0
76 to 100	70	0
101 to 200	85	0
201 to 300	95	0
301 to 400	100	0
401 to 600	105	0
601 to 800	110	0
801 to 4,000	115	0
4,001 to 10,000	195	1
10,001 to 100,000	200	1

d. Lot Tolerance Percent Defective 3.0 percent:

Lot size	Sample Size	Acceptance No.

1 to 40	All	0
41 to 55	40	0
56 to 100	55	0
101 to 200	65	0
201 to 500	70	0
501 to 3,000	75	0
3,001 to 100,000	130	1

e. Lot Tolerance Percent Defective 4.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 35	All	0
36 to 50	34	0
51 to 100	44	0
101 to 200	50	0
201 to 2,000	55	0
2,001 to 100,000	95	1

f. Lot Tolerance Percent Defective 5.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 30	All	0
31 to 50	30	0
51 to 100	37	0
101 to 200	40	0
201 to 300	43	0
301 to 400	44	0
401 to 2,000	45	0
2,001 to 100,000	75	1

g. Lot Tolerance Percent Defective 7.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 25	All	0
26 to 50	24	0
51 to 100	28	0
101 to 200	30	0
201 to 300	31	0
301 to 800	32	0
801 to 1,000	33	0
1,001 to 100,000	55	1

h. Lot Tolerance Percent Defective 10.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 20	All	0
21 to 50	17	0

51 to 100	20	0
101 to 200	22	0
201 to 800	23	0
801 to 100,000	39	0

3-015 SPECIAL REQUIREMENTS FOR ISSUANCE OF SPECIFIC LICENSES FOR SOURCE MATERIAL MILLING: In addition to the requirements set forth in 180 NAC 3-011, a specific license for source material milling will be issued if the applicant submits to the Department a satisfactory application as described herein and meets the other conditions specified below:

3-015.01 An Application for a License to Receive Title to, Receive, Possess, and Use Source Material for Milling or ~~Byproduct~~ Radioactive Material as Defined in 180 NAC 1-002 must address the following:

1. Description of the proposed project or action;
2. Area/site characteristics including geology, topography, hydrology, and
3. Radiological and nonradiological impacts of the proposed project or action, including waterway and groundwater impacts;
4. Environmental effects of accidents;
5. Long-term impacts including decommissioning, decontamination, and reclamation; and meteorology;
6. Site and project alternatives.

3-015.02 Pursuant to 180 NAC 3-011.01, the applicant must not commence construction of the project until the Department has weighed the environmental, economic, technical, and other benefits against the environmental costs and has concluded that the issuance of the license is appropriate.

3-015.03 At least 1 full year prior to any major site construction, a pre-operational monitoring program must be conducted to provide complete baseline data on a milling site and its environs. Throughout the construction and operating phases of the mill, an operational monitoring program must be conducted to measure or evaluate compliance with applicable standards and regulations; to evaluate performance of control systems and procedures; to evaluate environmental impacts of operation; and to detect potential long-term effects.

3-015.04 Prior to issuance of the license, the applicant must establish financial surety arrangements consistent with the requirements of 180 NAC 3-011.02.

1. The amount of funds to be ensured by financial surety arrangements will be based on Department-approved cost estimates in an approved plan for decontamination and decommissioning of mill buildings and the milling site to levels which would allow unrestricted use of these areas upon decommissioning, and the reclamation of tailings and/or waste disposal areas. The licensee must submit this plan in conjunction with an environmental report that addresses the expected environmental impacts of the milling operation, decommissioning and tailings reclamation, and that evaluates alternatives for

mitigating these impacts. In establishing specific surety arrangements, the licensee's cost estimates will take into account total costs that would be incurred if an independent contractor were hired to perform the decommissioning and reclamation work. In order to avoid unnecessary duplication and expense, the Department may accept financial sureties that have been consolidated with financial surety arrangements established to meet requirements of other Federal or State agencies and/or local governing bodies for such decommissioning, decontamination, reclamation, and long-term site surveillance, provided such arrangements are considered adequate to satisfy these requirements and that portion of the surety which covers the decommissioning and reclamation of the mill, mill tailings site and associated areas, and the long-term funding charge are clearly identified. The licensee's surety mechanism will be reviewed annually by the Department to assure that sufficient funds will be available for completion of the reclamation plan if the work had to be performed by an independent contractor. The amount of surety liability should be adjusted to recognize any increases or decreases resulting from inflation, changes in engineering plans, activities performed, and any other conditions affecting costs. Regardless of whether reclamation is phased through the life of the operation or takes place at the end of operations, an appropriate portion of surety liability will be retained until final compliance with the reclamation plan is determined. This will yield a surety that is at least sufficient at all times to cover the costs of decommissioning, decontamination, and reclamation of the areas that are expected to be disturbed before the next license renewal. The term of the surety mechanism must be open ended, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance could be provided with a surety instrument which is written for a specified period of time (e.g., 5 years) which must be automatically renewed unless the surety agent notifies the beneficiary (the State regulatory agency) and the principal (the licensee) some reasonable time (e.g., 90 days) prior to the renewal date of their intention not to renew. In such a situation, the surety requirement still exists and the licensee would be required to submit an acceptable replacement surety within a brief period of time to allow at least 60 days for the regulatory agency to collect.

2. The total amount of funds for reclamation or long term surveillance and control will be transferred to the United States if title and custody of such material and its disposal site is transferred to the United States upon termination of a license. Such funds include, but are not limited to, sums collected for long term surveillance and control. Such funds do not, however, include monies held as surety where no default has occurred, and the reclamation or other bonded activity has been performed.

3-015.05 The applicant must provide procedures describing the means employed to meet the following requirements during the operational phase of any project:

1. Milling operations must be conducted so that all effluent releases are below the limits of 180 NAC 4 and are as low as is reasonably achievable.

2. The mill operator must conduct daily inspections of any tailings or waste retention systems. Such inspections must be conducted by a qualified engineer or scientist. Records of such inspections must be maintained for review by the Department.
3. The mill operator must immediately notify the Department of the following:

    a. Any failure in a tailings or waste retention system which results in a release of tailings or waste into unrestricted areas, and
    b. Any unusual conditions or conditions not contemplated in the design of the retention system which, if not corrected, could lead to failure of the system and result in a release of tailings or waste into unrestricted areas.

3-015.06 Continued Surveillance Requirements for Source Material Millings Having Reclaimed Residues.

1. The final disposition of tailings or wastes at source material milling sites should be such that the need for ongoing active maintenance is not necessary to preserve isolation. As a minimum, annual site inspections must be conducted by the government agency retaining ultimate custody of the site where tailings or wastes are stored to confirm the integrity of the stabilized tailings or waste systems and to determine the need, if any, for maintenance and/or monitoring. Results of the inspection must be reported to the Department within 60 days following each inspection. The Department may require more frequent site inspections, if, on the basis of a site-specific evaluation, such a need appears necessary due to the features of a particular tailings or waste disposal system.

2. If site surveillance or control requirements at a particular site are determined, on the basis of a site-specific evaluation, to be significantly greater than those specified in, 180 NAC 3-015.06, item 1 additional funding requirements may be specified by the Department. The charge will be reviewed annually to recognize or adjust for inflation.

3-016 ISSUANCE OF SPECIFIC LICENSES

3-016.01 Upon a determination that an application meets the requirements of the Act and the regulations of the Department, the Department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary, based on quantities and types of radioactive materials, proposed use and upon the training and experience of the user(s).

3-016.02 The Department may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material including the requirement of reports, keeping of records and to provide for inspections as it deems appropriate or necessary in order to:

1. Minimize danger to public health and safety or property; and
2. Prevent loss or theft of material subject to 180 NAC 3-016.02.

3-017 SPECIFIC TERMS AND CONDITIONS OF LICENSE

3-017.01 Each license issued pursuant to 180 NAC 3, 5, 7, 12, 14 and 19 will be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Department.

3-017.02 No license issued or granted under 180 NAC 3, 5, 7, 12, 14, and 19 and no right to possess or utilize radioactive material granted by any license issued pursuant to 180 NAC 3, 5, 7, 12, 14, and 19 may 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 Department , after securing full information find that the transfer is in accordance with the provisions of the Act, and gives its consent in writing.

3-017.03 Each person licensed by the Department pursuant to,180 NAC 3, 5, 7, 12, 14 and 19 must confine use and possession of the material licensed to the locations and purposes authorized in the license.

3-017.04 Each licensee must notify the Department in writing when the licensee decides to permanently discontinue all activities involving materials under the license. This notification requirement applies to all specific licenses issued under,180 NAC 3, 5, 7, 12, 14, and 19.

3-017.05 Each general licensee that is required to register by 180 NAC 3-005 and each specific licensee must notify the Department, 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. The licensee;
2. An entity (as that term is defined in 11 U.S.C. 101(15)) (attached hereto as Attachment Number 3-1 and incorporated herein by this reference) 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)) (attached hereto as Attachment Number 3-1 and incorporated herein by this reference) of the licensee.
4. This notification must indicate:

    a. The bankruptcy court in which the petition for bankruptcy was filed; and
    b. The date of the filing of the petition.

3-017.06 Security requirements for portable gauges. Each portable gauge licensee must use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

3-017.07 Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators must test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with180 NAC 7-045. The licensee musl record the results of each test and retain each record for 3 years after the record is made.

3-017.08 Positron Emission Tomography (PET)

1. Authorization under 180 NAC 3-010-11 to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.
2. Each licensee authorized under 180 NAC 3-010.11 to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium must:
   a. Satisfy the labeling requirements in 180 NAC 3-014.10, item 1.d. for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.
   b. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 180 NAC 3-014.10, item 3.
3. A licensee that is a pharmacy authorized under 180 NAC 3-010.11 to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium will require that any individual that prepares PET radioactive drugs must be:
   a. An authorized nuclear pharmacist that meets the requirements in 180 NAC 3-014.10, item 2.b. or
   b. An individual under the supervision of an authorized nuclear pharmacist as specified in 180 NAC 7-018.
4. A pharmacy, authorized under 180 NAC 3-010.11 to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of 180 NAC 3-014.10, item 2.e.

3-018 FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING

3-018.01 Each:

1. Applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in 180 NAC 4, Appendix 4-F must submit a decommissioning funding plan as described in 180 NAC 3-018.05. The decommissioning funding plan must also be

submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix 4-F of 180 NAC 4.

2. Holder of, or applicant for, any specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in 180 NAC 4, Appendix 4-F (or when a combination of isotopes is involved if R, as defined in 180 NAC 3-018.01, item 1, divided by 10^{12} is greater than 1), must submit a decommissioning funding plan as described in 180 NAC 3-018.05. ~~The decommissioning funding plan must be submitted to the Department by (two years from effective date of these regulations)~~**.**

3-018.02 Each applicant for a specific license authorizing possession and use of ~~byproduct~~radioactive material of half-life greater than 120 days and in quantities specified in 180 NAC 3-018.04 must either:

1. Submit a decommissioning funding plan as described in 180 NAC 3-018.05 or
2. Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 180 NAC 3-018.04 using one of the methods described in 180 NAC 3-018.06. 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 radioactive material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy 180 NAC 3-018.06 must be submitted to the Department before receipt of radioactive material. If the applicant does not defer execution of the financial instrument, the applicant must submit to the Department as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of 180 NAC 3-018.06.

3-018.03 Each:

1. Holder of a specific license issued on or after May 30, 1994 and of a type described in 180 NAC 3-018.01 or 3-018.02, must provide financial assurance for decommissioning in accordance with the criteria set for 180 NAC 3-018.03.
2. Holder of a specific license issued before May 30, 1994, and of a type described in 180 NAC 3-018.01 must submit, on or before May 30, 1994, and of type described in 180 NAC 3-018.01 must submit a decommissioning funding plan as described in 180 NAC 3-018.05 or a certification of financial assurance for decommissioning in an amount at least equal to $1,125,000 in accordance with the criteria set forth in 180 NAC 3-018.03, item 2. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee must include a decommissioning funding plan in any application for license renewal.
3. Holder of a specific license issued before May 30, 1994, and of a type described in 180 NAC 3-018.02 must submit, on or before May 30, 1994, a

certification of financial assurance for decommissioning in accordance with the criteria set forth in 180 NAC 3-018.03.

4. Waste collectors and waste processors, as defined in 180 NAC 4, Appendix 4-D, must provide financial assurance in an amount based on a decommissioning funding plan as described in 180 NAC 3-018.05. The decommissioning funding plan must include the cost of disposal of the maximum amount (curies) of radioactive material permitted by license, and the cost of disposal of the maximum quantity, by volume, of radioactive material which could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of 180 NAC 3. The decommissioning funding plan must be submitted by (two years from effective date of these regulations).

3-018.04 Table of required amounts of financial assurance for decommissioning by quantity of material. Licensees required to submit the $1,125,000 amount must do so by (one year from effective date of these regulations). Licensees required to submit the $113,000 or $225,000 amount must do so by (one and a half years from effective date of these regulations). Licensees having possession limits exceeding the upper bound of this table must base financial assurance on a decommission funding plan.

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of 180 NAC 4, Appendix 4-F in unsealed form. (For a combination of isotopes, if R, as defined in 180 NAC 3-018.01, item 1 divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.)	$1,125,000
Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of 180 NAC 4, Appendix 4-F in unsealed form. (For a combination of isotopes, if R, as defined in 180 NAC 3-018.01, item 1 divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.)	$225,000
Greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities of 180 NAC 4, Appendix 4-F in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in180 NAC 3-018.01, item 1 divided by 10^{10} is greater than 1, but R divided by 10^{12} is less than or equal to 1.)	$113,000

3-018.05 Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from 180 NAC 3-018.06, including means of adjusting cost estimates and associated funding levels periodically over the life of the facility. Cost estimates must be adjusted at intervals not to exceed three years. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for

decommissioning and a signed original of the financial statement obtained to satisfy the requirements of 180 NAC 3-018.06.

3-018.06 Financial assurance for decommissioning must be provided by one or more of the following methods:

1. Prepayment. 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. 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. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in 180 NAC 3, Appendix 3-F. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of 180 NAC 3-018.06, item 2. A guarantee of funds by the applicant or licensee for decommissioning based on a financial test may be used if the guarantee and test are as contained in 180 NAC 3, Appendix 3-D. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of 180 NAC 3-018.06, item 2 or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

   a. The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Department, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Department within 30 days after receipt of notification of cancellation.

   b. The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Department. An acceptable trustee 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.

c. The surety method or insurance must remain in effect until the Department has terminated the license.

3. An external sinking fund in which 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. 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. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in 180 NAC 3-018.06, item 2.

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 Table in 180 NAC 3-018.04, and indicating that funds for decommissioning will be obtained when necessary.

3-018.07 Each person licensed under 180 NAC 3, 5, 7, 12, 14 and 19 must keep records of information important to the decommissioning of the facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with 180 NAC 3-017.02, licensees must transfer all records described in 180 NAC 3-018.07 to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Department considers important to decommissioning consists of:

1. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. 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. These records must 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 used and/or stored and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee must substitute appropriate records of available information concerning these areas and locations.

3. Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or ~~byproduct~~radioactive materials having only half-lives of less than 65 days, a list contained in a single document and updated every 2 years, of the following:

   a. All areas designated and formerly designated as restricted areas as defined under 180 NAC 1-002 ;
   b. All areas outside of restricted areas that require documentation under 180 NAC 3-018.07, item 1.;
   c. All areas outside of restricted areas where current and previous wastes have been buried as documented under 180 NAC 4-054; and
   d. All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under 180 NAC 4-040.

4. 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.

3-018.08 Each person applying for a specific license authorizing the possession and use of more than 100 mCi of source material in a readily dispersible form must submit a decommissioning funding plan as described in 180 NAC 3-018.05.

3-018.09 Each person applying for a specific license authorizing the possession and use of quantities of source material greater than 10 mCi but less than or equal to 100 mCi in a readily dispersible form shall either:

1. Submit a decommissioning funding plan as described in 180 NAC 3-018.05 or
2. Submit a certification that financial assurance for decommissioning has been provided in the amount of $225,000 using one of the methods described in 180 NAC 3-018.06. 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 before the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of 180 NAC 3-018.06 must be submitted to Department prior to receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant must submit to Department, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of 180 NAC 3-18.06.

3-019 EXPIRATION AND TERMINATION OF LICENSES AND DECOMMISSIONING OF SITES AND SEPARATE BUILDINGS OR OUTDOOR AREAS

3-019.01 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 under 180

NAC 3-020 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 Department makes a final determination to deny the renewal application or if the determination states an expiration date, the expiration date stated in the determination.

3-019.02 Each specific license revoked by the Department expires at the end of the day on the date of the Department's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Department Order.

3-019.03 Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Department notifies the licensee in writing that the license is terminated. During this time, the licensee must-

1. Limit actions involving radioactive material to those related to decommissioning; and
2. Continue to control entry to restricted area until they are suitable for release in accordance with Department requirements.

3-019.04 Within 60 days of the occurrence of any of the following, consistent with the administrative directions in 180 NAC 1-012, each licensee must provide notification to the Department 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 Department requirements, or submit within 12 months of notification a decommissioning plan, if required by 180 NAC 3-019.07 and begin decommissioning upon approval of that plan if -

1. The license has expired pursuant to180 NAC 3-019.01 and 3-019.02; or
2. The licensee has decided to permanently cease principal activities, as defined in 180 NAC 3-002, 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 Department requirements; or
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 Department requirements.

3-019.05 Coincident with the notification required by 180 NAC 3-019.04, the licensee must maintain in effect all decommissioning financial assurances established by the licensee pursuant to 180 NAC 3-018 in conjunction with a license issuance or renewal or as required by 180 NAC 3-019.05. The amount of the financial assurance must be

increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to 180 NAC 3-019.07, item 4.e.

1. Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan must do so.
2. Following 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 Department.

3-019.06 The Department may grant a request to extend the time periods established in 180 NAC 3-019.04 if the Department determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to 180 NAC 3-019.04. The schedule for decommissioning set forth in 180 NAC 3-019.04 may not commence until the Department has made a determination on the request.

3-019.07 Decommissioning Plans

1. A decommissioning plan must 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 Department and these procedures could increase potential health and safety impacts to workers or to the public; such as in the following cases;

    a. Procedures would involve techniques not applied routinely during cleanup or maintenance operations;
    b. Workers could be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;
    c. Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or
    d. Procedures could result in significantly greater releases of radioactive materials to the environment than those associated with operation.

2. The Department may approve an alternate schedule for submittal of a decommissioning plan required pursuant to 180 NAC 3-019.04 if the Department 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.

3. Procedures such as those listed in 180 NAC 3-019.07, item 1 with potential health and safety impacts may not be carried out prior to the approval of the decommissioning plan.

4. The proposed decommissioning plan for the site or separate building or outdoor area must include:

a. A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;
b. A description of planned decommissioning activities;
c. A description of methods used to ensure the protection of workers and the environment against radiation hazards during decommissioning;
d. A description of the planned final radiation survey; and
e. 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.
f. For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan must include a justification for the delay based on the criteria in 180 NAC 3-019.09.

5. The proposed decommissioning plan will be approved by the Department 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 adequately protected.

3-019.08 Decommissioning

1. Except as provided in 180 NAC 3-019.09, licensees must complete decommissioning of the site or separate building or outdoor area as soon as is practicable but no later than 24 months following the initiation of decommissioning.

2. Except as provided in 180 NAC 3-019.09, when decommissioning involves the entire site, the licensee must request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

3-019.09 The Department 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 Department 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 Department may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored

natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

3-019.10 As the final step in decommissioning, the licensee must:

1. Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed Department Form NRH-60 or equivalent information; 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 must, as appropriate:

   a. Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters - removable and fixed - for surfaces, megabecquerels (microcuries) per milliliter for water, becquerels (picocuries) per gram for solids such as soil or concrete; and

   b. Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

3-019.11 Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Department determines:

1. Radioactive material has been properly disposed;

2. Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

3. Demonstration of suitability for release.

   a. A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with Department requirements; or
   b. Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with Department requirements.

4. Records required by 180 NAC 3-030.06 and 3-030.08 have been received.

3-020 RENEWAL OF LICENSES

3-020.01 Applications for renewal of specific licenses must be filed in accordance with 180 NAC 3-010.

3-020.02 In any case in which a licensee, not less than 30 days prior to expiration of the existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license will not expire until the application has been finally determined by the Department.

3-021 AMENDMENT OF LICENSES AT REQUEST OF LICENSEE: Applications for amendment of a license must be filed in accordance with 180 NAC 3-010 and must specify the respects in which the licensee desires his/her license to be amended and the grounds for such amendment.

3-022 DEPARTMENT ACTION ON APPLICATIONS TO RENEW AND AMEND: In considering an application by a licensee to renew or amend his/her license, the Department will apply the criteria set forth in 180 NAC 3-011, 3-013 or 3-014, and 3-015 and in 180 NAC 5, 7, 12, 14 or 19 as applicable.

3-023 RESERVED

3-024 RESERVED

3-025 TRANSFER OF MATERIAL

3-025.01 No licensee shall transfer radioactive material except as authorized pursuant to180 NAC 3-025.

3-025.02 Except as otherwise provided in his/her license and subject to the provisions of 180 NAC 3-025.03 and 3-025.04, any licensee may transfer radioactive material:

1. To the Department;[11]
2. To the U.S. Department of Energy;
3. To any person exempt from the regulations to the extent permitted under such exemption;
4. To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Department, the U.S. Nuclear Regulatory Commission, or any Agreement State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Department, or any Agreement State, or
5. As otherwise authorized by the Department in writing.
6. To the agency in any Agreement State which regulates radioactive material pursuant to an agreement under § 274 of the Atomic Energy Act of 1954[12]

[11]A licensee may transfer material to the Department only after receiving prior approval from the Department.
[12]Ibid. p. 64

3-025.03 Before transferring radioactive material to a specific licensee of the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State, or to a general licensee who is required to register with the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State prior to receipt of the radioactive material, the licensee transferring the material must verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

3-025.04 The following methods for the verification required by 180 NAC 3-025.03 are acceptable:

1. The transferor may have in his/her possession, and read, a current copy of the transferee's specific license or registration certificate;
2. The transferor may have in his/her possession a written certification by the transferee that s/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 s/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, that the oral certification is confirmed in writing within ten days;
4. The transferor may obtain other sources of information compiled by a reporting service from official records of the Department, the U.S. Nuclear Regulatory Commission, 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 180 NAC 3-025.04, items 1. through 4. are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Department, the U.S. Nuclear Regulatory Commission, or the licensing agency of an Agreement State that the transferee is licensed to receive the radioactive material.

3-025.05 Preparation for shipment and transport of radioactive material must be in accordance with the provisions of 180 NAC 13.

3-026 REPORTING REQUIREMENTS

3-026.01 Immediate Report: Each licensee must notify the Department 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 radiation or radioactive materials that could exceed regulatory limits or releases of radioactive material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

3-026.02 Twenty-Four Hour Report: Each licensee must notify the Department within 24 hours after the discovery of any of the following events involving 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 180 NAC 4, Appendix 4-B for the material; and
   c. Has access to the area restricted 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 regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;
   b. The equipment is required to be available and operable when 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 spreadable radioactive contamination on the individual's clothing or body.
4. An unplanned fire or explosion damaging any radioactive material or any device, container, or equipment containing radioactive material when:

   a. The quantity of radioactive material involved is greater than five times the lowest annual limit on intake specified in 180 NAC 4, Appendix 4-B for the material; and
   b. The damage affects the integrity of the radioactive material or its container.

3-026.03 Preparation and submission of reports: Reports made by licensees in response to the requirements of 180 NAC 3-026.03 must be made as follows:

1. Licensees must make reports required by 180 NAC 3-026.01 and 3-026.02 by telephone to the Department.[13] To the extent that the information is available at the time of notification, the information provided in these reports must include:

[13]The telephone number for the Department is (402) 471-2168.

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 radioactive material involved; and
e. Any personnel radiation exposure data available.

2. Written report. Each licensee who makes a report required by 180 NAC 3-026.01 or 180 NAC 3-026.02 must submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations 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 must be sent to:

Department of Health and Human Services
Division of Public Health, Radiological Health
301 Centennial Mall South
P.O. Box 95026
Lincoln, NE 68509-5026

The reports must 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 radioactive material involved;
d. Date and time of the event;
e. Corrective actions taken or planned and the results of any evaluations or assessments; and
f. The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

3-027 MODIFICATION AND REVOCATION OF LICENSES: The terms and conditions of all licenses will be subject to amendment, revision, modification, limitation, suspension or revocation upon:

3-027.01 Amendments to the Radiation Control Act or the rules and regulations adopted pursuant thereto;

3-027.02 Voluntary application for license amendment, revision, modification, limitation, suspension or surrender made by the licensee;

3-027.03 Disciplinary action pursuant to 180 NAC 17 ;or

3-027.04 Pursuant to emergency order as provided by § 71-3513(6) of the Act.

RECIPROCITY

3-028 RECIPROCAL RECOGNITION OF LICENSES

3-028.01 Licenses of Radioactive Material Except Special Nuclear Material in Quantities Sufficient to Form a Critical Mass

1. Subject to Title 180, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or any Agreement State, and issued by the Department 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 12 consecutive months.~~calendar year~~ provided that:

   a. The licensing document does not limit the activity authorized by such document to specified installations or locations;
   b. The out-of-state licensee notifies the Department in writing at least three (3) days prior to engaging in such activity. Such notification must include:

      (1) Name of company for whom services will be performed, an individual to be contacted representing the company and telephone number.
      (2) The exact location, start date, duration, and type of activity to be conducted.
      (3) The name(s), documentation of training, and in-state address(es) of the individual(s) performing the activity,
      (4) The identification of the sources of radiation to be used,
      (5) A copy of the pertinent license,
      (6) A copy of the licensee's operating and emergency procedures, and
      (7) An annual fee as specified in 180 NAC 18 .
      (8) The out-of-state licensee notifies the Department of changes in work locations, radioactive material, or work activities different from the information contained on the initial notification.

      If, for a specific case, the three day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner. The Department 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 180 NAC 3-028.01.

c. The out-of-state licensee complies with all applicable regulations of the Department and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Department;
d. The out-of-state licensee maintains a current copy of the appropriate license, and all amendments thereto, issued by the Department;
e. The out-of-state licensee supplies such other information as the Department may request;
f. The out-of-state licensee must not transfer or dispose of radioactive material possessed or used under the general license provided in 180 NAC 3-028.01, item 1 except by transfer to a person:
   (1) Specifically licensed by the Department or by the U.S. Nuclear Regulatory Commission to receive such material, or
   (2) Exempt from the requirements for a license for such material under 180 NAC 3-004.01.

2. Notwithstanding the provisions of 180 NAC 3-028.01, item 1 any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in 180 NAC 3-008.04, item 1 within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service such a device in this State provided that:

   a. Such person must file a report with the Department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each report must identify each general licensee to whom the device is transferred by name and address, the type and model of device transferred, and the quantity and type of radioactive material contained in the device;
   b. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an Agreement State;
   c. Such person must assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and
   d. The holder of the specific license must furnish to each general licensee to whom s/he transfers the device or on whose premises s/he installs the device a copy of the general license contained in 180 NAC 3-008.04.
3. The Department 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 such action is necessary in order to achieve compliance with Title 180 or to prevent undue hazard to public health and safety or property.

3-028.02 Recognition of Agreement State Licensees

1. Before radioactive materials can be used at a temporary job site within the State at any Federal facility, the jurisdictional status of the job site must be determined. If the jurisdictional status is unknown, the Federal agency should be contacted to determine if the job site is under exclusive Federal jurisdiction.

   a. In areas of exclusive Federal jurisdiction, the general license is subject to all the applicable rules, regulations, orders and fees of the U.S. Nuclear Regulatory Commission, and
   b. Authorizations for use of radioactive materials at job sites under exclusive Federal jurisdiction must be obtained from the U.S. Nuclear Regulatory Commission by either (1) filing a NRC Form-241 in accordance with 10 CFR 150.20(b); or (2) by applying for a specific U.S. Nuclear Regulatory Commission license.

2. Before radioactive material can be used at a temporary job site in another State, authorization must be obtained for the State if it is an Agreement State, or from the U.S. Nuclear Regulatory Commission for any non-Agreement State, either by filing for reciprocity or applying for a specific license.

3-029 RESERVED

3-030 RECORDS

3-030.01 Each person who receives radioactive material pursuant to a license issued pursuant to 180 NAC 3, 5, 7, 12, 14, and 19 must keep records showing the receipt, use, transfer, and disposal of such radioactive material.

3-030.02 Records which are required pursuant to 180 NAC 3-030.01 must be maintained for the period specified by the appropriate regulation. If a retention period is not otherwise specified by regulation such records must be maintained for a period of one year after the records of the licensee have been inspected by the Department unless any litigation, claim, negotiation, audit, licensure action, or other action involving the records has been initiated before the expiration of the one-year period, in which case the records must be retained until the completion of the action and resolution of all issues, or until the end of the regular one-year period, whichever is later.

3-030.03 Records of receipt of radioactive material which must be maintained pursuant to 180 NAC 3-030.01 will be maintained as long as the licensee retains possession of the radioactive material and for five years following transfer, or disposition of the radioactive material and;

1. Records of transfer of radioactive material must be maintained by the licensee who transferred the material until the Department authorizes their disposition and;

2. Records of disposal of radioactive material must be maintained in accordance with 180 NAC 4-054.
3. If radioactive material is combined or mixed with other licensed material and subsequently treated in a manner which makes direct correlation of a receipt record with a transfer, export, or disposition record impossible, evaluative techniques such as first-in-first-out may be used for purposes of the records retention requirements of 180 NAC 3-030.

3-030.04 Records which must be maintained pursuant to 180 NAC 3-030.01 may be the original or reproduced copy of microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Department regulations. The record may also be stored in electronic media with the capability for producing legible, accurate and complete record during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee must maintain adequate safeguards against tampering with and loss of records.

3-030.05 If there is a conflict between the Department's regulations in 180 NAC 3, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in 180 NAC 3-030 for such records will apply unless the Department pursuant to 180 NAC 1-003.01 has granted a specific exemption from the record retention requirements specified in 180 NAC 3-030.05.

3-030.06 Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, must forward the following records to the Department:

1. Records of disposal of licensed material made under 180 NAC 4-040, 4-041, 4-042 and 4-043; and
2. Records required by 180 NAC 4-048.02, item 4.

3-030.07 If licensed activities are transferred or assigned in accordance with 180 NAC 3-017.02, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, must transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

1. Records of disposal of licensed material made under, 180 NAC 3-038, 3-039, 3-040, 3-041 and
2. Records required by 180 NAC 4-048.02, item 4.

3-030.08 Prior to license termination, each licensee must forward the records required by 180 NAC 3-018.07 to the Department.

THIS PAGE WAS INTENTIONALLY LEFT BLANK

EXEMPT CONCENTRATIONS:

Element (atomic number)	Isotope	Column I Gas Concentration µCi/ml*	Column II Liquid and Solid Concentration µCi/ml**
Antimony (51)	Sb-122		3E-4
	Sb-124		2E-4
	Sb-125		1E-3
Argon (18)	Ar-37	1E-3	
	Ar-41	4E-7	
Arsenic (33)	As-73		5E-3
	As-74		5E-4
	As-76		2E-4
	As-77		8E-4
Barium (56)	Ba-131		2E-3
	Ba-140		3E-4
Beryllium (4)	Be-7		2E-2
Bismuth (83)	Bi-206		4E-4
Bromine (35)	Br-82	4E-7	3E-3
Cadmium (48)	Cd-109		2E-3
	Cd-115m		3E-4
	Cd-115		3E-4
Calcium (20)	Ca-45		9E-5
	Ca-47		5E-4
Carbon (6)	C-14	1E-6	8E-3
Cerium (58)	Ce-141		9E-4
	Ce-143		4E-4
	Ce-144		1E-4
Cesium (55)	Cs-131		2E-2
	Cs-134m		6E-2
	Cs-134		9E-5
Chlorine (17)	Cl-38	9E-7	4E-3
Chromium (24)	Cr-51		2E-2
Cobalt (27)	Co-57		5E-3
	Co-58		1E-3

Element (atomic number)	Isotope	Column I Gas Concentration µCi/ml*	Column II Liquid and Solid Concentration µCi/ml**
	Co-60		5E-4
Copper (29)	Cu-64		3E-3
Dysprosium (66)	Dy-165		4E-3
	Dy-166		4E-4
Erbium (68)	Er-169		9E-4
	Er-171		1E-3
Europium (63)	Eu-152 (T/2=9.2hrs)		6E-4
	Eu-155		2E-3
Fluorine (9)	F-18	2E-6	8E-3
Gadolinium (64)	Gd-153		2E-3
	Gd-159		8E-4
Gallium (31)	Ga-72		4E-4
Germanium (32)	Ge-71		2E-2
Gold (79)	Au-196		2E-3
	Au-198		5E-4
	Au-199		2E-3
Hafnium (72)	Hf-181		7E-4
Hydrogen (1)	H-3	5E-6	3E-2
Indium (49)	In-113m		1E-2
	In-114m		2E-4
Iodine (53)	I-126	3E-9	2E-5
	I-131	3E-9	2E-5
	I-132	8E-8	6E-4
	I-133	1E-8	7E-5
	I-134	2E-7	1E-3
Iridium (77)	Ir-190		2E-3
	Ir-192		4E-4
	Ir-194		3E-4
Iron (26)	Fe-55		8E-3
	Fe-59		6E-4
Krypton (36)	Kr-85m	1E-6	
	Kr-85	3E-6	
Lanthanum (57)	La-140		2E-4

Element (atomic number)	Isotope	Column I Gas Concentration µCi/ml*	Column II Liquid and Solid Concentration µCi/ml**
Lead (82)	Pb-203		4E-3
Lutetium (71)	Lu-177		1E-3
Manganese (25)	Mn-52		3E-4
	Mn-54		1E-3
	Mn-56		1E-3
Mercury (80)	Hg-197m		2E-3
	Hg-197		3E-3
	Hg-203		2E-4
Molybdenum (42)	Mo-99		2E-3
Neodymium (60)	Nd-147		6E-4
	Nd-149		3E-3
Nickel (28)	Ni-65		1E-3
Niobium (Columbium)(41)	Nb-95		1E-3
	Nb-97		9E-3
Osmium (76)	Os-185		7E-4
	Os-191m		3E-2
	Os-191		2E-3
	Os-193		6E-4
Palladium (46)	Pd-103		3E-3
	Pd-109		9E-4
Phosphorus (15)	P-32		2E-4
Platinum (78)	Pt-191		1E-3
	Pt-193m		1E-2
	Pt-197m		1E-2
	Pt-197		1E-3
Potassium (19)	K-42		3E-3
Praseodymium (59)	Pr-142		3E-4
	Pr-143		5E-4
Promethium (61)	Pm-147		2E-3
	Pm-149		4E-4
Rhenium (75)	Re-183		6E-3
	Re-186		9E-4
	Re-188		6E-4

Element (atomic number)	Isotope	Column I Gas Concentration µCi/ml*	Column II Liquid and Solid Concentration µCi/ml**
Rhodium (45)	Rh-103m		1E-1
	Rh-105		1E-3
Rubidium (37)	Rb-86		7E-4
Ruthenium (44)	Ru-97		4E-3
	Ru-103		8E-4
	Ru-105		1E-3
	Ru-106		1E-4
Samarium (62)	Sm-153		8E-4
Scandium (21)	Sc-46		4E-4
	Sc-47		9E-4
	Sc-48		3E-4
Selenium (34)	Se-75		3E-3
Silicon (14)	Si-31		9E-3
Silver (47)	Ag-105		1E-3
	Ag-110m		3E-4
	Ag-111		4E-4
Sodium (11)	Na-24		2E-3
Strontium (38)	Sr-85		1E-3
	Sr-89		1E-4
	Sr-91		7E-4
	Sr-92		7E-4
Sulfur (16)	S-35	9E-8	6E-4
Tantalum (73)	Ta-182		4E-4
Technetium (43)	Tc-96m		1E-1
	Tc-96		1E-3
Tellurium (52)	Te-125m		2E-3
	Te-127m		6E-4
	Te-127		3E-3
	Te-129m		3E-4
	Te-131m		6E-4
	Te-132		3E-4
Terbium (65)	Tb-160		4E-4
Thallium (81)	Tl-200		4E-3

Element (atomic number)	Isotope	Column I Gas Concentration µCi/ml*	Column II Liquid and Solid Concentration µCi/ml**
	Tl-201		3E-3
	Tl-202		1E-3
	Tl-204		1E-3
Thulium (69)	Tm-170		5E-4
	Tm-171		5E-3
Tin (50)	Sn-113		9E-4
	Sn-125		2E-4
Tungsten (Wolfram)(74)	W-181		4E-3
	W-187		7E-4
Vanadium (23)	V-48		3E-4
Xenon (54)	Xe-131m	4E-6	
	Xe-133	3E-6	
	Xe-135	1E-6	
Ytterbium (70)	Yb-175		1E-3
Yttrium (39)	Y-90		2E-4
	Y-91m		3E-2
	Y-91		3E-4
	Y-92		6E-4
	Y-93		3E-4
Zinc (30)	Zn-65		1E-3
	Zn-69m		7E-4
	Zn-69		2E-2
Zirconium (40)	Zr-95		6E-4
	Zr-97		2E-4
Beta and/or gamma emitting radioactive material not listed above with half-life less than 3 years		1E-10	1E-6

*Values are given in Column I only for those materials normally used as gases.

**µCi/gm for solids.

NOTE 1: Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in 180 NAC 3, Appendix 003-A the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of 180 NAC 3-004 where there is involved a combination of isotopes, the limit for the combination should 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 Appendix 003-A for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

EXAMPLE:

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

NOTE 3: To convert μCi/ml to SI units of megabecquerels per liter multiply the above value by 37.

EXAMPLE: Zirconium (40) Zr-97 2E-4 μCi/ml multiplied by 37 is equivalent to 74E+4 MBq /l)

APPENDIX 3-B

Radioactive Material	Microcuries
EXEMPT QUANTITIES	
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

APPENDIX 3-B

Radioactive Material	Microcuries
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 68 (Ge 68)	10
Germanium-71 (Ge 71)	100
Gold 195 (Au 195)	10
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

APPENDIX 3-B

Radioactive Material	Microcuries
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

APPENDIX 3-B

Radioactive Material	Microcuries
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
Sulphur-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

APPENDIX 3-B

Radioactive Material	Microcuries
Yttrium 88 (Y 88)	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

NOTE: To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

EXAMPLE: Zirconium-97 (10 μCi multiplied by 37 is equivalent to 370 kBq).

APPENDIX 3-B

This page was left blank intentionally.

APPENDIX 3-C

LIMITS FOR BROAD LICENSES 180 NAC 3-013:

Radioactive Material	Col. I curies	Col. II curies
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1.0
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1.0
Cesium-134m	100	1.0
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1.0
Chromium-51	100	1.0
Cobalt-57	10	0.1
Cobalt-58m	100	1.0
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1.0
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2h)	10	0.1
Europium-152 (13 y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01

APPENDIX 3-C

Radioactive Material	Col. I curies	Col. II curies
Fluorine-18	100	1.0
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1.0
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1.0
Indium-113m	100	1.0
Indium-114m	1	0.01
Indium-115m	100	1.0
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1.0
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1.0
Osmium-185	1	0.01

APPENDIX 3-C

Radioactive Material	Col. I curies	Col. II curies
Osmium-191m	100	1.0
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1.0
Platinum-193	10	0.1
Platinum-197m	100	1.0
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10.0
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1.0
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10.0
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1

APPENDIX 3-C

Radioactive Material	Col. I curies	Col. II curies
Sulphur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1.0
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1.0
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10.0
Xenon-133	100	1.0
Xenon-135	100	1.0
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1.0
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than source material, special nuclear material, or alpha emitting radioactive material not listed above.	0.1	0.001

APPENDIX 3-C

NOTE: To convert curies (Ci) to SI units of gigabecquerels (GBq) multiply the above values by 37

EXAMPLE: Zirconium-97 (Col. II) (0.01 Ci multiplied by 37 is equivalent to 0.37 GBq)

APPENDIX 3-D

Criteria Relating to Use of Financial Tests and Self-Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

1. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section 2 of this Appendix. The terms of this self-guarantee are in Section 3 of this Appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for obtaining a self-guarantee.

2. Financial Test

A. To pass the financial test, a company must meet all of the following criteria:

(1) Tangible net worth of at least 10 times the total current decommissioning cost estimate (or the current amount if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and a parent-guarantor.

(2) Assets located in the United States amounting to at least 90% of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and a parent-guarantor.

(3) A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poor's (S&P) or Aaa, Aa, or A as issued by Moody's.

B. To pass the financial test, a company must meet all of the following additional requirements:

(1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

(2) The company's independent certified public accountant must have compared the data used by the 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 must inform the Department within 90 days of any matters coming to the attention of the auditor that 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.

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

C. If the company no longer meets the requirements of Section 2.A. of this Appendix, the licensee must send immediate notice to the Department of its intent to establish

alternate financial assurance as specified in the Department's regulations within 120 days of such notice.

3. Company Self-Guarantee
   The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

   A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Department. Cancellation may not occur, however during the 120 days beginning on the date of receipt of the notice of cancellation by the Department, as evidenced by the return receipt.

   B. The licensee must provide alternative financial assurance as specified in the Department's regulations within 90 days following receipt by the Department of a notice of cancellation of the guarantee.

   C. The guarantee and financial test provisions must remain in effect until the Department has terminated the license or until another financial assurance method acceptable to the Department has been put in effect by the licensee.

   D. The licensee will promptly forward to the Department and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of Section 13 of the Securities and Exchange Act of 1934.

   E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moody's, the licensee will provide notice in writing of such fact to the Department within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by both Standard and Poors or Moody's, the licensee no longer meets the requirements of Section 2.A. of this Appendix.

   F. The applicant or licensee must provide to the Department a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Department, the licensee will set up and fund a trust in the amount of the current cost estimate for decommissioning.

APPENDIX 3-E

Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release.

Radioactive material[1]	Release fraction	Quantity (curies)
Actinium-228	0.001	4,000
Americium-241	0.001	2
Americium-242	0.001	2
Americium-243	0.001	2
Antimony-124	0.01	4,000
Antimony-126	0.01	6,000
Barium-133	0.01	10,000
Barium-140	0.01	30,000
Bismuth-207	0.01	5,000
Bismuth-210	0.01	600
Cadmium-109	0.01	1,000
Cadmium-113	0.01	80
Calcium-45	0.01	20,000
Californium-252	0.00	19 (20 mg)
Carbon-14 (Non CO)	0.01	50,000
Cerium-141	0.01	10,000
Cerium-144	0.01	300
Cesium-134	0.01	2,000
Cesium-137	0.01	3,000
Chlorine-36	0.5	100
Chromium-51	0.01	300,000
Cobalt-60	0.001	5,000
Copper-64	0.01	200,000
Curium-242	0.001	60
Curium-243	0.001	3
Curium-244	0.001	4
Curium-245	0.001	2
Europium-152	0.01	500
Europium-154	0.01	400
Europium-155	0.01	3,000
Germanium-68	0.01	2,000
Gadolinium-153	0.01	5,000
Gold-198	0.01	30,000
Hafnium-172	0.01	400
Hafnium-181	0.01	7,000
Holmium-166m	0.01	100
Hydrogen-3	0.5	20,000
Iodine-125	0.5	10
Iodine-131	0.5	10

APPENDIX 3-E

Radioactive material[1]	Release fraction	Quantity (curies)
Indium-114m	0.01	1,000
Iridium-192	0.001	40,000
Iron-55	0.01	40,000
Iron-59	0.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	0.01	8
Manganese-56	0.01	60,000
Mercury-203	0.01	10,000
Molybdenum-99	0.01	30,000
Neptunium-237	0.001	2
Nickel-63	0.01	20,000
Niobium-94	0.01	300
Phosphorus-32	0.5	100
Phosphorus-33	0.5	1,000
Polonium-210	0.01	10
Potassium-42	0.01	9,000
Promethium-145	0.01	4,000
Promethium-147	0.01	4,000
Radium-226	0.001	100
Ruthenium-106	0.01	200
Samarium-151	0.01	4,000
Scandium-46	0.01	3,000
Selenium-75	0.01	10,000
Silver-110m	0.01	1,000
Sodium-22	0.01	9,000
Sodium-24	0.01	10,000
Strontium-89	0.01	3,000
Strontium-90	0.01	90
Sulfur-35	0.5	900
Technetium-99	0.01	10,000
Technetium-99m	0.01	400,000
Tellurium-127m	0.01	5,000
Tellurium-129m	0.01	5,000
Terbium-160	0.01	4,000
Thulium-170	0.01	4,000
Tin-113	0.01	10,000
Tin-123	0.01	3,000
Tin-126	0.01	1,000
Titanium-44	0.01	100
Vanadium-48	0.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	0.01	2,000
Zinc-65	0.01	5,000
Zirconium-93	0.01	400
Zirconium-95	0.01	5,000
Any other beta-gamma emitter	0.01	10,000

APPENDIX 3-E

Radioactive material[1]	Release fraction	Quantity (curies)
Mixed fission products	0.01	1,000
Mixed Corrosion products	0.01	10,000
Contaminated equipment beta-gamma	0.001	10,000
Irradiated material, any form other than solid noncombustible	0.01	1,000
Irradiated material, solid noncombustible	0.001	10,000
Mixed radioactive waste, beta-gamma	0.01	1,000
Packaged mixed waste, beta-gamma[2]	0.001	10,000
Any other alpha emitter	0.001	2
Contaminated equipment, alpha	0.0001	20
Packaged waste, alpha[2]	0.0001	20
Combinations of radio-active materials listed above[1]	-----	-----

[1]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 180 NAC 3, Appendix 003-E exceeds one.

[2]Waste packaged in Type B containers does not require an emergency plan.

APPENDIX 3-F

Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

I. Introduction

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 appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

II. Financial Test

A. To pass the financial test, the parent company must meet the criteria of either paragraph A.1 or A.2 of this section:

1. The parent company must have:

(i) 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

(ii) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used); and

(iii) Tangible net worth of at least $10 million; and

(iv) Assets located in the United States amounting to at least 90% of the total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used).

2. The parent company must have:

(i) 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

(ii) Tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used); and

(iii) Tangible net worth of at least $10 million; and

(iv) Assets located in the United States amounting to at least 90% of the total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used)

APPENDIX 3-F

B. The parent company's independent certified public accountant must 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 must inform Department 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.

C. 1. After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

2. If the parent company no longer meets the requirements of paragraph A of this section, the licensee must send notice to the Department of intent to establish alternate financial assurance as specified in the Department's regulations. The notice must 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 must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Parent Company Guarantee

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Department. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Department, as evidenced by the return receipts.

B. If the licensee fails to provide alternate financial assurance as specified in the Department's regulations within 90 days after receipt by the licensee and Department of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

C. The parent company guarantee and financial test provisions must remain in effect until the Department has terminated the license.

D. If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Department. An acceptable trustee 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.

Form NRH-5
Effective Date:

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIVISION OF PUBLIC HEALTH - RADIOACTIVE MATERIALS PROGRAM

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE

INSTRUCTIONS - (Use additional sheets where necessary.)
New or Renewal Application - Complete Items 1. through 15.
Amendment to License - Complete Items1.a, 3., and 15. And indicate other changes as appropriate.
Retain one copy for your files and submit original application to: Department of Health and Human Services, Division of Public Health, Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, NE 68509-5026.
Upon approval of this application, the applicant will receive a Radioactive Material License, issued in accordance with the requirements contained in Title 180, Regulations for the Control of Radiation and the Nebraska Radiation Control Act.

1.a Legal Name and Street address of Applicant (Institution, Firm, Person, etc.)

Applicant Name: _____

Address: _____

_____

City, State Zip +4: _____

Telephone #: _____

FAX #: _____

E-Mail Address:

1.b Street address(es) at which Radioactive Material will be used. (If different than 1.a)

(1) Permanent Address: _____

_____

City, State Zip+4: _____

(2) Temporary Job Sites Throughout Nebraska? ☐ Yes ☐ No

2. Department to Use Radioactive Material

_____

Person to Contact:_____

Telephone #:_____

3. This is an application for:

☐ New License

☐ Amendment to License No._____

☐ Renewal of License No._____

4. Individual User(s)

☐ Individual users approved by the Licensee's radiation safety committee.

☐ Individual users approved by the Licensee's radiation safety officer.

☐ Individual users satisfy the requirements of 180 NAC 3-013

OR

☐ Name and Title of individual(s) who will use or directly supervise use of, Radioactive Materials. Give training and experience in Items 7. And 8.

First Name + Middle Initial	Last Name	Title

5. Radiation Safety Officer (RSO)
(Name and Title of Individual designated as Radiation Safety Officer.

_____

Telephone #:_____

Attach documentation of his/her training and experience as in Items 7. and 8.

Department Use Only

Date Received Stamp

6. Radioactive Material Data

☐ Type B Broad Scope, 180 NAC 3-013.01, item 2

☐ Type C Broad Scope, 180 NAC 3-013.01, item 3

☐ Specific License, Radioactive Material Listed below:

6.a. Element and Mass Number	6.b. Chemical or Physical Form (Make and Model if sealed source)	6.c. Maximum Activity Requested (Expressed as Curies, Millicuries or Microcuries)	6.d. Use of Each Form (If sealed source, also give Make and Model Number of the storage and/or device in which sealed source will be stored and/or used)

7. Training of Individuals in Items 4. and 5.

Name of Individual:

	Formal Course Title	Location and Date(s) of Training	Clock Hours in Lecture or Laboratory
7.a. Radiation Physics and Instrumentation			
7.b. Radiation Protection			
7.c. Mathematics Pertaining to the Use and Measurement of Radioactivity			
7.d. Biological Effects of Radiation			

8. Experience with Radiation of Individuals in Items 4. and 5.

(Actual use of Radioisotopes or Equivalent Experience)

Name of Individual:

Isotope	Maximum Activity	Where Experience Was Gained	Months/Years	Type of Use

9. Radiation Detection Instruments					
Type of Instrument	Manufacturers Name	Model Number	Number Available	Radiation Detected	Sensitivity Range
	‘				

10. Calibration of Instruments Listed in Item 9.

☐ **a. Calibrated by Service Company** Name and Address of Service Company and Frequency of Calibration	☐ **b. Calibrated by Applicant**

11. Personnel Monitoring Devices

(Check and/or complete as appropriate)

Type	Supplier (Service Company)	Exchange Frequency
☐ Film Badge ☐ TLD ☐ DOSL ☐ Other (Specify) ☐_____		☐ Monthly ☐ Quarterly ☐ Other (specify) _____

Information to be Submitted on Additional Sheets

12. Facilities and Equipment

Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Attach an explanatory sketch of the facility.

13. Radiation Protection Program

Describe the radiation protection program as appropriate for the material to be used, including: the duties and responsibilities of the Radiation Safety Officer (RSO); control measures; bioassay procedures (if needed); day-to-day general safety instructions to be followed; etc. If the application is for sealed sources also submit leak testing procedures, or if leak testing will be performed using a leak test kit, specify manufacturer and model number of the leak test kit.

14. Waste Disposal

If a commercial waste disposal service is employed, specify the name and address of the company. Otherwise, submit a detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved. If the application is for sealed sources and devices and they will be returned to the manufacturer, so state.

15. CITIZENSHIP ATTESTATION

☐ It is not necessary to complete the Attestation part of this application below if the application is for a corporation or other separate legal entity. **Explain why:** (For example: This application is for a corporation, partnership, etc.) _____ _____ **OR**

☐ **If the entity is owned by an individual, complete the United States Citizenship Attestation Form below.**

UNITED STATES CITIZENSHIP ATTESTATION FORM

For the purpose of complying with Neb. Rev Stat. §§. 4-108 through 4-114, I attest as follows:

☐ I am a citizen of the United States OR

☐ I am a qualified alien under the Federal Immigration and Nationality Act, my Immigration status and alien number are as follows: _____ and I am providing a copy of my USCIS documentation.

I hereby attest that my response and the information provided on this form and any related application for public benefits are true, complete and accurate and I understand that this information may be used to verify my lawful presence in the United States.

Name (type or print first, middle, last)	Signature	Date

16~~5~~. CERTIFICATION
(This item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1.a., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services , Title 180, Regulations for the Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief. I am authorized to make binding commitments and to sign official documents on the behalf of the applicant.

_____
Applicant Name From Item 1.a.

By: _____ *Date:* _____
Signature

_____
Print Name and Title of certifying official authorized to act on behalf of the applicant

Your Application will not be processed without items 15 and 16 being completed.

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH

CERTIFICATE - USE OF DEPLETED URANIUM UNDER GENERAL LICENSE

180 NAC 3-007.04 establishes a general license authorizing a person to receive, acquire, possess, use, or transfer in accordance with the provisions of 180 NAC 3-007.04, items 2, 3, 4 and 5, 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.

Possession of depleted uranium is not authorized under 180 NAC 3-007.04 until a licensee has filed Form NRH-11 and received from the Department a validated copy of NRH-11 with a certification number.

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 3-007.04

3-007.04 Depleted Uranium In Industrial Products and Devices.

1. A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 180 NAC 3-007.04 items 2. through 5., 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.

2. The general license in 180 NAC 3-007.04, item 1 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 180 NAC 3-014.13 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.

3. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 180 NAC 3-007.04, item 1 must:

   a. File Department Form NRH-11 "Certificate - Use of Depleted Uranium Under General License," with the Department. The form must be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant must furnish on Department Form NRH-11 the following information and such other information as may be required by that form:

      (1) Name and address of the general licensee;

      (2) A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 180 NAC 3-007.04, item 1 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

      (3) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the general

licensee in supervising the procedures identified in 180 NAC 3-007.04, item 3.a.(2).

b. Report in writing to the Department any changes in information furnished by him in Department Form NRH-11 "Certificate - Use of Depleted Uranium Under General License." The report must 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 180 NAC 3-007.04, item 1 must:

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 180 NAC 3-025. In the case where the transferee receives the depleted uranium pursuant to the general license established by 180 NAC 3-007.04, item 1., the transferor must furnish the transferee a copy of this regulation and a copy of Department Form NRH-11. 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's regulation equivalent to 180 NAC 3-007.04, item 1., the transferor must furnish the transferee a copy of Title 180 and a copy of Department Form NRH-11 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 Title 180.

d. Within 30 days of any transfer, report in writing to the Department the name and address of the person receiving the depleted uranium pursuant to such transfer.

5. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 180 NAC 3-007.04, item 1 is exempt from the requirements of 180 NAC 4 and 180 NAC 10 with respect to the depleted uranium covered by that general license.

INSTRUCTIONS

Submit this form in duplicate to the Department of Health and Human Services, Division of Public Health, Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, Nebraska 68509-5026.

A certification number will be assigned and a validated copy of NRH-11 will be returned.

(Print or Type)

1. Licensee Information

Legal Name of Licensee: _____

Address of Licensee: _____

_____

City, State and Zip+4 of Licensee _____

Person Authorized to sign binding documents for the Licensee _____

Address of authorized person _____

_____

City, State amd Zip+4 of authorized person. _____

Telephone # of authorized person _____

2. I hereby apply for a Certificate number pursuant to 180 NAC 3-007.04 on behalf of the above Licensee.

3. CITIZENSHIP ATTESTATION

☐ It is not necessary to complete the Attestation part of this application below if the application is for a corporation or other separate legal entity. **Explain why:** (For example: This application is for a corporation, partnership, etc.) _____ **OR**

☐ **If the entity is owned by an individual, complete the United States Citizenship Attestation Form below.**

UNITED STATES CITIZENSHIP ATTESTATION FORM

For the purpose of complying with Neb. Rev Stat. §§. 4-108 through 4-114, I attest as follows:

☐ I am a citizen of the United States OR

☐ I am a qualified alien under the Federal Immigration and Nationality Act, my Immigration status and alien number are as follows: _____ and I am providing a copy of my USCIS documentation.

I hereby attest that my response and the information provided on this form and any related application for public benefits are true, complete and accurate and I understand that this information may be used to verify my lawful presence in the United States.

Name (type or print first, middle, last)	Signature	Date

~~3~~4. Certification:

I certify that:

a. All information in this certificate is true and complete.

b. I understand the Department's regulations require that any change in the information furnished on this certificate be reported to the Department within 30 days from the date of such change.

c. I have read and understand the provisions of 180 NAC 3-007.04 of the Department's regulations, and I understand that I am required to comply with those provisions as to the depleted uranium which I receive, possess, use, or transfer under the general license.

_____

(Signature of Authorized Person listed in Item 1.) (Date)

4. To be completed by the Department:

***Certification Number*_____*Date*_____**

Radioactive Materials Program Manager_____

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH

CERTIFICATE - IN VITRO TESTING WITH RADIOACTIVE MATERIAL UNDER GENERAL LICENSE

180 NAC 3-008.09 establishes a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to possess certain small quantities of radioactive material for In Vitro clinical or laboratory tests not involving the internal or external administration of the radioactive material or the radiation therefrom to human beings or animals. Possession of radioactive material under 180 NAC 3-008.09 is not authorized until the physician, veterinarian, clinical laboratory, or hospital has filed Form NRH-17 and received from the Department a validated copy of Form NRH-17 with a certification number.

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 180 NAC 3-008.09

3-008.09 General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing

1. A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 180 NAC 3-008.09, items 2. through 6., the following radioactive materials in prepackaged units for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

    a. Iodine-125, iodine-131, selenium-75, cobalt-57, and carbon-14 in units not exceeding 370 kBq (10 microcuries) each.
    b. Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 microcuries) each.
    c. Iron-59, in units not exceeding 740 kBq (20 microcuries) each.
    d. Mock Iodine-125 reference or calibration sources, in units not exceeding 1.85 kBq (0.05 microcurie) of iodine-129 and 1.85 Bq (0.005 microcurie) of americium-241 each.

2. No person receives, acquires, possesses, uses or transfers radioactive material pursuant to the general license established by 180 NAC 3-008.09, item 1. until s/he has filed Department Form NRH-17, "Certificate - In Vitro Testing with Radioactive Material Under General License", with the Department and received from the Department a validated copy of Department Form NRH-17 with certification number assigned. The physician, veterinarian, clinical laboratory or hospital must furnish on Department Form NRH-17 the following information and such other information as may be required by that form:

    a. Name and address of the physician, veterinarian, clinical laboratory or hospital;
    b. The location of use; and
    c. A statement that the physician, veterinarian in the practice of veterinary medicine, 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 180 NAC 3-008.09, item 1. and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

3. A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 180 NAC 3-008.09, item 1. must comply with the following:

    a. The general licensee must not possess at any one time, pursuant to the general license in 180 NAC 3-008.09, item 1. at any one location of storage or use a total amount of iodine-125, iodine-131, iron-59, cobalt-57 and/or selenium-75 in excess of 7.4 MBq (200 microcuries).

    b. The general licensee must store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

    c. The general licensee must use the radioactive material only for the uses authorized by 180 NAC 3-008.09, item 1.

    d. The general licensee must not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Department, the U.S. Nuclear Regulatory Commission, or any Agreement State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

    e. The general licensee must dispose of the Mock Iodine-125 reference or calibration sources described in 180 NAC 3-008.09, item 1.d. as required by 180 NAC 4-039 and 4-040.

4. The general licensee must not receive, acquire, possess, or use radioactive material pursuant to 180 NAC 3-008.09, item 1.:

    a. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 180 NAC 3-014.08 or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, or any Agreement State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under 180 NAC 3-008.09 or its' equivalent, and

    b. Unless the following statement, or 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 must be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, 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 of a State in which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of Manufacturer

5. The physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital possessing or using radioactive material under the general license of 180 NAC 3-008.09, item 1. must report in writing to the Department, any changes in the information furnished by him/her in the "Certificate - In Vitro Testing with Radioactive Material Under General License", Department Form NRH-17. The report must be furnished within 30 days after the effective date of such change.

6. Any person using radioactive material pursuant to the general license of 180 NAC 3-008.09, item 1. is exempt from the requirements of 180 NAC 4 and 180 NAC 10 with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 180 NAC 3-008.09 item 1.d. must comply with the provisions of 180 NAC 4-039, 4-057, and 4-058.

INSTRUCTIONS

Submit this form in duplicate to the Department of Health and Human Services, Division of Public Health , Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, Nebraska 68509-5026.

A certification number will be assigned and a validated copy of NRH-17 will be returned.

(Print or Type)

1. Licensee Information

Legal Name: (Physician, Veterinarian, Clinical Laboratory or Hospital) _____

Address: _____

_____

City, State and Zip+4 _____

Person Authorized to sign binding documents for the Licensee _____

2. I hereby apply for a Certificate Number pursuant to 180 NAC 3-008.09 for use of radioactive materials for:

[ ] a. Myself, a duly licensed physician authorized to dispense drugs in the practice of medicine, or a veterinarian licensed to practice veterinary medicine.

[ ] b. The above named clinical laboratory.

[ ] c. The above named hospital.

3. If place of use is different from address in Item 1, please give complete address:

4. CITIZENSHIP ATTESTATION

☐ It is not necessary to complete the Attestation part of this application below if the application is for a corporation or other separate legal entity. **Explain why:** (For example: This application is for a corporation, partnership, etc.) _____ **OR**

☐ **If the entity is owned by an individual, complete the United States Citizenship Attestation Form below.**

UNITED STATES CITIZENSHIP ATTESTATION FORM

For the purpose of complying with Neb. Rev Stat. §§. 4-108 through 4-114, I attest as follows:

☐ I am a citizen of the United States OR

☐ I am a qualified alien under the Federal Immigration and Nationality Act, my Immigration status and alien number are as follows: _____ and I am providing a copy of my USCIS documentation.

I hereby attest that my response and the information provided on this form and any related application for public benefits are true, complete and accurate and I understand that this information may be used to verify my lawful presence in the United States.

Name (type or print first, middle, last)	Signature	Date

5~~4~~. Certification:

I certify that:

a. All information in this certificate is true and complete.

b. Appropriate radiation measuring instruments are available to carry out the tests for which radioactive material will be used under the general license of 180 NAC 3-008.09. The tests will be performed only by personnel competent in the use of the instruments and in the handling of the radioactive materials.

c. I understand that Department regulations require that any change in the information furnished on this certificate be reported to the Department within 30 days from the date of such change.

d. I have read and understand the provisions of 180 NAC 3-008.09 of the Department regulations; and I understand that compliance with those provisions is required as to all radioactive material which is received, acquired, possessed, used, or transferred under the general license for which this certification number is filed with the Department.

_____

(Signature of Person listed in Item 1.) (Date)

4. To be completed by the Department:

Certification Number _____ ***Date*** _____

Radioactive Materials Program Manager _____

THIS PAGE WAS INTENTIONALLY LEFT BLANK

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH
RADIOACTIVE MATERIALS PROGRAM

CERTIFICATION OF DISPOSITION OF MATERIALS

INSTRUCTIONS - (Use additional sheets where necessary.)
Type or Print except where indicated.
Retain one copy for your files and submit original application to: Department of Health and Human Services, Division of Public Health, Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, NE 68509-5026.
Upon approval of this Certification of Disposition of Materials the licensee will receive a termination notice of this radioactive material license.

1. Licensee Information

Licensee Number:_____

License Expiration Date:_____

2. Person to Contact Regarding this Application

_____

Telephone #:_____

Licensee Name and Street Address:

Applicant Name: _____

Address: _____

_____

City, State Zip+4 _____

Telephone #: _____

FAX#: _____

E-mail Address:

3. Materials Data

☐ No Materials have ever been procured or possessed by the Licensee under this License.

☐ All Materials procured and/or possessed by the Licensee under the License Number cited above have been disposed of in the following manner:

☐ Transfer
Specify the date of the transfer, the name of the licensed recipient and the recipient's Department, U.S. Nuclear Regulatory Commission or Agreement State license number.
Describe specific materials transfer actions and if there were radioactive wastes generated in terminating this license, the disposal actions, including the disposition of low-level radioactive waste, mixed waste, Greater-than-Class-C waste, and sealed sources, if applicable.

☐ Disposed of directly by Licensee
Describe specific disposal procedures (e.g. decay in storage).

4. Other Data

☐ Our License has not yet expired, please terminate it.
A Radiation Survey was conducted to confirm the absence of licensed radioactive materials and to determine whether any contamination remains on the premises covered by the license:

☐ NO (Attach Explanation)

☐ YES, the results:

☐ Are attached

☐ Were forwarded to the Department on (Date)_____

4. Other Data *(Continued)*

Address all future correspondence regarding this license to:

Name: _____

Address: _____

_____

City, State Zip+4: _____

Telephone #: _____

FAX#: _____

E-mail Address: _____

5. CERTIFICATION
(This item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services , Title 180, Regulations for the Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

_____
Applicant Name From Item 1.

By: _____ *Date:* _____
Signature

_____

_____
Print Name and Title of certifying official authorized to act on behalf of the applicant

Form NRH 653
Effective Date

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIVISION OF PUBLIC HEALTH – RADIOACTIVE MATERIAL PROGRAM

TRANSFERS OF INDUSTRIAL DEVICES REPORT

(Continue on Form NRH 653, 653A or 653B, as appropriate)

NAME OF VENDOR	REPORTING PERIOD	
	FROM	TO
LICENSE NUMBER:		

For each "person" to whom a devices(s) has been transferred during the reporting period, supply the following:

INTERMEDIATE PERSON (if any)

NAME OF INTERMEDIATE PERSON	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER		MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE	
TITLE OF RESPONSIBLE INDIVIDUAL		

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY & UNITS

INTERMEDIATE PERSON (if any)

NAME OF INTERMEDIATE PERSON	NAME OF RESPONSIBLE INDIVIDUAL	INDIVIDUAL TITLE OF RESPONSIBLE	TELEPHONE

GENERAL LICENSE USER INFORMATION

NAME OF GENERAL LICENSEE USER		MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE	
TITLE OF RESPONSIBLE INDIVIDUAL		

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY & UNITS

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH – RADIOACTIVE MATERIAL PROGRAM

TRANSFERS OF INDUSTRIAL DEVICES REPORT (TO GENERAL LICENSEES)

INTERMEDIATE PERSON (if any)

NAME OF INTERMEDIATE PERSON	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER		MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE	
TITLE OF RESPONSIBLE INDIVIDUAL		

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY & UNITS

INTERMEDIATE PERSON (if any)

NAME OF INTERMEDIATE PERSON	NAME OF RESPONSIBLE INDIVIDUAL	INDIVIDIUAL TITLE OF RESPONSIBLE	TELEPHONE

GENERAL LICENSE USER INFORMATION

NAME OF GENERAL LICENSEE USER		MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE	
TITLE OF RESPONSIBLE INDIVIDUAL		

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY & UNITS

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH – RADIOACTIVE MATERIAL PROGRAM

TRANSFERS OF INDUSTRIAL DEVICES REPORT (FROM GENERAL LICENSEE)

For each "person" to whom a devices(s) has been transferred during the reporting period, supply the following:

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT	

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY & UNITS

GENERAL LICENSE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT	

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY & UNITS

GENERAL LICENSE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT	

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY & UNITS

Form NRH 653B
Effective Date9

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH – RADIOACTIVE MATERIAL PROGRAM

TRANSFERS OF INDUSTRIAL DEVICES REPORT (LABEL CHANGES)

For each device for which required label information has been changed, supply the following::

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT	

INFORMATION ON DEVICE(S) RECEIVED

TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITYAND UNITS

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT	

INFORMATION ON DEVICE(S) RECEIVED

TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITYAND UNITS

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE (No. P.O. Boxes, include Zip Code)
DEPARTMENT	

INFORMATION ON DEVICE(S) RECEIVED

TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITYAND UNITS

Attachment 3-1

11 U.S.C. 101(2) AND (15)

CITE-
11 USC CHAPTER 1 - GENERAL PROVISIONS 01/03/05

TITLE 11 - BANKRUPTCY
CHAPTER 1 - GENERAL PROVISIONS

-HEAD-
Sec. 101. Definitions

-STATUTE-
In this title -

(2) **"affiliate"** means -

(A) entity that directly or indirectly owns, controls, or holds with power to vote, 20% or more of the outstanding voting securities of the debtor, other than an entity that holds such securities -

(i) in a fiduciary or agency capacity without sole discretionary power to vote such securities; or

(ii) solely to secure a debt, if such entity has not in fact exercised such power to vote;

(B) corporation 20% or more of whose outstanding voting securities are directly or indirectly owned, controlled, or held with power to vote, by the debtor, or by an entity that directly or indirectly owns, controls, or holds with power to vote, 20% or more of the outstanding voting securities of the debtor, other than an entity that holds such securities -

(i) in a fiduciary or agency capacity without sole discretionary power to vote such securities; or

(ii) solely to secure a debt, if such entity has not in fact exercised such power to vote;

(C) person whose business is operated under a lease or operating agreement by a debtor, or person substantially all of whose property is operated under an operating agreement with the debtor; or

(D) entity that operates the business or substantially all of the property of the debtor under a lease or operating agreement;

(15) **"entity"** includes person, estate, trust, governmental unit, and United States trustee;

http://uscode.house.gov/download/pls/11C1.txt