

**DEPARTMENT OF ENVIRONMENTAL QUALITY
WASTE & HAZARDOUS MATERIALS DIVISION
IONIZING RADIATION RULES**

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PART 2. LICENSING OF RADIOACTIVE MATERIAL

R325.5051. Purpose and scope.

Rule 51. (1) This part provides for the licensing of radioactive material. A person shall not own, receive, acquire, possess, use or transfer radioactive material except as authorized in a specific or general license issued pursuant to this part or as otherwise provided in this part.

(2) In addition to the requirements of this part, a licensee is subject to the requirements of parts 1 and 5. A licensee engaged in industrial radiographic operations is subject to the requirements of part 6, a licensee using certain particle accelerators is subject to part 11, and a licensee using sealed sources in the healing arts is subject to the requirements of part 12.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

EXEMPTIONS SOURCE MATERIAL

R325.5052. Source material as a low percentage of weight.

Rule 52. A person is exempt from this part to the extent that he receives, possesses, uses or transfers source material in any chemical mixture, compound, solution or alloy in which the source material is by weight less than 1/20 of 1% (0.05%) of the mixture, compound, solution or alloy.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5053. Unprocessed ore containing source material.

Rule 53. A person is exempt from this part to the extent that he receives, possesses, uses or transfers unrefined and unprocessed ore containing source material. However, the person shall not refine or process such ore except as authorized in a specific license.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5054. Thorium used in certain articles.

Rule 54. A person is exempt from this part to the extent that he receives, possesses, uses or transfers any quantity of thorium contained in:

- (a) Incandescent gas mantles.
- (b) Vacuum tubes.
- (c) Welding rods.
- (d) Electric lamps for illuminating purposes if each lamp does not contain more than 50 milligrams of thorium.
- (e) Germicidal lamps, sunlamps and lamps for outdoor or industrial lighting if each lamp does not contain more than 2 grams of thorium.
- (f) Rare earth metals and compounds, mixtures and products containing not more than 0.25% by weight thorium, uranium or any combination of these.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5055. Source material contained in ceramic and other articles.

Rule 55. A person is exempt from this part to the extent that he receives, possesses, uses or transfers:

- (a) Source material contained in the following products:
 - (i) Glazed ceramic tableware, if the glaze contains not more than 20% by weight source material.
 - (ii) Glassware, glass enamel and glass enamel frit containing not more than 10% by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass, glass enamel or ceramic used in construction.
 - (iii) Piezoelectric ceramic containing not more than 2% by weight source material.
- (b) Photographic film, negatives and prints containing uranium or thorium.
- (c) A finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, if the thorium content of the alloy does not exceed 4% by weight. The exemption contained in this paragraph does not authorize the chemical, physical or metallurgical treatment or processing of any such product or part.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5056. Uranium contained in counterweights.

Rule 56. (1) A person is exempt from this part to the extent that he receives, possesses, uses or transfers uranium contained in counterweights installed in aircraft, marinecraft, rockets, projectiles and missiles, or stored or handled in connection with installation or removal of such counterweights if:

- (a) The counterweights are manufactured in accordance with a specific license issued by the department, the NRC or an agreement state authorizing distribution by the licensee pursuant to this rule or equivalent regulations of the NRC or an agreement state.
- (b) Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: **"DEPLETED URANIUM"**.
- (c) Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: **"UNAUTHORIZED ALTERATIONS PROHIBITED"**.

(2) The requirements specified in subdivisions (1)(b) and (c) need not be met by counterweights manufactured before December 31, 1969 if the counterweights are impressed with the legend, **"CAUTION - RADIOACTIVE MATERIAL - URANIUM"**, as previously required by applicable regulations.

(3) The exemption contained in this rule does not authorize the chemical, physical or metallurgical treatment or processing of counterweights other than repair or restoration of any plating or other covering.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5057. Uranium contained in shipping container shields.

Rule 57. A person is exempt from this part to the extent that he receives, possesses, uses or transfers uranium used as shielding constituting part of any shipping container which is conspicuously and legibly impressed with the legend **"CAUTION - RADIOACTIVE SHIELDING - URANIUM"** and which meets the specifications for containers for radioactive materials prescribed by section 178.250, specification 55, part 178, of the regulations published by the United States department of transportation, 49 CFR §178.250.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5058. Thorium contained in lenses.

Rule 58. A person is exempt from this part to the extent that he receives, possesses, uses or transfers thorium contained in finished optical lenses, if each lens does not contain more than 30% by weight of thorium. The exemption contained in this rule does not authorize either of the following:

- (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.
- (b) The receipt, possession, use or transfer of thorium contained in contact lenses, in spectacles or in eyepieces in binoculars or other optical instruments.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5059. Uranium contained in fire detection units.

Rule 59. A person is exempt from this part to the extent that he receives, possesses, uses or transfers uranium contained in detector heads for use in fire detection units, if each detector head contains not more than 5 nanocuries of uranium.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5060. Thorium contained in aircraft engine parts.

Rule 60. A person is exempt from this part to the extent that he receives, possesses, uses or transfers thorium contained in any finished aircraft engine part containing nickel-thoria alloy, if:

- (a) The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide).
- (b) The thorium content in the nickel-thoria alloy does not exceed 4% by weight.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5061. Exemptions do not authorize manufacture.

Rule 61. The exemptions in rules 54 to 60 do not authorize the manufacture of any of the products described.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL

R325.5065. Exempt concentrations.

Rule 65. Except as provided in rule 66, a person is exempt from this part to the extent that he owns, receives, acquires, possesses, uses or transfers products or materials containing radioactive material in concentrations not in excess of those listed in rule 146.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5066. Material transferred to exempt persons.

Rule 66. A person may not introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under rule 65 or equivalent regulations of the NRC or an agreement state, except in accordance with a specific license issued pursuant to rule 109 or the general license provided in rule 131.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5067. Items containing tritium, promethium-147 or radium.

Rule 67. Except for persons who apply tritium, promethium-147 or radium to, or persons who incorporate tritium, promethium-147 or radium into, the following products, a person is exempt from these rules to the extent that he owns, receives, acquires, possesses, uses or transfers the following products:

- (a) Timepieces or timepiece hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:
 - (i) 25 millicuries of tritium per timepiece.
 - (ii) 5 millicuries of tritium per hand.
 - (iii) 15 millicuries of tritium per dial; bezels when used shall be considered as part of the dial.
 - (iv) 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per any other timepiece.
 - (v) 20 microcuries of promethium-147 per watch hand or 40 microcuries of

promethium-147 per other timepiece hand.

- (vi) 60 microcuries of promethium-147 per watch dial or 120 microcuries of promethium-147 per other timepiece dial; bezels when used shall be considered as part of the dial.
- (vii) The levels of radiation from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:
 - (aa) For wrist watches, 0.1 millirad per hour at 10 centimeters from any surface.
 - (bb) For pocket watches, 0.1 millirad per hour at 1 centimeter from any surface.
 - (cc) For any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface.
- (b) Timepieces or timepiece hands or dials containing not more than the following specified quantities of radium and meeting the following expressed conditions:
 - (i) 0.15 microcuries of radium per watch.
 - (ii) 0.03 microcuries of radium per watch hand.
 - (iii) 0.09 microcuries of radium per watch dial.
 - (iv) 0.20 microcuries of radium per clock.
 - (v) 0.04 microcuries of radium per clock hand.
 - (vi) 0.12 microcuries of radium per clock dial.
 - (vii) The timepiece is not a pocket watch.
 - (viii) Timepieces or timepiece hands or dials containing radium which were manufactured before the effective date of these rules.
 - (ix) The timepiece is marked or coded to identify the date of manufacture and that it contains radium.
 - (x) The timepiece emits sufficient luminosity, omitting photoactivation, that its dial can be read in the dark during its entire design lifetime.
- (c) Lock illuminators containing not more than 15 millicuries of tritium or not more than 2 millicuries of promethium-147 installed in automobile locks. The levels of radiation from each lock illuminator containing promethium-147 will not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.
- (d) Precision balances containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part.
- (e) Automobile shift quadrants containing not more than 25 millicuries of tritium.
- (f) Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas.
- (g) Thermostat dials and pointers containing not more than 25 millicuries of tritium per thermostat.

- (h) Electron tubes, including spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents, if the level of radiation due to radioactive material contained in each electron tube does not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber and if each tube does not contain more than 1 of the following specified quantities of radioactive materials:
 - (i) 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube.
 - (ii) 1 microcurie of cobalt-60.
 - (iii) 5 microcuries of nickel-63.
 - (iv) 30 microcuries of krypt' on-85.
 - (v) 5 microcuries of cesium-137.
 - (vi) 30 microcuries of promethium-147.
- (j) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, a source of radioactive material not exceeding the applicable quantity set forth in rule 147.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5071. Resins containing scandium-46 for sand consolidation in oil wells.

Rule 71. A person is exempt from these rules to the extent that he owns, receives, acquires, possesses, uses or transfers synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells if the resins were manufactured or imported in accordance with a specific license issued by the NRC, or were manufactured in accordance with the specifications contained in a specific license issued by the department or an agreement state to the manufacturer of such resins pursuant to licensing requirements equivalent to those in sections 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the NRC. This exemption does not authorize the manufacturer of resins containing scandium-46.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5072. Gas and aerosol detectors.

Rule 72. Except for persons who manufacture, process or produce gas and aerosol detectors, a person is exempt from these rules to the extent that he owns, receives, acquires, possesses, uses or transfers:

- (a) Byproduct material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, if the detectors containing byproduct material were manufactured, imported or transferred in accordance with a specific license issued by the NRC pursuant to section 32.26 of 10 CFR Part 32, which license authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.
- (b) Naturally occurring material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, if the detectors containing naturally occurring material were manufactured, imported or transferred in accordance with a specific license issued by the department or an agreement state pursuant to equivalent conditions as in section 32.26 of 10 CFR Part 32, which license authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5073. Self-luminous products containing tritium, krypton-85, promethium-147 or radium-226.

Rule 73. (1) Except for a person who manufactures, processes, or produces self-luminous products, a person is exempt from these regulations to the extent that he owns, receives, acquires, possesses, uses or transfers:

- (a) Tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, imported, or transferred in accordance with a specific license issued by the NRC pursuant to section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements.
- (b) Naturally occurring material in self-luminous products manufactured, processed, imported or transferred in accordance with a specific license issued by the department or an agreement state pursuant to equivalent conditions as in section 32.22 of 10 CFR Part 32.

(2) The exemptions in subrule (1) do not apply to tritium, krypton-85, promethium-147, or naturally occurring material used in products for frivolous purposes or in toys or adornments.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5074. Exempt quantities.

Rule 74. (1) Except as provided in subrules (3) and (4), a person is exempt from these rules to the extent that he owns, receives, acquires, possesses, uses or transfers a byproduct, naturally occurring or accelerator material in individual quantities each of which does not exceed the applicable quantity set forth in rule 147.

(2) A person who possesses radioactive material formerly received or acquired under the general license provided in 10 CFR Part 31, § 31.4 of the NRC regulations is exempt from the requirements for a license set forth in this part to the extent that he owns, possesses, uses or transfers such radioactive material.

(3) Subrule (1) does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(4) A person, for purposes of commercial distribution, shall not transfer radioactive material in the individual quantities set forth in rule 147, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under subrule (1) or equivalent regulations of the NRC or an agreement state, except in accordance with a specific license issued by the NRC pursuant to section 32.18 of 10 CFR Part 32 which license states that the radioactive material may be transferred by the licensee to persons exempt under subrule (1) or the equivalent regulations of the NRC or an agreement state.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

GENERAL LICENSES

R325.5081. Types of licenses.

Rule 81. (1) Licenses for radioactive materials are of 2 types: general or specific. General licenses provided in this part are effective without the filing of applications with the department or the issuance of licensing documents to particular persons. Specific licenses are issued to named persons upon applications filed pursuant to this part.

(2) Rules 82 to 92 are different general licenses, each of which has its own specific conditions and requirements.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

SOURCE MATERIAL

R325.5082. Use and transfer of source material.

Rule 82. (1) This rule is a general license issued to own, receive, acquire, possess, use and transfer not more than 6.8 kilograms (15 pounds) of source material at any 1 time by persons in the following categories:

- (a) Pharmacists using the source material solely for the compounding of medicinals.
- (b) Physicians using the source material for medicinal purposes.
- (c) Persons receiving possession of source material from pharmacists and physicians in the form of medicinals or drugs.
- (d) Commercial and industrial firms, and research, educational and medical institutions for research, development, educational or commercial purposes.

(2) A person, pursuant to the general license issued in subrule (1), shall not receive more than a total of 68 kilograms (150 pounds) of source material in any 1 calendar year.

(3) A person who owns, receives, acquires, possesses, uses or transfers source material pursuant to the general license issued in subrule (1) is exempt from the provisions of part 5 to the extent that the receipt, possession, use or transfer is within the terms of the general license. This exemption does not apply to a person who is also in possession of source material under a specific license issued pursuant to this part.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5083. Ownership of source material.

Rule 83. This rule is a general license issued to own source material without regard to quantity. Notwithstanding any other provisions of this part this general license does not authorize the manufacture, production, transfer, receipt, possession or use of source material.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL

R325.5084. Static eliminators and air ionizers.

Rule 84. (1) This rule is a general license issued to own, receive, acquire, possess, use and transfer 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

department, the NRC, or an agreement state, and authorizing distribution under the general license of this rule or its equivalent:

- (a) Devices designed for use as static eliminators which contain, as sealed sources, radioactive material consisting of a total not to exceed 500 microcuries of polonium-210 or 50 microcuries of radium-226 per device.
- (b) Devices designed for ionization of air which contain, as sealed sources, radioactive material consisting of a total not to exceed 500 microcuries of polonium-210 per device or a total not to exceed 50 millicuries of hydrogen-3 (tritium) per device.

(2) The general license provided in subrule (1) is subject to rules 41 to 43, 66, 119, 123 and 124 and part 5 and particularly the provisions of Part 5 relating to the labeling of containers.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5085. Certain measuring, gauging and controlling devices.

Rule 85. (1) This rule is a general license issued to own, receive, acquire, possess, and use radioactive material when 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 ionizing atmosphere, when the devices are manufactured in accordance with the specifications contained in a specific license issued to the supplier pursuant to rule 107 or its equivalent by the department, the NRC, or an agreement state, and authorizing distribution under the general license of this rule or its equivalent; if:

- (a) The devices are labeled in accordance with the specific license which authorizes the distribution of the devices. Regulations under the federal food, drug, and cosmetic act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR Part 121, § 121.3001.
- (b) The devices bear a label containing the following or a substantially similar statement which contains the information called for in the following statement:

The receipt, possession, use and transfer of this device, Model*_____, Serial No.*_____, are subject to a general license or the equivalent and the regulations of the U.S. NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. Removal of this label is prohibited.

CAUTION: RADIOACTIVE MATERIAL

Name of Supplier*_____

- (c) The devices are installed on the premises of the general licensee by a person authorized to install them under a specific license issued to the installer by the department, the NRC or an agreement state, if a label affixed to the device at the time of receipt states that installation by a specific licensee is required. The requirement of this subdivision does not apply while devices are held in storage in the original shipping container pending installation by a specific licensee.
- (d) Radium devices bear a label containing the following or a substantially similar statement which contains the information called for in the following statement:

The receipt, possession, use, and transfer of this device, Model*_____, Serial No.*_____, are subject to a general license or the equivalent and the regulations of (name of state) which licenses radium. Removal of this label is prohibited.

CAUTION: RADIOACTIVE MATERIAL

Name of Supplier*_____

(2) A person who owns, receives, acquires, possesses, or uses a device pursuant to the general license contained in subrule (1):

- (a) Shall not transfer, abandon or dispose of the device except by transfer to a person duly authorized to receive the device by a specific license or equivalent licensing document issued by the department, the NRC, or an agreement state, and shall furnish to the department, within 30 days after a transfer, a report containing the name of the manufacturer of the device, the type of device, the manufacturer's serial number of the device and the name and address of the person receiving the device.
- (b) Shall assure that all labels affixed to the device at the time of receipt and bearing the statement, "**Removal of this label is prohibited**" are maintained thereon and shall comply with all instructions contained in the labels.
- (c) Shall have the device tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at the time of installation of the device or replacement of the radioactive material on the premises of the general licensee and thereafter at no longer than 6 month intervals or at such longer intervals not to exceed 3 years as are specified in the label required by subdivision (1)(a). Devices containing only krypton need not be tested for leakage, and devices containing only tritium need not be tested for any purpose.

*The model, serial number, and name of supplier may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

- (d) Shall have the tests required by subdivision (2)(c) and all other services involving the radioactive material, its shielding and containment, performed by the supplier or other person duly authorized by a specific license issued by the department, the NRC, or an agreement state, to manufacture, install or service the devices.
- (e) Within 30 days after the occurrence of a failure of or damage to the shielding of the radioactive material or the on-off mechanism or indicator or upon the detection of 5 nanocuries or more of removable radioactive material, shall furnish to the department a report containing the name of the manufacturer of the device, the type of device, the manufacturer's serial number of the device and a brief description of the event and the remedial action taken; and shall maintain records of all tests performed on the devices as required under this rule, including the dates and results of the tests and the names of the persons conducting the tests.
- (f) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding or containment of the radioactive material or the on-off mechanism or indicator, immediately shall suspend operation of the device until it has been repaired by a person holding a specific license issued by the department, the NRC, or an agreement state, to manufacture, install or service the devices, or disposed of by transfer to a person holding a specific license issued by the department, the NRC, or an agreement state to receive the radioactive material contained in the device.
- (g) Shall be exempt from the requirements of part 5 except that they shall comply with the provisions of rules 246, 247 and 255 of part 5.
- (h) Within 10 days after the receipt of the device, shall notify the department of the type of device and the name and address of the supplier.

(3) The general license provided in subrule (1) is subject to rules 41 to 43, 119, 123 and 124.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5086. Luminous safety devices for aircraft.

Rule 86. (1) This rule is a general license issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, if:

- (a) Each device contains not more than 10 curies of tritium or 300 millicuries of promethium-147.
- (b) Each device was manufactured, assembled or imported in accordance with a specific license issued by the NRC, or was manufactured or assembled in accordance with the specifications contained in a specific license

issued by the department or an agreement state to the manufacturer or assembler of the device pursuant to licensing requirements equivalent to those in section 32.53 of 10 CFR Part 32 of the regulations of the NRC.

(2) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in subrule (1) are exempt from the requirements of part 5 except that they shall comply with rules 246, 247 and 255.

(3) The general license provided in subrule (1) does not authorize the manufacture, assembly or repair of luminous safety devices containing tritium or promethium-147.

(4) The general license provided in subrule (1) does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

(5) The general license provided in subrule (1) is subject to rules 41 to 43, 119, 123 and 124.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5087. Ownership of radioactive material.

Rule 87. This rule is a general license issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this part, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5088. Calibration and reference sources.

Rule 88. (1) This subrule is a general license issued to the following persons to own, receive, acquire, possess, use and transfer, in accordance with subrules (4) and (5), americium-241 in the form of calibration or reference sources:

- (a) A person who holds a specific license issued by the department which authorizes him to receive, possess, use and transfer radioactive material.
- (b) A person who holds a specific license issued by the NRC which authorizes him to receive, possess, use and transfer special nuclear material.

(2) This subrule is a general license issued to own, receive, acquire, possess, use and transfer plutonium in the form of calibration or reference sources in

accordance with subrules (4) and (5) to a person who holds a specific license issued by the department which authorizes him to receive, possess, use and transfer radioactive material.

(3) This subrule is a general license issued to own, receive, acquire, possess, use and transfer radium in the form of calibration or reference sources in accordance with subrules (4), (5) and (6) as related to states or agencies which license radium, if the source does not exceed 0.1 μ Ci of radium.

(4) The general licenses in subrules (1) and (2) 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 NRC pursuant to section 32.57 of 10 CFR Part 32 or section 70.39 of 10 CFR Part 70, or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the department or an agreement state pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 of the regulations of the NRC.

(5) The general licenses provided in subrules (1), (2) and (3) are subject to rules 41 to 43, 119, 123 and 124 and part 5. In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:

- (a) Shall not possess at any 1 time, at any 1 location of storage or use, more than 5 microcuries of americium-241 and 5 microcuries of plutonium in the sources.
- (b) Shall not receive, possess, use or transfer the source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement:

The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Removal of this label is prohibited. CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (AMERICIUM-241) (PLUTONIUM) (RADIUM) (Showing only the name of the appropriate material). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.
(Name of Manufacturer or Importer).

- (c) Shall not transfer, abandon or dispose of the source except by transfer to a person authorized by a license from the department, the NRC, or an agreement state to receive the source.
- (d) Shall store the source, except when the source is being used, in a closed container adequately designed and constructed to contain

americium-241, plutonium or radium which might otherwise escape during storage.

- (e) Shall not use the source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(6) The general licenses provided in subrules (1), (2) and (3) do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium or radium.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5089. Medical diagnostic uses.

Rule 89. (1) This rule is a general license issued to a physician to own, receive, acquire, possess, use and transfer radioactive material set forth in this rule for the stated diagnostic uses, if the use is in accordance with subrules (2), (3) and (4); the radioactive material is in the form of capsules, disposable syringes or other prepackaged individual doses; and the radioactive material was manufactured in accordance with a specific license issued pursuant to rule 110 by the department, by the NRC or by an agreement state authorizing distribution under the general license granted in this rule or its equivalent:

- (a) Iodine-131 as sodium iodide (NaI^{131}) for measurement of thyroid uptake.
- (b) Iodine-131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume.
- (c) Iodine-125 as iodinated human serum albumin (IHSA) for determination of blood and blood plasma volume.
- (d) Cobalt-57 for the measurement of intestinal absorption of cyanocobalamin.
- (e) Cobalt-58 for the measurement of intestinal absorption of cyanocobalamin.
- (f) Cobalt-60 for the measurement of intestinal absorption of cyanocobalamin.
- (g) Chromium-51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time.

(2) A physician shall not receive, possess, use or transfer radioactive material pursuant to the general license in subrule (1) until he has filed Form RH-200 Certificate - Medical Use of Radioactive Material Under General License with the department and received from the department a validated copy of this form with certification number assigned. The generally licensed physician shall furnish on this form the following information and such other information as may be required by this form:

- (a) Name and address of the generally licensed physician.
- (b) A statement that the generally licensed physician is a licensed physician authorized to practice medicine in this state.
- (c) A statement that the generally licensed physician has appropriate radiation measuring

instruments to carry out the diagnostic procedures for which he proposes to use radioactive material under the general license of subrule (1) and that he is competent in the use of the instruments.

(3) A physician who receives, possesses or uses a pharmaceutical containing radioactive material pursuant to the general license in subrule (1) shall comply with all of the following:

- (a) He shall not possess at any 1 time, pursuant to the general license in subrule (1), more than:
 - (i) 200 microcuries of iodine-131.
 - (ii) 200 microcuries of iodine-125.
 - (iii) 5 microcuries of cobalt-57.
 - (iv) 5 microcuries of cobalt-58.
 - (v) 5 microcuries of cobalt-60.
 - (vi) 200 microcuries of chromium-51.
- (b) He shall store the pharmaceutical until administered in the original shipping container, or a container providing equivalent radiation protection.
- (c) He shall use the pharmaceutical only for the uses authorized in subrule (1).
- (d) He shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age. See rules 101 to 106 for requirements for issuance of specific licenses for human use.
- (e) He shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the department, the NRC or an agreement state, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.

(4) A generally licensed physician possessing or using radioactive material under the general license in subrule (1) shall report in duplicate to the department, any changes in the information furnished by him in the Certificate - Medical Use of Radioactive Material Under General License, Form RH-200. The report shall be submitted within 30 days after the effective date of the change.

(5) A person using radioactive material pursuant to the general license in subrule (1) is exempt from the requirements of part 5 with respect to the radioactive material covered by the general license.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5090. Certain *in vitro* clinical or laboratory testing.

Rule 90. (1) This rule is a general license issued to a physician, clinical laboratory or hospital to own, receive, acquire, possess, use and transfer, for any of the following stated tests, in accordance with subrules (2) to

(6), the following radioactive materials in prepackaged units:

- (a) Iodine-125, in units not exceeding 10 microcuries each 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.
- (b) Iodine-131, in units not exceeding 10 microcuries each 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.
- (c) Carbon-14, in units not exceeding 10 microcuries each 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.
- (d) Hydrogen-3 (tritium), in units not exceeding 50 microcuries each 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.
- (e) Iron-59, in units not exceeding 20 microcuries each 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.

(2) A person shall not receive, acquire, possess, use or transfer radioactive material pursuant to the general license in subrule (1) until he has filed Form RH-201 Certificate - *In Vitro* Testing with Radioactive Material Under General License, with the department and received from the department a validated copy of this form with certification number assigned or until authorized pursuant to subrule (3) of rule 105 to use radioactive material under this general license. The registrant shall furnish on this form the following information and such other information as may be required by this form:

- (a) Name and address of the physician, clinical laboratory or hospital.
- (b) The location of use.
- (c) A statement that the physician, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out *in vitro* clinical or laboratory tests with radioactive materials as authorized under the general license in Subrule (1) and that the tests will be performed only by personnel competent in the use of the 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 in subrule (1) shall comply with all of the following:

- (a) The general licensee shall not possess at any one time, pursuant to the general license in subrule (1), at any one location of storage or use a total amount of iodine-125, iodine-131,

iron-59 or all three in excess of 200 microcuries.

- (b) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
 - (c) The general licensee shall use the radioactive material only for the uses authorized in subrule (1).
 - (d) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the department, the NRC, or an agreement state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.
- (4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to subrule (1):
- (a) Except as prepackaged units which are labeled in accordance with a specific license issued under rule 110 or in accordance with a specific license issued by the NRC, or an agreement state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), or iron-59 for distribution to persons generally licensed under subrule (1) or its equivalent.
 - (b) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material may be received, acquired, possessed and used only by physicians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the United States Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____ Name of Manufacturer

(5) The physician, clinical laboratory or hospital possessing or using radioactive material under the general license in subrule (1) shall report in writing to the department, any change in the information furnished by him in the Certificate - *In Vitro* Testing With Radioactive Material Under General License, Form RH-201. The report shall be furnished within 30 days after the effective date of the change.

(6) A person using radioactive material pursuant to the general license in subrule (1) is exempt from the requirements of part 5 with respect to radioactive material covered by that general license.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5091. Ice detection devices.

Rule 91. (1) This rule is a general license issued to own, receive, acquire, possess, use and transfer strontium-90 contained in ice detection devices, if each device contains not more than 50 microcuries of strontium-90 and was manufactured or imported in accordance with a specific license issued by the NRC or was manufactured in accordance with the specifications contained in a specific license issued by the department or an agreement state to the manufacturer of the device pursuant to licensing requirements equivalent to those in section 32.61 of 10 CFR Part 32 of the regulations of the NRC.

(2) Persons who own, receive, acquire, possess, use or transfer strontium-90 contained in ice detection devices pursuant to the general license in subrule (1):

- (a) Upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, to the device, shall discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the department, the NRC or an agreement state to manufacture or service the devices; or shall dispose of the device pursuant to rule 238.
- (b) Shall 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.
- (c) Are exempt from the requirements of part 5 except that they shall comply with the provisions of rules 238, 246, 247 and 255.

(3) The general license provided in subrule (1) does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

(4) The general license provided in subrule (1) is subject to the provisions of rules 41 to 43, 119, 123, 124 and 255.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5092. Items possessed before these rules.

Rule 92. This rule is a general license issued to individuals who possessed, before the effective date of these rules, articles containing naturally occurring and accelerator produced material to own, possess and use the articles if the alpha emitting radioactive material does not exceed 1.0 µCi per unit or in the case of beta-

gamma emitting radioactive material, each unit does not exceed the value specified in rule 147.

SPECIFIC LICENSES

R325.5101. Applications.

Rule 101. (1) An application for a specific license shall be filed on a form prescribed by the department and shall be accompanied by the appropriate license fee as specified in rules 141 to 145.

(2) The application shall be signed by the applicant or licensee or a person authorized to act for and on his behalf.

(3) An application for a license may include a request for a license authorizing 1 or more activities.

(4) In his application, the applicant may incorporate by reference information contained in previous applications, statements or reports filed with the department if the references are clear and specific.

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

(6) The application 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.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5102. General requirements for specific licenses.

Rule 102. The department shall approve a license application if it determines all of the following:

- (a) The applicant or the designated individual user is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these rules in such a manner as to minimize danger to public health and safety or property.
- (b) The applicant's proposed equipment, facilities and procedures are adequate to minimize danger to public health and safety or property.
- (c) The issuance of the license will not be inimical to the health and safety of the public.
- (d) The applicant satisfies any applicable special requirements in rules 103 to 117a.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and

compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.

SPECIAL REQUIREMENTS FOR ISSUANCE OF CERTAIN SPECIFIC LICENSES

R325.5103. Human use of radioactive material in institutions.

Rule 103. (1) The department shall issue a specific license for human use of radioactive material in institutions when it determines all of the following:

- (a) The applicant has appointed a medical isotopes committee of not less than 3 members to evaluate all proposals for research, diagnostic, and therapeutic use of radioisotopes within the institution. Membership of the committee should include physicians expert in nuclear medicine, hematology, therapeutic radiology and a person experienced in assay of radioisotopes and protection against radiation.
- (b) The applicant possesses adequate facilities for the clinical care of patients.
- (c) The physician designated on the application as the individual user has substantial experience in the handling and administration of radioisotopes and, where applicable, the clinical management of radioactive patients.
- (d) The applicant's staff has substantial experience in the use of a variety of radioactive materials for a variety of human uses if the application is for a license to use unspecified quantities or multiple types of radioactive material.

(2) A license to use unspecified quantities or multiple types of radioactive material issued pursuant to this rule shall be termed a broad medical license and shall be subject to rules 112 to 117.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5104. Human use of radioactive material by individual physicians.

Rule 104. The department shall issue a specific license for human use of radioactive materials to an individual physician if it determines both of the following:

- (a) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable.
- (b) The applicant has extensive experience in the handling and administration of radioisotopes and, where applicable, the clinical management of radioactive patients.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5105. Groups of medical uses.

Rule 105. (1) The department shall approve an application for a specific license pursuant to rules 103 or 104 for any medical use of radioactive material specified in 1 or more of Groups I to VII, inclusive, of schedule C of rule 148 for all of the uses within the group or groups which include the use or uses specified in the application if:

- (a) The applicant satisfies the requirements of rules 103 or 104.
- (b) The applicant, or the physician designated in the application as the individual user, has adequate clinical experience in the types of uses included in the group or groups.
- (c) The applicant or the physicians and all other personnel who will be involved in the preparation and use of the radioactive material have adequate training and experience in the handling of radioactive material appropriate to their participation in the uses included in the group or groups.
- (d) The applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the uses included in the group or groups.
- (e) The applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses included in the group or groups.

(2) A licensee who is authorized to use radioactive material pursuant to 1 or more groups in subrule (1) and rule 148 is subject to the following conditions:

- (a) For Groups I, II, IV, and V a licensee shall not receive, possess, or use radioactive material except as a radiopharmaceutical manufactured in the form to be administered to the patient, labeled, packaged, and distributed in accordance with any 1 of the following:
 - (i) A specific license issued by the NRC pursuant to section 32.72 of 10 CFR Part 32.
 - (ii) A specific license issued to the manufacturer by the department pursuant to rule 111a.
 - (iii) A specific license issued to the manufacturer by an agreement state pursuant to equivalent state regulations.
 - (iv) An application filed with the NRC pursuant to section 32.72 of 10 CFR Part 32 on or before October 15, 1974 for a license to manufacture and distribute a radiopharmaceutical that the applicant distributed commercially on or before August 16, 1974 on which application the NRC has not acted.
 - (v) An application filed with the department pursuant to rule 111a not less than 60 days after the effective date of these rules

for a license to manufacture and distribute a radiopharmaceutical that the applicant distributed commercially on or before the effective date of these rules on which application the department has not acted.

- (vi) An application filed with an agreement state pursuant to equivalent state regulations not less than 60 days after the effective date of that agency's regulations for a license to manufacture and distribute a radiopharmaceutical that the applicant distributed commercially on or before the effective date of that agency's regulations on which application that agency has not acted.
- (b) For Group III, a licensee shall not receive, possess, or use generators or reagent kits containing radioactive material or use reagent kits that do not contain radioactive material to prepare radiopharmaceuticals containing radioactive material, except any of the following:
 - (i) Reagent kits not containing radioactive material that are approved by the department, the NRC or an agreement state for use by persons licensed pursuant to this rule and Group III of Schedule C of rule 148 or equivalent regulations.
 - (ii) Generators or reagent kits containing radioactive material that are manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the NRC pursuant to section 32.73 of 10 CFR Part 32 or by the department or an agreement state pursuant to equivalent state regulations.
 - (iii) Generators or reagent kits that the manufacturer distributed on or before August 16, 1974 for which an application for license or approval was filed with the NRC pursuant to section 32.73 of 10 CFR Part 32 on or before October 15, 1974 on which application the NRC has not acted.
 - (iv) Generators or reagent kits that the manufacturer distributed on or before the effective date of these rules for which an application for license or approval was filed with the department pursuant to rule 111b not less than 60 days after the effective date of these rules on which application the department has not acted.
 - (v) Generators or reagent kits that the manufacturer distributed on or before the effective date of the rules of an agreement state for which an application for license or approval was filed with that agreement state pursuant to equivalent state regulations not less than 60 days after the effective date of that agency's regulations on which application that agency has not acted.
- (c) For Group VI a licensee shall not receive, possess or use radioactive material except as contained in a source or device that has been manufactured, labeled, packaged, and distributed in accordance with any one of the following:

- (i) A specific license issued by the NRC pursuant to section 32.74 of 10 CFR Part 32.
 - (ii) A specific license issued to the manufacturer by the department pursuant to rule 111c.
 - (iii) A specific license issued to the manufacturer by an agreement state pursuant to equivalent state regulations.
 - (iv) An application filed with the NRC pursuant to section 32.74 of 10 CFR Part 32 on or before October 15, 1974 for a license to manufacture and distribute a source or device that the applicant distributed commercially on or before August 16, 1974 on which application the NRC has not acted.
 - (v) An application filed with the department pursuant to rule 111c not less than 60 days after the effective date of these rules for a license to manufacture and distribute a source or device that the applicant distributed commercially on or before the effective date of these rules on which application the department has not acted.
 - (vi) An application filed with an agreement state pursuant to equivalent state regulations not less than 60 days after the effective date of that agency's regulations for a license to manufacture and distribute a source or device that the applicant distributed commercially on or before the effective date of that agency's regulations on which application that agency has not acted.
- (d) For Group III, a licensee who uses generators or reagent kits shall elute the generator or process radioactive material with the reagent kit in accordance with instructions which are approved by the department, the NRC or an agreement state and are furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.
- (e) For Groups VI and VII a licensee who possesses and uses sources or devices containing radioactive material shall:
- (i) Cause each source or device containing more than 100 microcuries of radioactive material with a half-life greater than 30 days, except iridium-192 seeds encased in nylon ribbon, to be tested for contamination or leakage or both at intervals not to exceed six months or at such other intervals as are approved by the department, the NRC or an agreement state and described by the manufacturer on the label attached to the source, device or permanent container thereof, or in the leaflet or brochure which accompanies the source or device. Each source or device shall be so tested prior to its first use unless the supplier furnishes a certificate that the source or device has been so tested within 6 months prior to transfer.
 - (ii) Assure that the test required by subdivision (e)(i) is capable of detecting the presence of 5 nanocuries of radioactive material on the test sample. The test sample shall be taken from the source or from the surfaces of the device in which the source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak tests results shall be kept in units of nanocuries and maintained for inspection by the department.
- (iii) If the test required by subdivision (e)(i) reveals the presence of 5 nanocuries or more of removable contamination, immediately withdraw the source from use and cause it to be decontaminated and repaired or disposed of in accordance with rule 238. A report shall be filed within 5 days of the test with the department describing the equipment involved, the test results, and the corrective action taken.
 - (iv) Follow the radiation safety and handling instructions approved by the department, the NRC or an agreement state and furnished by the manufacturer on the label attached to the source, device or permanent container thereof, or in the leaflet or brochure that accompanies the source or device, and maintain such instructions in a legible and conveniently available form.
 - (v) Conduct a quarterly physical inventory to account for all sources and devices received and possessed. Records of the inventories shall be maintained for inspection by the department and shall include the quantities and kinds of radioactive material, location of sources and devices, and the date of the inventory.
 - (vi) Assure that needles or standard medical applicator cells containing cobalt-60 as wire are not opened while in the licensee's possession unless specifically authorized by a license issued to him by the department.
 - (vii) Assure that patients containing cobalt-60, cesium-137, iridium-192 or radium-226 implants shall remain hospitalized until the implants are removed.
- (3) A licensee who is licensed pursuant to subrule (1) for one or more of the medical use groups in schedule C of rule 148 also is authorized to use radioactive material under the general license in rule 90 for the specified *in vitro* uses without filing Form RH-201. However, the licensee is subject to the other provisions of rule 90.
- (4) A licensee who is licensed pursuant to subrule (1) for 1 or more of the medical use groups in schedule C of rule 148 also is authorized, subject to the provisions of subrules (5) and (7) to receive, possess, and use for calibration and reference standards:
- (a) Any radioactive material listed in Group I, Group II, or Group III of schedule C of rule 148

with a half-life not longer than 100 days, in amounts not to exceed 15 millicuries total.

- (b) Any radioactive material listed in Group I, Group II, or Group III of schedule C of rule 148 with half-life greater than 100 days in amounts not to exceed 200 microcuries total.
- (c) Technetium-99m in amounts not to exceed 30 millicuries.
- (d) Any radioactive material, in amounts not to exceed 3 millicuries per source, contained in calibration or reference sources that have been manufactured, labeled, packaged, and distributed in accordance with any one of the following:
 - (i) A specific license issued by the NRC pursuant to section 32.74 of 10 CFR Part 32.
 - (ii) A specific license issued to the manufacturer by the department pursuant to rule 111c.
 - (iii) A specific license issued to the manufacturer by an agreement state pursuant to equivalent state regulations.
 - (iv) An application filed with the NRC pursuant to section 32.74 of 10 CFR Part 32 on or before October 15, 1974 for a license to manufacture and distribute a source or device that the applicant distributed commercially on or before August 16, 1974 on which application the NRC has not acted.
 - (v) An application filed with the department pursuant to rule 111c not less than 60 days after the effective date of these rules for a license to manufacture and distribute a source or device that the applicant distributed on or before the effective date of these rules on which application the department has not acted.
 - (vi) An application filed with an agreement state pursuant to equivalent state regulations not less than 60 days after the effective date of that agency's regulations for a license to manufacture and distribute a source or device that the applicant distributed commercially on or before the effective date of that agency's regulations on which application that agency has not acted.

(5) A licensee who possesses sealed sources as calibration or reference sources pursuant to subrule (4) shall cause each sealed source containing radioactive material, other than hydrogen-3, with a half-life greater than 30 days in any form other than gas to be tested for leakage or contamination or both at intervals not to exceed 6 months. In the absence of a certificate from the transferor indicating that a test has been made within 6 months prior to the transfer, the sealed source shall not be used until tested. However, leak tests are not required when the source contains 100 microcuries or less of beta or gamma emitting material or is stored and is not being used. Such sources shall, however, be tested for leakage after storage prior to any use or transfer unless they have been leak tested within 6 months prior to the date of use or transfer.

(6) The leak test shall be capable of detecting the presence of 5 nanocuries of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which contamination might be expected to accumulate. Records of leak test results shall be kept in units of nanocuries and maintained for inspection by the department.

(7) If the leak test reveals the presence of 5 nanocuries or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with rule 238. A report shall be filed within 5 days of the test with the department describing the equipment involved, the test results, and the corrective action taken.

(8) A licensee who possesses and uses calibration and reference sources pursuant to subdivision (4)(d) shall:

- (a) Follow the radiation safety and handling instructions approved by the department, the NRC or an agreement state and furnished by the manufacturer on the label attached to the source, or permanent container thereof, or in the leaflet or brochure that accompanies the source, and maintain such instructions in a legible and conveniently available form.
- (b) Conduct a quarterly physical inventory to account for all sources received and possessed. Records of the inventories shall be maintained for inspection by the department and shall include the quantities and kinds of radioactive material, location of sources, and the date of the inventory.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5106. Human use of sealed sources.

Rule 106. The department shall issue a specific license for human use of sealed sources only if the applicant, or if the application is made by an institution, the individual user, is a physician and has specialized training in the therapeutic use of the sealed source considered, such as a teletherapy unit or radium applicator, or has experience equivalent to that training.

[Note: As a result of Executive Orders 12996-1 and 1996-2, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5107. Distribution of devices to persons generally licensed.

Rule 107. (1) The department shall issue a specific license to distribute certain devices of the types

enumerated in rule 85 to persons generally licensed under rule 85 if:

- (a) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling, proposed uses and potential hazards of the device to provide reasonable assurance that:
 - (i) The radioactive material contained in the device will not be lost.
 - (ii) An individual will not receive a radiation dose to a major portion of his body in excess of 0.5 rem in a year under ordinary circumstances of use.
 - (iii) The device can be operated safely by individuals not having training in radiological protection.
 - (iv) The radioactive material within the device will not be accessible to unauthorized individuals.
- (b) In describing the label and contents thereon to be affixed to the device, the applicant separately indicates those instructions and precautions that are necessary to assure safe operation of the device. The instructions and precautions shall be contained on labels bearing the statement, "**Removal of this label is prohibited.**"
- (c) The applicant desires that the device be tested for proper operation of the on-off mechanism and indicator, if any, and for leakage of radioactive material, subsequent to the initial tests required in Rule 85 (2)(c), at intervals longer than six months but not exceeding three years, the applicant includes in his application sufficient information to demonstrate that the 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. In determining the acceptable interval for test of leakage of radioactive material, the department shall consider information on particulars which include:
 - (i) Primary containment (source capsule).
 - (ii) Protection of primary containment.
 - (iii) Method of sealing containment.
 - (iv) Containment construction materials.
 - (v) Form of contained radioactive material.
 - (vi) Maximum temperature withstood during prototype tests.
 - (vii) Maximum pressure withstood during prototype tests.
 - (viii) Maximum quantity of contained radioactive material.
 - (ix) Radiotoxicity of contained radioactive material.
 - (x) Operating experience with identical devices or similarly designed and constructed devices.

(2) A licensee authorized under this rule to distribute certain devices to generally licensed persons:

- (a) Shall report to the department all transfers of such devices to persons generally licensed under rule 85. The report shall identify each

general licensee by name and address, the type of device transferred and the quantity and type of radioactive material contained in the device. The report shall be submitted within 30 days after the end of each calendar quarter in which a device is transferred to persons generally licensed.

- (b) Shall furnish to each general licensee in this state to whom he transfers a device a copy of the general license contained in rule 85.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5108. Use of sealed sources in industrial radiography.

Rule 108. The department shall issue a specific license for use of sealed sources in industrial radiography if:

- (a) The applicant proposes an adequate program for training radiographers and radiographers' assistants and submits to the department a schedule or description of the program which specifies the:
 - (i) Initial training.
 - (ii) Periodic training.
 - (iii) On-the-job training.
 - (iv) Means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with department rules and licensing requirements, and the operating and emergency procedures of the applicant.
 - (v) Means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant.
- (b) The applicant proposes and submits to the department satisfactory written operating and emergency procedures as described in rule 302.
- (c) The applicant proposes an adequate internal inspection system, or other management control, to assure that license provisions, these rules, and the applicant's operating and emergency procedures are followed by radiographers and radiographers' assistants.
- (d) The applicant submits to the department a description of his overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program.
- (e) The applicant who desires to conduct his own leak tests has established adequate procedures to be followed in leak testing sealed sources for possible leakage and contamination and submits to the department a description of such procedures including:
 - (i) Instrumentation to be used.

- (ii) Method of performing tests, such as points on equipment to be smeared and method of taking smear.
- (iii) Pertinent experience of the person who will perform the test.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5109. Introduction of radioactive material into products in exempt concentrations.

Rule 109. (1) The department shall issue a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under rule 65 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.
- (b) The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in rule 146, that reconcentration of the radioactive material in concentrations exceeding those in rule 146 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 subrule (1) shall file an annual report with the department which identifies the type and quantity of each product or material into which radioactive material was introduced during the reporting period; the name and address of the person who owned or possessed the product or material into which radioactive material was introduced at the time of introduction; the type and quantity of radionuclide introduced into each 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 transfers of radioactive material were not made pursuant to subrule (1) during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5110. Manufacture and distribution for medical use under general license.

Rule 110. The department shall issue a specific license authorizing the distribution of radioactive material for use by physicians under the general license in rule 89 if:

- (a) The applicant submits evidence that the radioactive material is to be manufactured, labeled and packaged in accordance with a new drug application which the commissioner of food and drugs of the United States Food and Drug Administration (FDA), has approved, or in accordance with a license for a biologic product issued by the secretary of the United States Department of Health, Education, and Welfare.
- (b) One of the following statements, or substantially similar statements which contains the information called for in the appropriate following statement, appears on the label affixed to the container or appears in the leaflet or brochure which accompanies the package:
 - (i) Byproduct material statement.
This radioactive drug may be received, acquired, possessed and used only by physicians licensed to dispense drugs in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license or its equivalent of the United States Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

(Name of Manufacturer)

- (ii) Accelerator material statement.
This radioactive drug may be received, acquired, possessed, and used only by physicians licensed to dispense drugs in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations of the state agency responsible for radiological health.

(Name of Manufacturer)

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5111. Manufacture and distribution for certain *in vitro* clinical or laboratory testing under general license.

Rule 111. The department shall issue a specific license to manufacture and distribute radioactive material for use under the general license in rule 90 if:

- (a) The applicant satisfies the general requirements specified in rule 102.
- (b) The radioactive material is to be prepared for distribution in prepackaged units of:
 - (i) Iodine-125 in units not exceeding 10 microcuries each.
 - (ii) Iodine-131 in units not exceeding 10 microcuries each.
 - (iii) Carbon-14 in units not exceeding 10 microcuries each.
 - (iv) Hydrogen-3 (tritium) in units not exceeding 50 microcuries each.
 - (v) Iron-59 in units not exceeding 20 microcuries each.
- (c) Each prepackaged unit bears a durable, clearly visible label:
 - (i) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries of iodine-131, iodine-125, or carbon-14; 50 microcuries of hydrogen-3 (tritium); or 20 microcuries of iron-59.
 - (ii) Displaying the radiation caution symbol described in rule 224 and the words, "**CAUTION, RADIOACTIVE MATERIAL,**" and "**Not for Internal or External Use in Humans or Animals.**"
- (d) One of the following statements or substantially similar statements which contains the information called for in the appropriate following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:
 - (i) Byproduct material statement.
This radioactive material may be received, acquired, possessed and used only by physicians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the United States Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

(Name of Manufacturer)

- (ii) Accelerator material statement.
This radioactive material may be received, acquired, possessed and used only by physicians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or

external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, possession, use and transfer are subject to the regulations of the state agency responsible for radiological health.

(Name of Manufacturer)

- (e) 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 the radioactive material.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5111a. Manufacture and distribution of radiopharmaceuticals for medical use under group licenses.

Rule 111a. (1) An application for a specific license to manufacture and distribute radiopharmaceuticals for use by persons licensed pursuant to rule 105 for the uses listed in Group I, Group II, Group IV, or Group V of Schedule C of rule 148 will be approved if:

- (a) The applicant satisfies the general requirements specified in rule 102.
- (b) The applicant submits evidence of either of the following:
 - (i) The radiopharmaceutical will be manufactured, labeled, and packaged in accordance with the federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a New Drug Application (NDA) approved by the federal food and drug administration (FDA), a biologic product license issued by FDA, or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) accepted by FDA.
 - (ii) The manufacture and distribution of the radiopharmaceutical is not subject to the federal food, drug, and cosmetic act and the public health service act.
- (c) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material that is appropriate for safe handling and storage of radiopharmaceuticals by group licensees.
- (d) The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay, and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the department for distribution to persons licensed pursuant to rule 105 and Group I, Group II, Group IV, or Group V of schedule C of rule

148, as appropriate, or under equivalent licenses of the NRC or an agreement state or that an application for such license has been filed with the department, the NRC or an agreement state not less than 60 days after the effective date of the respective agency's regulations and is still pending.

(2) The labels, leaflets or brochures required by subrule (1) are in addition to the labeling required by FDA and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

(3) If an application is filed pursuant to subrule (1) not less than 60 days after the effective date of these rules for a license to manufacture and distribute a radiopharmaceutical that was distributed commercially on or before the effective date of these rules, the applicant may continue the distribution of such radiopharmaceutical to group licensees until the department issues the license or notifies the applicant otherwise.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5111b. Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals.

Rule 111b. (1) An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to rule 105 for the uses listed in Group III of Schedule C of rule 148 will be approved if (see subrule (4)):

- (a) The applicant satisfies the general requirements specified in rule 102.
- (b) The applicant submits evidence of either of the following:
 - (i) The generator or reagent kit will be manufactured, labeled, and packaged in accordance with the federal food, drug, and cosmetic act or the public health service act, such as a new drug application (NDA) approved by the federal food and drug administration (FDA), a biologic product license issued by FDA, or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) accepted by FDA.
 - (ii) The manufacture and distribution of the generator or reagent kit are not subject to the federal food, drug, and cosmetic act and the public health service act.
- (c) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit.

- (d) The label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay.
- (e) The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:
 - (i) Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit.
 - (ii) A statement that this generator or reagent kit (as appropriate) is approved for use by persons licensed by the department pursuant to rule 105 and Group III of schedule C of rule 148 or under equivalent licenses of the NRC or an agreement state or that an application for such license has been filed with the department, the NRC or an agreement state not less than 60 days after the effective date of the respective agency's regulations and is still pending.

(2) The labels, leaflets or brochures required by subrule (1) are in addition to the labeling required by FDA and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

(3) If an application is filed pursuant to subrule (1) not less than 60 days after the effective date of these rules for a license to manufacture and distribute a generator or reagent kit that was distributed commercially on or before the effective date of these rules, the applicant may continue the distribution of such generator or reagent kit until the department issues the license or notifies the applicant otherwise.

(4) Although the department does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the department for use by persons licensed pursuant to rule 105 and Group III of Schedule C of rule 148 may submit the pertinent information specified in this rule.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5111c. Manufacture and distribution of radioactive sources or devices for medical use.

Rule 111c. (1) An application for a specific license to manufacture and distribute radioactive sources and devices to persons licensed pursuant to rule 105 for

use as a calibration or reference source or for the uses listed in Group VI of Schedule C of rule 148 will be approved if:

- (a) The applicant satisfies the general requirements in rule 102.
- (b) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:
 - (i) The radioactive material contained, its chemical and physical form, and amount.
 - (ii) Details of design and construction of the source or device.
 - (iii) 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.
 - (iv) The radiation profile of a prototype device.
 - (v) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests.
 - (vi) Procedures and standards for calibrating sources and devices.
 - (vii) Legend and methods for labeling sources and devices as to their radioactive content.
 - (viii) 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. Instructions which are too lengthy for the label may be summarized on the label and printed in detail on a brochure which is referenced on the label.
- (c) 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 source or device is licensed by the department for distribution to persons licensed pursuant to rule 105 and Group VI of schedule C of rule 148 or under equivalent licenses of the NRC or an agreement state or that a pending application for such license has been filed with the department, the NRC or an agreement state not less than 60 days after the effective date of the respective agency's regulations. Labeling for sources which do not require long term storage (e.g., gold-198 seeds) may be on a leaflet or brochure which accompanies the sources.

(2) 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 6 months, he shall include in his application sufficient information to demonstrate that a 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.

(3) In determining the acceptable interval for test of leakage of radioactive material, the department will consider information that includes:

- (i) Primary containment (source capsule).
- (ii) Protection of primary containment.
- (iii) Method of sealing containment.
- (iv) Containment construction materials.
- (v) Form of contained radioactive material.
- (vi) Maximum temperature withstood during prototype tests.
- (vii) Maximum pressure withstood during prototype tests.
- (viii) Maximum quantity of contained radioactive material.
- (ix) Radiotoxicity of contained radioactive material.
- (x) Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(4) If an application is filed pursuant to subrule (1) not less than 60 days after the effective date of these rules for a license to manufacture and distribute a source or device that was distributed commercially on or before the effective date of these rules, the applicant may continue the distribution of such source or device to group licensees until the department issues the license or notifies the applicant otherwise.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5112. Specific licenses of broad scope.

Rule 112. (1) Rules 113 to 117 define and prescribe requirements for the issuance of specific licenses of broad scope for radioactive material also known as broad licenses and certain rules governing holders of such licenses.

(2) Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity or other product containing source material or byproduct material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20545.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5113. Types of broad licenses.

Rule 113. The different types of broad licenses are defined as follows:

- (a) "Type A specific license of broad scope" means a specific license authorizing ownership, receipt, acquisition, 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.
- (b) "Type B specific license of broad scope" means a specific license authorizing ownership, receipt, acquisition, possession, use and transfer of any chemical or physical form of radioactive material specified in rule 149, for any authorized purpose. The possession limit for a type B broad license, if only 1 radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Column I of rule 149. If 2 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 Column I of rule 149 for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.
- (c) "Type C specific license of broad scope" means a specific license authorizing ownership, receipt, acquisition, possession, use and transfer of any chemical or physical form of radioactive material specified in rule 149 for any authorized purpose. The possession limit for a type C broad license, if only 1 radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Column II of rule 149. 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 Column II of rule 149 for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5114. Type A broad license.

Rule 114. An application for a type A specific license of broad scope shall be approved if:

- (a) The applicant satisfies the general requirements specified in rule 102.
- (b) The applicant has engaged in a reasonable number of activities involving the use of radioactive material.
- (c) 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:

- (i) The establishment of a radiation safety committee composed of such individuals as a radiation protection supervisor, a representative of management and individuals trained and experienced in the safe use of radioactive materials.
- (ii) The appointment of a full-time radiation protection supervisor who is qualified by training and experience in radiation protection, and available for advice and assistance on radiological safety matters.
- (iii) The establishment of appropriate administrative procedures to assure:
 - (aa) Control of procurement and use of radioactive material.
 - (bb) Completion of safety evaluations of proposed uses of radioactive material which consider such matters as the adequacy of facilities and equipment, training and experience of the user and the operating or handling procedures.
 - (cc) Review, approval and recording by the radiation safety committee of safety evaluation of proposed uses prepared in accordance with subdivision (bb) before use of the radioactive material.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5115. Type B broad license.

Rule 115. An application for a Type B specific license of broad scope shall be approved if:

- (a) The applicant satisfies the general requirements specified in rule 102.
- (b) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review, necessary to assure safe operations, including:
 - (i) The appointment of a full-time radiation protection supervisor who is qualified by training and experience in radiation protection, and available for advice and assistance on radiological safety matters.
 - (ii) The establishment of appropriate administrative procedures to assure:
 - (aa) Control of procurement and use of radioactive material.
 - (bb) Completion of safety evaluations of proposed uses of radioactive material which consider such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures.

- (cc) Review, approval, and recording by the radiation protection supervisor of safety evaluations of proposed uses prepared in accordance with subdivision (bb) before use of the radioactive material.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5116. Type C broad license.

Rule 116. An application for a type C specific license of broad scope shall be approved if:

- (a) The applicant satisfies the general requirements specified in rule 102.
- (b) The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:
 - (i) A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering.
 - (ii) At least 40 hours of training and experience in the safe handling of radioactive materials, and in the characteristics of ionizing radiation, radiation quantities and units, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type of forms of radioactive material to be used.
- (c) 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.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5117. Requirements for all types of broad licenses.

Rule 117. Specific licenses of broad scope are subject to the following requirements:

- (a) Persons licensed pursuant to rules 112 to 117 shall not:
 - (i) Conduct tracer studies in the environment involving direct release of radioactive material.
 - (ii) Receive, acquire, own, possess, use or transfer devices containing 100,000 curies or more of radioactive material in sealed sources used for irradiation of materials.
 - (iii) Conduct activities for which a specific license issued by the department under

rules 104 to 111 is required except as authorized in a broad medical license issued pursuant to rule 103(1)(d).

- (iv) 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 except as authorized in a broad medical license issued pursuant to rule 103(1)(d).
- (b) A type A specific license of broad scope issued under this part is subject to the condition that radioactive material possessed under the license may be used only by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.
- (c) A type B specific license of broad scope issued under this part is subject to the condition that radioactive material possessed under the license may be used only by, or under the direct supervision of, individuals approved by the licensee's radiation protection supervisor.
- (d) A type C specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may be used only by, or under the direct supervision of, individuals who satisfy the requirements of rule 116(b).

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5117a. Particle accelerator licenses.

Rule 117a. (1) A particle accelerator capable of producing radioactive material in excess of exempt quantities listed in schedule B of rule 147 shall not be operated in a manner likely to produce such quantities of radioactive material unless a person is authorized to operate in a specific license issued pursuant to this rule.

(2) A particle accelerator licensed pursuant to this rule is exempt from registration under part 4.

(3) Subject to rule 122 a person shall submit an application for a specific license to operate a particle accelerator subject to this rule in accordance with rule 101.

(4) The department shall issue a specific license for a particle accelerator subject to licensing under this rule when it determines all of the following:

- (a) The applicant will have an adequate program for training accelerator operators and submits to the department a schedule or description of the program which specifies the:
 - (i) Initial training.
 - (ii) Periodic training.
 - (iii) On-the-job training.

- (iv) Means to be used by the licensee to determine the operator's knowledge and understanding of and ability to comply with department rules and licensing requirements, and the operating and emergency procedures of the applicant.
- (b) The applicant has established and submits to the department satisfactory written operating and emergency procedures.
- (c) The applicant will have an adequate internal inspection system, or other management control, to assure that license provisions, rules and the applicant's operating and emergency procedures are followed by operators and all other individuals associated with the accelerator operation.
- (d) The applicant submits to the department a description of his overall organizational structure pertaining to the particle accelerator program, including specified delegations of authority and responsibility for operation of the program.
- (e) The applicant has applied for or has been issued a valid license to own, receive, acquire, possess, use and transfer radioactive material produced or used in connection with accelerator operation.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5118. Issuance of specific licenses.

Rule 118. (1) As used in this rule the term "as it deems appropriate or necessary" means as the department determines is appropriate or necessary in order to minimize danger to public health and safety or property; and prevent loss or theft of material subject to this part.

(2) Upon a determination that an application meets the requirements of the act and these rules the department shall issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(3) The department may incorporate in any license at the time of issuance, or thereafter by appropriate rule or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this part as it deems appropriate or necessary.

(4) The department may require such reports and the keeping of such records, and may provide for such inspections of activities under the license as it deems appropriate or necessary.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan

Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5119. Specific terms and conditions of licenses.

Rule 119. (1) A license issued under this part is subject to all the provisions of the act, now or hereafter in effect, and to all rules and orders of the department.

(2) A license issued or granted under this part and a right to possess or utilize radioactive material granted by a license issued under this part shall not 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 finds that the transfer is in accordance with the provisions of the act, and gives its consent in writing.

(3) A person licensed by the department under this part shall confine his use and possession of the material licensed to the locations and purposes authorized in the license.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5120. Expiration, renewal and amendment of licenses.

Rule 120. (1) Except as provided in subrule (3), each specific license expires at the end of the day, in the month and year stated therein.

(2) An application for renewal of a specific license shall be filed in accordance with rule 101.

(3) If a licensee, not less than 30 days before expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, the existing license does not expire until the application has been finally determined by the department.

(4) An application for amendment of a license shall be filed in accordance with rule 101 and shall specify the respects in which the licensee desires his license to be amended and the grounds for such amendment.

(5) In considering an application by a licensee to renew or amend his license, the department shall apply the criteria set forth in rules 102 to 111, or rules 112 to 117.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5121. Existing NRC licenses for agreement material.

Rule 121. A person who, on the effective date of these rules, possesses a general or specific license issued by the NRC for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass, is deemed to possess a like license issued under this part and the act. The license expires either 90 days after receipt from the department of a notice of expiration of the license, or on the date of expiration specified in the NRC license, whichever is earlier.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5122. Radioactive material other than agreement material possessed before these rules.

Rule 122. A person who, on the effective date of these rules, possesses naturally occurring or accelerator-produced radioactive material or a particle accelerator for which a specific license is required by this part or the act is deemed to possess a like license issued under this part and the act. The license expires 90 days after the effective date of these rules; however, if within the 90 days the person possessing the material files an application in proper form for a license, the existing license does not expire until the application has been finally determined by the department.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5123. Transfer of material.

Rule 123. (1) A licensee shall not transfer radioactive material except as authorized pursuant to this rule.

(2) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of rule 255.

- (3) A licensee may transfer radioactive material:
- (a) To the department.
 - (b) To the NRC.
 - (c) To a person exempt from the rules in this part to the extent permitted under the exemption.
 - (d) To a person authorized to receive the material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the department, the NRC, or an agreement state, or to a person otherwise authorized to receive the material by the federal government or any

agency thereof, the department, or an agreement state.

- (e) As otherwise authorized by the department in writing.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5124. Modification, revocation, and termination of licenses.

Rule 124. (1) The terms and conditions of a license are subject to amendment, revision or modification or the license may be suspended or revoked by reason of amendments to the act, or by reason of rules and orders issued by the department.

(2) A license may be revoked, suspended or modified, in whole or in part, for:

- (a) A material false statement in the application or any statement of fact required under the act.
- (b) A condition revealed by the application or statement of fact or any report, record or inspection or other means which would warrant the department to refuse to grant a license on an original application.
- (c) A violation of, or failure to observe any of the terms and conditions of the act, the license, or any rule or order of the department.

(3) Except in a case of willfulness or where the public health, interest or safety requires otherwise, a license shall not be modified, suspended or revoked unless, before the institution of proceedings therefor, facts or conduct which may warrant the action have been called to the attention of the licensee in writing and the licensee has been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

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

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5125. Environmental impact report.

Rule 125. An application for a license to receive and possess radioactive material for commercial waste disposal by land burial in Michigan or for the conduct of any other activity which the department determines will significantly affect the quality of the environment shall be filed at least 9 months before the beginning of construction of the plant or facility in which the activity will be conducted and shall be accompanied by an environmental report. The report shall contain

information similar to the information specified in rules 212 and 238.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

RECIPROCITY

R325.5131. General license for limited period.

Rule 131. This rule is a general license issued to a person who holds a specific license from the NRC or an agreement state issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, to conduct the activities authorized in the license in this state for a period not in excess of 180 days in any calendar year if:

- (a) The license does not limit the activity authorized by it to specified installations or locations.
- (b) The licensee notifies the department in writing at least 3 days prior to engaging in the activity. The notification shall indicate the location, period and type of proposed possession and use within this state, and shall be accompanied by a copy of the pertinent license. If, for a specific case, the 3 day period would impose an undue hardship on the licensee, he may obtain permission to proceed sooner upon application to the department. 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 this rule.
- (c) The licensee complies with all applicable rules of the department and with all the terms and conditions of his license, except terms and conditions which may be inconsistent with applicable rules of the department.
- (d) The licensee supplies such other information as the department may request.
- (e) The licensee does not transfer or dispose of radioactive material possessed or used under the general license provided in this rule except by transfer to a person specifically licensed by the department or by the NRC to receive such material; or exempt from the requirements for a license for such material under rule 65.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5132. General license to install, transfer or service certain devices.

Rule 132. Notwithstanding the provisions of rule 131, this rule is a general license issued to a person who holds a specific license issued by the NRC or an agreement state authorizing the holder to manufacture, transfer, install or service a device described in rule 85 within areas subject to the jurisdiction of the licensing agency, to install, transfer or service the device in this state if:

- (a) The person files a report with the department within 30 days after the end of each calendar quarter in which a device is transferred to or installed in this state. The report shall identify the general licensee to whom the device is transferred by name and address, the type of device transferred and the quantity and type of radioactive material contained in the device.
- (b) The device was manufactured, labeled, installed and serviced in accordance with applicable provisions of the specific license issued to the person by the NRC or an agreement state.
- (c) The person assures that any labels required to be affixed to the device under regulations of the agency which licensed manufacture of the device bear a statement that "**Removal of this label is prohibited**".
- (d) The holder of the specific license furnishes to each general licensee to whom he transfers a device or on whose premises he installs a device a copy of the general license contained in rule 85.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5133. Limited acceptance of reciprocal licenses.

Rule 133. The department may withdraw, limit or qualify its acceptance of a specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining that the action is necessary to prevent undue hazard to public health and safety or property.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

LICENSE FEES

R325.5141. Application fees.

Rule 141. (1) A license application for which a fee is prescribed in rule 144 shall be accompanied by a remittance in the full amount of the fee unless the applicant has been exempted from fee payment under rule 143.

(2) An application will not be accepted for filing or processed before payment of the full amount specified unless exempted from fee payment. An application for which a remittance is not received may be returned to the applicant.

(3) All application fees shall be retained irrespective of the department's disposition of the application or a withdrawal of the application.

(4) The application fee serves as the license fee for the first year after issuance of the license irrespective of the time interval between date of application and date of issuance.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5142. Annual fees.

Rule 142. (1) An annual license fee is payable 1 year after the date of issuance of the license and annually thereafter.

(2) The annual fee shall be submitted in a timely manner so that its receipt is assured on or before the due date in order to maintain the license in effect.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5143. Exemptions.

Rule 143. (1) Application fees or annual fees are not required for licenses applied for by, or issued to:

- (a) An agency of this state or any political subdivision thereof for radioactive material or accelerators to be used primarily for services rendered on a charitable basis or in connection with a facility used primarily for charitable purposes.
- (b) A nonprofit educational institution for radioactive material or accelerators to be used exclusively for teaching or training purposes or in connection with a facility used exclusively for teaching or training purposes.

(2) Application fees or annual fees are not required for licenses authorizing the use of source material as shielding only in devices and containers, but all other licensed radioactive material in the device or container is subject to the fees prescribed in Rule 144 unless otherwise exempted under this rule.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5144. Fee schedule.

Rule 144. Applicants for specific radioactive material licenses and licensees issued these licenses shall pay the appropriate license fees and shall be subject to the footnotes specified in the following fee schedule unless exempted under Rule 143.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

SCHEDULE OF RADIOACTIVE MATERIAL LICENSE FEES

Category of License ¹	Application Fee ³	Annual Fee ^{3,4}
1. Special Nuclear Material: ⁵		
A. Specific licenses for special nuclear material in quantities not sufficient to form a critical mass, except those licenses covered by categories 4A, 4B, 5A, 6A, 7A, 7B, 7C, 7D or 8A.	\$ 200	\$ 200
2. Source Material:		
A. Specific licenses for source material for use in milling operations and licenses for refining mill concentrates to uranium hexafluoride.	\$ 10,000	\$ 10,000
B. Specific licenses for source material in quantities greater than 50 kilograms except licenses for storage only and licenses for use only of source material in counterweights.	\$ 150	\$ 150
C. All other specific licenses for source material, except those licenses covered by Categories 4A, 4B, 6A, 7A, 7B, 7C, 7D or 8A.	\$ 75	\$ 75
3. Radioactive Material Other than Special Nuclear Material or Source Material: ⁶		
A. Specific licenses for possession and use of radioactive material for processing, or manufacturing of items containing radioactive material for commercial distribution that require product safety evaluation.	\$ 2,000	\$ 2,000

Category of License ¹	Application Fee ³	Annual Fee ^{3,4}
B. Specific licenses for possession and use of radioactive material for processing, or manufacturing of items containing radioactive material where no product safety evaluation is required or quantities of radioactive material for commercial distribution except exempt quantities as defined in rule 74.	\$ 1,000	\$ 1,000
C. Specific licenses for radioactive material for industrial radiography operations at 1 location.	\$ 300	\$ 300
D. Specific licenses for radioactive material for industrial radiography operations at more than 1 location.	\$ 600	\$ 600
E. Specific licenses for possession and use of radioactive material in quantities of less than 10,000 curies in sealed sources for irradiation of materials.	\$ 100	\$ 100
F. Specific licenses for possession and use of radioactive material in quantities of 10,000 curies or more in sealed sources for irradiation of materials.	\$ 200	\$ 200
G. Specific licenses issued pursuant to rule 107 to distribute items containing radioactive material or quantities of radioactive material to persons generally licensed under rules 84 to 92 except, specific licenses authorizing redistribution of items which have been manufactured or imported under a specific license and licensed by the department, the NRC or an agreement state for distribution to persons generally licensed under rules 84 to 92.	\$ 300	\$ 300
H. Specific licenses for possession and use of radioactive material for research and development, except those licenses covered by Categories 3A or 3B, and licenses covered by Categories 7B, 7C, or 7D authorizing medical research.	\$ 250	\$ 250
I. Non-human use of radium.	\$ 50	\$ 50
J. All other specific radioactive material licenses except those in Categories 4A, 4B, 5A, 6A, 7A, 7B, 7C, 7D or 8A.	\$ 50	\$ 50
4. Waste Disposal:		
A. Waste disposal licenses specifically authorizing the receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee by land burial.	\$ 3,000	\$ 3,000
B. Waste disposal licenses specifically authorizing the receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee by transfer to another person authorized to receive such material.	\$ 400	\$ 400
5. Well Logging, Well Surveys and Tracer Studies:		
A. Specific licenses for possession and use of radioactive material for well logging, well surveys and tracer studies.	\$ 250	\$ 250
6. Nuclear Laundries:		
A. Specific licenses for commercial collection and laundry of items contaminated with radioactive material.	\$ 500	\$ 500
7. Human Use:		
A. Specific licenses for human use of radioactive material in sealed sources contained in teletherapy devices.	\$ 150	\$ 150
B. Specific licenses for human use of radium in sealed sources for brachytherapy.	\$ 100	\$ 100
C. Specific licenses issued to medical institutions for human use of radioactive material, except licenses in Categories 7A or 7B.	\$ 200	\$ 200

Category of License ¹	Application Fee ³	Annual Fee ^{3 4}
D. Specific licenses issued to physicians for human use of radioactive material, except licenses in Categories 7A or 7B.	\$ 100	\$ 100
8. Civil Defense:		
A. Specific licenses for possession and use of radioactive material for civil defense activities.	\$ 35	\$ 35
9. Particle Accelerators:		
A. Specific licenses for particle accelerators for production of radioactive material for transfer to other persons.	\$ 2,000	\$ 2,000
B. Specific licenses for particle accelerators for production of radioactive material not to be transferred to other persons except for disposal.	\$ 1,500	\$ 1,500
C. Specific licenses for particle accelerators used exclusively for high-energy research. (Research and development)	\$ 1,000	\$ 1,000
D. Specific licenses for particle accelerators used exclusively for food processing or materials processing or control.	\$ 500	\$ 500
E. Specific licenses for particle accelerators for human use.	\$ 300	\$ 300
F. All other specific licenses for particle accelerators.	\$ 250	\$ 250

**FOOTNOTES
TO
SCHEDULE OF RADIOACTIVE MATERIAL LICENSE FEES**

¹ Amendments based on applications filed after the due date of the annual license fee reducing the scope of a licensee's program or cancelling a license, will not entitle the licensee to a partial refund of an annual fee that has been paid by the licensee for the year in which such amendment or cancellation occurs. Applications for amendments increasing the scope of a program to a higher fee category will not be accepted for filing unless accompanied by the prescribed fee less the amount of the currently prescribed fee for the activities already licensed.

² Applications for specific licenses covering more than 1 fee category shall be accompanied by the prescribed fee for each category.

³ Payment of the prescribed annual fee does not automatically renew the license for which the fee is paid. Renewal applications shall be filed in accordance with the requirements of rule 120. Applications for reissuance of licenses that have expired because a timely renewal application was not filed shall be accompanied by the prescribed application fee.

⁴ The annual fee will be waived where an application is filed to cancel the license prior to the due date of the annual fee, and the amount of the annual fee will be reduced where an application is filed to amend the license to reduce its scope before the due date of the annual fee. However, an annual fee will not be waived or reduced unless the application filed before the due date of the fee contains all the information necessary to permit the department to complete the requested action.

⁵ Specific licenses for special nuclear material in quantities sufficient to form a critical mass may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20545.

⁶ Such radioactive material includes accelerator material, byproduct material, and naturally occurring material.

⁷ Particle accelerators not capable of producing radioactive material in excess of exempt quantities listed in schedule B of rule 147 and radiation machines excluded from the particle accelerator definition by design and use are exempted from licensing under this part. However, such radiation machines are subject to registration under part 4. Particle accelerators licensed under this part are exempt from registration under part 4.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5145. Payment of fees.

Rule 145. (1) License fee payments shall be by check, draft or money order payable to the "State of Michigan".

(2) Fee payments shall be received by the Michigan Department of Public Health, Division of Radiological Health, Licensing and Compliance Control Section, 3500 North Logan Street, Lansing, Michigan 48914.

(3) In any case where the department finds that a licensee has failed to pay the applicable annual fee required in this part, the department may suspend or

revoke the license or may issue such order with respect to licensed activities as the department determines to be necessary to carry out the provisions of these rules and the act.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5146. Schedule A - Exempt concentrations.

Rule 146. See rule 65.

Element (atomic number)	Radionuclide	Column I Gas concentration μCi/ml*	Column II Liquid and solid concentration μCi/ml**
Antimony (51)	Sb 122		3×10^{-4}
	Sb 124		2×10^{-4}
	Sb 125		1×10^{-3}
Argon (18)	Ar 37	1×10^{-3}	
	Ar 41	4×10^{-7}	
Arsenic (33)	As 73		5×10^{-3}
	As 74		5×10^{-4}
	As 76		2×10^{-4}
	As 77		8×10^{-4}
Barium (56)	Ba 131		2×10^{-3}
	Ba 140		3×10^{-4}
Beryllium (4)	Be 7		2×10^{-2}
Bismuth (83)	Bi 206		4×10^{-4}
Bromine (35)	Br 82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd 109		2×10^{-3}
	Cd 115m		3×10^{-4}
	Cd 115		3×10^{-4}
Calcium (20)	Ca 45		9×10^{-5}
	Ca 47		5×10^{-4}
Carbon (6)	C 14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce 141		9×10^{-4}
	Ce 143		4×10^{-4}
	Ce 144		1×10^{-4}
Cesium (55)	Cs 131		2×10^{-2}
	Cs 134m		6×10^{-2}
	Cs 134		9×10^{-5}
Chlorine (17)	Cl 38	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr 51		2×10^{-2}
	Co 57		5×10^{-3}
Cobalt (27)	Co 58		1×10^{-3}
	Co 60		5×10^{-4}
	Cu 64		3×10^{-3}
Copper (29)	Dy 165		4×10^{-3}
	Dy 166		4×10^{-4}
Dysprosium (66)	Er 169		9×10^{-4}
	Er 171		1×10^{-3}
Erbium (68)	Eu 152		6×10^{-4}
	($T_{1/2}=9.2$ hrs)		
Europium (63)	Eu 155		2×10^{-3}
	F 18		8×10^{-3}
Fluorine (9)	Gd 153		2×10^{-3}
	Gd 159		8×10^{-4}
Gadolinium (64)	Ga 72		4×10^{-4}
	Ge 71		2×10^{-2}
Gallium (31)			
Germanium (32)			

Element (atomic number)	Radionuclide	Column I Gas concentration $\mu\text{Ci}/\text{ml}^*$	Column II Liquid and solid concentration $\mu\text{Ci}/\text{ml}^{**}$	
Gold (79)	Au 196	5×10^{-6}	2×10^{-3}	
	Au 198		5×10^{-4}	
	Au 199		2×10^{-3}	
Hafnium (72)	Hf 181		7×10^{-4}	
	Hydrogen (1)		3×10^{-2}	
Indium (49)	In 113m		1×10^{-2}	
	In 114m		2×10^{-4}	
Iodine (53)	I 126		3×10^{-9}	2×10^{-5}
	I 131		3×10^{-9}	2×10^{-5}
	I 132		8×10^{-8}	6×10^{-4}
	I 133		1×10^{-8}	7×10^{-5}
	I 134		2×10^{-7}	1×10^{-3}
Iridium (77)	Ir 190		2×10^{-3}	
	Ir 192		4×10^{-4}	
	Ir 194		3×10^{-4}	
Iron (26)	Fe 55	1×10^{-6}	8×10^{-3}	
	Fe 59		6×10^{-4}	
Krypton (36)	Kr 85m		3×10^{-6}	
	Kr 85			
Lanthanum (57)	La 140		2×10^{-4}	
Lead (82)	Pb 203		4×10^{-3}	
Lutetium (71)	Lu 177		1×10^{-3}	
Manganese (25)	Mn 52		3×10^{-4}	
	Mn 54		1×10^{-3}	
	Mn 56		1×10^{-3}	
	Mercury (80)		Hg 197m	2×10^{-3}
Molybdenum (42)	Hg 197		3×10^{-3}	
	Hg 203		2×10^{-4}	
	Mo 99		2×10^{-3}	
	Neodymium (60)		Nd 147	6×10^{-4}
Nd 149		3×10^{-3}		
Nickel (28)	Ni 65	1×10^{-3}		
Niobium (41) (Columbium)	Nb 95	1×10^{-3}		
	Nb 97	9×10^{-3}		
	Osmium (76)	Os 185	7×10^{-4}	
Os 191m		3×10^{-2}		
Os 191		2×10^{-3}		
Os 193		6×10^{-4}		
Palladium (46)	Pd 103	3×10^{-3}		
	Pd 109	9×10^{-4}		
Phosphorous (15)	P 32	2×10^{-4}		
Platinum (78)	Pt 191	1×10^{-3}		
	Pt 193m	1×10^{-2}		
	Pt 197m	1×10^{-2}		
	Pt 197	1×10^{-3}		
Polonium (84)	Po 210	7×10^{-6}		
Potassium (19)	K 42	3×10^{-3}		
Praseodymium(59)	Pr 142	3×10^{-4}		
	Pr 143	5×10^{-4}		
	Promethium (61)	Pm 147	2×10^{-3}	
Pm 149		4×10^{-4}		
Radium (88)	Ra 226	1×10^{-7}		
	Ra 228	3×10^{-7}		
Radon (86)	Rn 220	1×10^{-8}		
	Rn 222	1×10^{-7}		
	Rhenium (75)	Re 183	6×10^{-3}	
Re 186		9×10^{-4}		
Re 188		6×10^{-4}		
Rhodium (45)	Rh 103m	1×10^{-1}		
	Rh 105	1×10^{-3}		
Rubidium (37)	Rb 86	7×10^{-4}		

Element (atomic number)	Radionuclide	Column I Gas concentration $\mu\text{Ci}/\text{m}^3$ *	Column II Liquid and solid concentration $\mu\text{Ci}/\text{m}^{3**}$	
Ruthenium (44)	Ru 97	9×10^{-8}	4×10^{-3}	
	Ru 103		8×10^{-4}	
	Ru 105		1×10^{-3}	
	Ru 106		1×10^{-4}	
Samarium (62)	Sm 153		8×10^{-4}	
	Scandium (21)		Sc 46	4×10^{-4}
			Sc 47	9×10^{-4}
Sc 48			3×10^{-4}	
Selenium (34)	Se 75		3×10^{-3}	
Silicon (14)	Si 31		9×10^{-3}	
Silver (47)	Ag 105		1×10^{-3}	
	Ag 110m		3×10^{-4}	
	Ag 111		4×10^{-4}	
Sodium (11)	Na 24		2×10^{-3}	
Strontium (38)	Sr 85		1×10^{-3}	
	Sr 89		1×10^{-4}	
	Sr 91		7×10^{-4}	
	Sr 92		7×10^{-4}	
	Sulfur (16)		S 35	6×10^{-4}
Tantalum (73)	Ta 182		4×10^{-4}	
Technetium (43)	Tc 96m		1×10^{-1}	
	Tc 96		1×10^{-3}	
	Tellurium (52)		Te 125m	2×10^{-3}
Te 127m			6×10^{-4}	
Te 127			3×10^{-3}	
Te 129m			3×10^{-4}	
Te 131m			6×10^{-4}	
Te 132			3×10^{-4}	
Terbium (65)			Tb 160	4×10^{-4}
Thallium (81)	Tl 200		4×10^{-3}	
	Tl 201		3×10^{-3}	
	Tl 202		1×10^{-3}	
	Tl 204		1×10^{-3}	
Thulium (69)	Tm 170		5×10^{-4}	
	Tm 171		5×10^{-3}	
Tin (50)	Sn 113		9×10^{-4}	
	Sn 125		2×10^{-4}	
Tungsten (74) (Wolfram)	W 181		4×10^{-3}	
	W 187		7×10^{-4}	
Vanadium (23)	V 48		3×10^{-4}	
Xenon (54)	Xe 131m	4×10^{-6}		
	Xe 133	3×10^{-6}		
	Xe 135	1×10^{-6}		
Ytterbium (70)	Yb 175	1×10^{-3}		
	Yttrium (39)	Y 90	2×10^{-4}	
		Y 91m	3×10^{-2}	
		Y 91	3×10^{-4}	
		Y 92	6×10^{-4}	
Y 93		3×10^{-4}		
Zinc (30)	Zn 65	1×10^{-3}		
	Zn 69m	7×10^{-4}		
	Zn 69	2×10^{-2}		
Zirconium (40)	Zr 95	6×10^{-4}		
	Zr 97	2×10^{-4}		
	Beta and/or gamma emitting radioactive material not listed above with half-life less than 3 years.	1×10^{-10}	1×10^{-6}	

NOTE 1: Many radionuclides disintegrate into nuclides which are also radioactive. In expressing the concentrations in Schedule A the activity stated is that of the parent nuclide and takes into account the daughters.

NOTE 2: For purposes of rule 65 where there is involved a combination of nuclides, the limit for the combination should be derived as follows: Determine for each nuclide in the product the ratio between the concentration present in the product and the exempt concentration established in Schedule A for the specific nuclide when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

EXAMPLE:

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

* Values are given in Column 1 only for those materials normally used as gases.

** $\mu\text{Ci/gm}$ for solids.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5147. Schedule B - Exempt quantities.

Rule 147. See rule 74.

Radionuclide	Microcuries	Radionuclide	Microcuries
Antimony 122 (Sb 122)	100	Indium 114m (In 114m)	10
Antimony 124 (Sb 124)	10	Indium 115m (In 115m)	100
Antimony 125 (Sb 125)	10	Indium 115 (In 115)	10
Arsenic 73 (As 73)	100	Iodine 125 (I 125)	1
Arsenic 74 (As 74)	10	Iodine 126 (I 126)	1
Arsenic 76 (As 76)	10	Iodine 129 (I 129)	0.1
Arsenic 77 (As 77)	100	Iodine 131 (I 131)	1
Barium 131 (Ba 131)	10	Iodine 132 (I 132)	10
Barium 133 (Ba 133)	10	Iodine 133 (I 133)	1
Barium 140 (Ba 140)	10	Iodine 134 (I 134)	10
Bismuth 210 (Bi 210)	1	Iodine 135 (I 135)	10
Bromine 82 (Br 82)	10	Iridium 192 (Ir 192)	10
Cadmium 109 (Cd 109)	10	Iridium 194 (Ir 194)	100
Cadmium 115m (Cd 115m)	10	Iron 55 (Fe 55)	100
Cadmium 115 (Cd 115)	100	Iron 59 (Fe 59)	10
Calcium 45 (Ca 45)	10	Krypton 85 (Kr 85)	100
Calcium 47 (Ca 47)	10	Krypton 87 (Kr 87)	10
Carbon 14 (C 14)	100	Lanthanum 140 (La 140)	10
Cerium 141 (Ce 141)	100	Lutetium 177 (Lu 177)	100
Cerium 143 (Ce 143)	100	Manganese 52 (Mn 52)	10
Cerium 144 (Ce 144)	1	Manganese 54 (Mn 54)	10
Cesium 131 (Cs 131)	1,000	Manganese 56 (Mn 56)	10
Cesium 134m (Cs 134m)	100	Mercury 197m (Hg 197m)	100
Cesium 134 (Cs 134)	1	Mercury 197 (Hg 197)	100
Cesium 135 (Cs 135)	10	Mercury 203 (Hg 203)	10
Cesium 136 (Cs 136)	10	Molybdenum 99 (Mo 99)	100
Cesium 137 (Cs 137)	10	Neodymium 147 (Nd 147)	100
Chlorine 36 (Cl 36)	10	Neodymium 149 (Nd 149)	100
Chlorine 38 (Cl 38)	10	Nickel 59 (Ni 59)	100
Chromium 51 (Cr 51)	1,000	Nickel 63 (Ni 63)	10
Cobalt 58m (Co 58m)	10	Nickel 65 (Ni 65)	100
Cobalt 58 (Co 58)	10	Niobium 93m (Nb 93m)	10
Cobalt 60 (Co 60)	1	Niobium 95 (Nb 95)	10
Copper 64 (Cu 64)	100	Niobium 97 (Nb 97)	10
Dysprosium 165 (Dy 165)	10	Osmium 185 (Os 185)	10
Dysprosium 166 (Dy 166)	100	Osmium 191m (Os 191m)	100
Erbium 169 (Er 169)	100	Osmium 191 (Os 191)	100
Erbium 171 (Er 171)	100	Osmium 193 (Os 193)	100
Europium 152 (Eu 152) 9.2 h	100	Palladium 103 (Pd 103)	100
Europium 152 (Eu 152) 13 yr	1	Palladium 109 (Pd 109)	100
Europium 154 (Eu 154)	1	Phosphorus 32 (P 32)	10
Europium 155 (Eu 155)	10	Platinum 191 (Pt 191)	100
Fluorine 18 (F18)	1,000	Platinum 193m (Pt 193m)	100
Gadolinium 153 (Gd 153)	10	Platinum 193 (Pt 193)	100
Gadolinium 159 (Gd 159)	100	Platinum 197m (Pt 197m)	100
Gallium 72 (Ga 72)	10	Platinum 197 (Pt 197)	100
Germanium 71 (Ge 71)	100	Polonium 210 (Po 210)	0.1
Gold 198 (Au 198)	100	Potassium 42 (K 42)	10
Gold 199 (Au 199)	100	Praseodymium 142 (Pr 142)	100
Hafnium 181 (Hf 181)	10	Praseodymium 143 (Pr 143)	100
Holmium 166 (Ho 166)	100	Promethium 147 (Pm 147)	10
Hydrogen 3 (H 3)	1,000	Promethium 149 (Pm 149)	10
Indium 113m (In 113m)	100	Rhenium 186 (Re 186)	100

Radionuclide	Microcuries
Rhenium 188 (Re 188)	100
Rhodium 103m (Rh 103m)	100
Rhodium 105 (Rh 105)	100
Rubidium 86 (Rb 86)	10
Rubidium 87 (Rb 87)	10
Ruthenium 97 (Ru 97)	100
Ruthenium 103 (Ru 103)	10
Ruthenium 105 (Ru 105)	10
Ruthenium 106 (Ru 106)	1
Samarium 151 (Sm 151)	10
Samarium 153 (Sm 153)	100
Scandium 46 (Sc 46)	10
Scandium 47 (Sc 47)	100
Scandium 48 (Sc 48)	10
Selenium 75 (Se 75)	10
Silicon 31 (Si 31)	100
Silver 105 (Ag 105)	10
Silver 110m (Ag 110m)	1
Silver 111 (Ag 111)	100
Sodium 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 90 (Yb 90)	10
Yttrium 91 (Yb 91)	10
Yttrium 92 (Yb 92)	100
Yttrium 93 (Yb 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

Radionuclide	Microcuries
Zirconium 97 (Zr 97)	10
Any radionuclide not listed above other than alpha emitting radioactive material	0.1

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5148. Schedule C - Groups of medical uses.

Rule 148. See Rule 105.

Group I. Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution and excretion. This group does not include uses involving imaging and tumor localizations.

- (1) Iodine-131 as sodium iodide (NaI¹³¹) for measurement of thyroid uptake.
- (2) Iodine-125 as sodium iodide (NaI¹²⁵) for measurement of thyroid uptake.
- (3) Iodine-131 as Iodinated Human Serum Albumin (IHSA) for determinations of blood and blood plasma volume and for studies of cardiovascular function and protein turnover.
- (4) Iodine-125 as Iodinated Human Serum Albumin (IHSA) for determination of blood and blood plasma volume and for studies of cardiovascular function and protein turnover.
- (5) Iodine-131 as labeled rose bengal for liver function studies.
- (6) Iodine-125 as labeled rose bengal for liver function studies.
- (7) Iodine-131 as labeled fats or fatty acids for fat absorption studies.
- (8) Iodine-125 as labeled fats or fatty acids for fat absorption studies.
- (9) Iodine-131 as labeled iodopyracet, sodium iodohippurate, sodium diatrizoate, diatrizoate methylglucamine, sodium diprotrizoate, sodium acetrizoate, or sodium iothalamate for kidney function studies.
- (10) Iodine-125 as labeled iodopyracet, sodium iodohippurate, sodium diatrizoate, diatrizoate methylglucamine, sodium diprotrizoate, sodium acetrizoate, or sodium iothalamate for kidney function studies.
- (11) Cobalt-57 as labeled cyanocobalamin for intestinal absorption studies.
- (12) Cobalt-58 as labeled cyanocobalamin for intestinal absorption studies.
- (13) Cobalt-60 as labeled cyanocobalamin for intestinal absorption studies.
- (14) Chromium-51 as sodium chromate for determination of red blood cell volume, studies of red blood cell survival time and gastrointestinal blood loss.
- (15) Chromium-51 as labeled human serum albumin for gastrointestinal protein loss studies.
- (16) Iron-59 as chloride, citrate, or sulfate for iron turnover studies.

- (17) Potassium-42 as chloride for potassium space determinations.
- (18) Sodium-24 as chloride for sodium space determinations.
- (19) Technetium-99m as pertechnetate for blood flow studies.
- (20) Mercury as chlormerodrin for kidney function studies.
- (21) Any radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the FDA or for which a "New Drug Application" (NDA) has been approved by the FDA.

Group II. Use of prepared radiopharmaceuticals for diagnostic studies involving imaging and tumor localizations.

- (1) Iodine-131 as sodium iodide for thyroid imaging.
- (2) Iodine-125 as sodium iodide for thyroid imaging.
- (3) Iodine-131 as Iodinated Human Serum Albumin (IHSA) for brain tumor localizations and cardiac imaging.
- (4) Iodine-131 as macroaggregated iodinated human serum albumin for lung imaging.
- (5) Iodine-131 as colloidal (microaggregated) iodinated human serum albumin for liver imaging.
- (6) Iodine-131 as labeled rose bengal for liver imaging.
- (7) Iodine-131 as iodopyracet, sodium iodohippurate, sodium diatrizoate, diatrizoate methylglucamine, sodium diprotrizoate, or sodium acetrizoate for kidney imaging.
- (8) Iodine-131 as sodium iodipamide for cardiac imaging.
- (9) Iodine-131 as Iodinated Human Serum Albumin (IHSA) for placenta localization.
- (10) Chromium-51 as sodium chromate for spleen imaging.
- (11) Chromium-51 as labeled human serum albumin for placenta localization.
- (12) Gold-198 in colloidal form for liver imaging.
- (13) Mercury-197 as labeled chlormerodrin for kidney and brain imaging.
- (14) Mercury-203 as labeled chlormerodrin for brain imaging.
- (15) Selenium-75 as labeled selenomethionine for pancreas imaging.
- (16) Strontium-85 as nitrate or chloride for bone imaging in patients with suspected or diagnosed cancer.
- (17) Technetium-99m as pertechnetate for brain imaging.
- (18) Technetium-99m as pertechnetate for thyroid imaging.
- (19) Technetium-99m as pertechnetate for salivary gland imaging.
- (20) Technetium-99m as pertechnetate for blood pool imaging, including placenta localization.
- (21) Technetium-99m as labeled sulfur colloid for liver, spleen and bone marrow imaging.
- (22) Technetium-99m as labeled macroaggregated human serum albumin for lung imaging.
- (23) Any radioactive material in a radiopharmaceutical for a diagnostic use involving imaging for which a "Notice of Claimed Investigational Exemption for a

New Drug" (IND) has been accepted by the FDA or for which a "New Drug Application" (NDA) has been approved by the FDA.

- (24) Any radioactive material in a radiopharmaceutical prepared from a reagent kit listed in Section (3) of Group III of this rule.

Group III. Use of generators and reagent kits for the preparation and use of radiopharmaceuticals for certain diagnostic uses.

- (1) Molybdenum-99/technetium-99m generators for the elution of technetium-99m as pertechnetate for:
 - (i) Brain imaging.
 - (ii) Thyroid imaging.
 - (iii) Salivary gland imaging.
 - (iv) Blood pool imaging including placenta localization.
 - (v) Blood flow studies.
 - (vi) Use with reagent kits for preparation and use of radiopharmaceuticals containing technetium-99m as provided in (3) and (4) of this group.
- (2) Technetium-99m as pertechnetate for use with reagent kits for preparation and use of radiopharmaceuticals containing technetium-99m as provided in (3) and (4) of this group.
- (3) Reagent kits for preparation of technetium-99m labeled:
 - (i) Sulfur colloid for liver and spleen imaging.
 - (ii) Iron-ascorbate-diethylenetriamine pentaacetic acid complex for kidney imaging.
 - (iii) Diethylenetriamine pentaacetic acid (Sn) for kidney imaging and kidney function studies.
 - (iv) Diethylenetriamine pentaacetic acid (Sn) for brain imaging.
 - (v) Human serum albumin microspheres for lung imaging.
 - (vi) Polyphosphates for bone imaging.
 - (vii) Macroaggregated human serum albumin for lung imaging.
 - (viii) Disodium etidronate for bone imaging.
 - (ix) Stannous pyrophosphate for bone imaging.
- (4) Any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical for which generator or reagent kit a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the FDA or for which a "New Drug Application" (NDA) has been approved by the FDA.

Group IV. Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety.

- (1) Iodine-131 as iodide for treatment of hyperthyroidism and cardiac dysfunction.
- (2) Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases.
- (3) Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions.
- (4) Any radioactive material in a radiopharmaceutical and for a therapeutic use not normally requiring hospitalization for purposes of radiation safety for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the FDA or for which a "New Drug

Application" (NDA) has been approved by the FDA.

Group V. Use of prepared radiopharmaceuticals for certain therapeutic uses that normally require hospitalization for purposes of radiation safety.

- (1) Gold-198 as colloid for intracavitary treatment of malignant effusions.
- (2) Iodine-131 as iodide for treatment of thyroid carcinoma.
- (3) Any radioactive material in a radiopharmaceutical and for a therapeutic use normally requiring hospitalization for radiation safety reasons for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the FDA or for which a "New Drug Application" (NDA) has been approved by the FDA.

Group VI. Use of sources and devices containing radioactive material for certain medical uses.

- (1) Americium-241 as a sealed source in a device for bone mineral analysis.
- (2) Cesium-137 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment for cancer.
- (3) Cobalt-60 encased in needles and application cells for topical, interstitial, and intracavitary treatment of cancer.
- (4) Gold-198 as seeds for interstitial treatment of cancer.
- (5) Iodine-125 as a sealed source in a device for bone mineral analysis.
- (6) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer.
- (7) Strontium-90 sealed in an applicator for treatment of superficial eye conditions.

Group VII. Use of sources and devices containing radium-226 for certain medical uses.

- (1) Radium-226 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5149. Schedule D - Possession limits.

Rule 149. See rule 113.

Radionuclides	Column I Curies	Column 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

Radionuclides	Column I Curies	Column II Curies
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
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1
Cesium-134m	100	1
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
Chromium-51	100	1
Cobalt-57	10	0.1
Cobalt-58m	100	1
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152m 9.2h	10	0.1
Europium-152 13y	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1
Indium-113m	100	1
Indium-114m	1	0.01
Indium-115m	100	1
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
Krypton-87	10	0.1

Radionuclides	Column I Curies	Column II Curies
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
Osmium-185	1	0.01
Osmium-191m	100	1
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
Platinum-193	10	0.1
Platinum-197m	100	1
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
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1
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
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

Radionuclides	Column I Curies	Column 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
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
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
Xenon-133	100	1
Xenon-135	100	1
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
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radionuclide other than alpha emitting radionuclides not listed above	0.1	0.001

