



Paul R. LePage, Governor

Mary C. Mayhew, Commissioner

Department of Health and Human Services
Maine Center for Disease Control and Prevention
286 Water Street
11 State House Station
Augusta, Maine 04333-0011
Tel. (207) 287-8016
Fax (207) 287-9058; TTY (800) 606-0215

June 18, 2015

Pamela Henderson, Deputy Director
Division Material Safety, State, Tribal, and Rulemaking Programs
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
T8-E24
Washington, D.C. 20555-0001

Dear Ms. Henderson:

Enclosed is a copy of the affected pages of the final revisions to the Maine Radiation Control Program Rules [10-144 CMR ch. 220 adopted November 10, 2009]. The final regulations are identified by line-in/line-out text (or similar identification) and correspond to the following equivalent amendments to NRC's regulations.

| <u>Rats ID</u> | <u>Title</u> | <u>State Section</u> |
|----------------|--|------------------------------------|
| • 2001-1 | Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material | 220.C.6.C(3)(d) 220.C.6.C(3)(g) |
| • 2011-2 | Licenses, Certifications, and Approvals For Materials Licensees | 220.C.12 220.C.13 |
| • 2012-1 | Change in compatibility of 10 CFR 31.5 and 31.6 | 220.C.6.C(3) 220.C.6.I |

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-200 and specifically address all but one of the comments raised in NRC letter dated 8/31/2006 (ML062370173).

The one outstanding comment in the above letter and the comments in letter dated 6/16/2010 (ML101200008) will be sent, in draft form, under a separate cover letter.

RATS ID 2011-2

Maine doesn't have authority over Uranium mills (nor has NRC discontinued authority for such) (C.12) and Our equivalent regulation to part 30.33 is C.13 which has been reviewed previously. This Maine rule is attached.

RATS ID 2012-1

Changing the compatibility of 10 CFR 31.5 from B to C has brought the Maine Rules into compliance because our rules were previously more restrictive than the NRC rules for general licenses. This Maine rule is attached.

We believe that our current rules satisfy the RATS 2011-2 and 2012-1 compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-200.

If you have any questions, please feel free to contact me at 207-287-5677 or jay.hyland@maine.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Jay Hyland", with a large checkmark-like flourish at the end.

Jay Hyland PE, Program Manager
Maine Radiation Control Program
Department of Health and Human Services

Enclosures:

As stated

- a. shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;
- b. shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label, however,
 - (i) devices containing only krypton need not be tested for leakage of radioactive material, and
 - (ii) devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta and/or gamma emitting material or 10 microcuries (0.37 MBq) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;
- c. shall assure that other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:
 - (i) in accordance with the instructions provided by the labels, or
 - (ii) by a person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State, to perform such activities;
- d. shall maintain records showing compliance with the requirements of C.6.B(3)b. and c. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by C.6.B(3)b. shall be maintained for 3 years after the next required leak test is performed or until the sealed source is transferred or disposed. Records of tests of the on/off mechanism and indicator required by C.6.B(3)b. shall be maintained for 3 years after the next required test of the on/off mechanism and indicator is performed or until the sealed source is transferred or disposed. Records which are required by C.6.B(3)c. shall be maintained for a period of 3 years from the date of the recorded event or until the device is transferred or disposed;

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C.6.B.(3)e.

- e. upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State, to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the Agency a report containing a brief description of the event and the remedial action taken;
- f. shall not abandon the device containing radioactive material;
- g. Shall not export the device containing radioactive material except in accordance with 10 CFR Part 110.
- h. (i) Shall transfer or dispose of the device containing radioactive material only by export as provided by paragraph (g) of this section, by transfer to another general licensee as authorized in paragraph (i) of this section, or to a person authorized to receive the device by a specific license issued under Part C, that authorizes possession, use, waste collection, or equivalent regulations of an Agreement State, or as otherwise approved under paragraph (h)(iii) of this section.

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

B. A general license is hereby issued to receive title to and own special nuclear material without regard to quantity. Notwithstanding any other provision of this Part, a general licensee under C.6 is not authorized to acquire, deliver, receive, possess, use, transfer, import, or export special nuclear material, except as authorized in a specific license.

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C. Certain Measuring, Gauging or Controlling Devices.

- (1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and State or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provision of C.6.B(2), (3), (4), radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

C.6.B.(2)

- (2) The general license in C.6.C(1) applies only to radioactive material contained in devices, which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the Agency pursuant to C.11.D or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State, which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State. 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 Section 179.21 of the Code of Federal Regulations, Title 21. The devices must have been received from one of the specific licensees described in C.6.C(2) or through a transfer under C.6.C(3).

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- (3) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in C.6.C(1) shall file Agency Form HHE 861 "Registration Certificate - Use of Fixed Measuring, Gauging or Controlling Devices", Agency Form HHE 862 "Registration Certificate - Use of Portable Measuring, Gauging or Controlling Devices" or Agency Form HHE 864 "Registration Certificate for use of Static Eliminators, Electron Capture Devices, Gas Chromatographs, or Other Devices which Contain Radioactive Material Under a General License" with the Agency. The form shall be submitted within 30 days after the first receipt or acquisition of such device or 30 days after the effective date of these regulations for devices acquired prior to the effective date. The general licensee shall furnish such information as may be required by that form as well as the annual fee referenced in Appendix A of this Part and:

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C.6.C(3) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in C.6.C(1) shall file Agency Form HHE 861 "Registration Certificate - Use of Fixed Measuring, Gauging or Controlling Devices", Agency Form HHE 862 "Registration Certificate - Use of Portable Measuring, Gauging or Controlling Devices" or Agency Form HHE 864 "Registration Certificate for use of Static Eliminators, Electron Capture Devices, Gas Chromatographs, or Other Devices which Contain Radioactive Material Under a General License" with the Agency. The form shall be submitted within 30 days after the first receipt or acquisition of such device or 30 days after the effective date of these regulations for devices acquired prior to the effective date. The general licensee shall furnish such information as may be required by that form as well as the annual fee referenced in Appendix A of this Part and:

- (a) shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;
- (b) shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label, however,
 - (i) devices containing only krypton need not be tested for leakage of radioactive material, and
 - (ii) devices containing only tritium or not more than 3.7 MBq (100 µCi) of other beta and/or gamma emitting material or 0.37 MBq (10 µCi) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;
- (c) shall assure that other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:
 - (i) in accordance with the instructions provided by the labels, or
 - (ii) by a person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State to perform such activities;
- (d) shall maintain records showing compliance with the requirements of C.6.B(3)(b) and c. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by C.6.B(3)(b) shall be maintained for 3 years after the next required leak test is performed or until the sealed source is transferred or disposed. Records of tests of the on/off mechanism and indicator required by C.6.B(3)(b) shall be maintained for 3 years after the next required test of the on/off mechanism and indicator is performed or until the sealed source is transferred or disposed. Records which are required by C.6.B(3)(c) shall be maintained for a period of 3 years from the date of the recorded event or until the device is transferred or disposed;

- (e) upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 Bq (0.005 μ Ci) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the Agency a report containing a brief description of the event and the remedial action taken;
- (f) shall not abandon the device containing radioactive material;
- (g) shall not export the device containing radioactive material except in accordance with 10 CFR Part 110;
- (h)
 - (i) shall transfer or dispose of the device containing radioactive material only by export as provided by paragraph (g) of this section, by transfer to another general licensee as authorized in paragraph (i) of this section, or to a person authorized to receive the device by a specific license issued under Part C, that authorizes possession, use, waste collection, or equivalent regulations of an Agreement State, or as otherwise approved under paragraph (h)(iii) of this section.
 - (ii) shall, within 30 days after the transfer of a device to a specific licensee or export, furnish a report to the "Manager, Radiation Control Program". The report must contain—
 - (a) The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;
 - (b) The name, address, and license number of the person receiving the device (license number not applicable if exported); and
 - (c) The date of the transfer.
 - (iii) shall obtain written Agency approval before transferring the device to any other specific licensee not specifically identified in paragraph (c)(8)(i) of this section; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if the holder:
 - (a) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;
 - (b) Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by paragraph (a) of this section) so that the device is labeled in compliance with Part D.1904; however the manufacturer, model number, and serial number must be retained;
 - (c) Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and
 - (d) Reports the transfer under paragraph (h)(ii) of this section.
- (i) shall transfer the device to another general licensee only;

- (i) where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this Section, a copy of Sections 10 CFR 31.2, 31.51, C.25, D.2201, D.2202, and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Agency: the manufacturer's (or initial transferor's) name and model and serial number of device transferred, the name, address for the location of use of the transferee, and the name and/or position of an individual who may constitute a point of contact between the Agency and the transferee; or
- (ii) where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee;
- (j) shall comply with the provisions of D.2201. and D.2202. of these regulations for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Parts D and J of these regulations;
- (k) shall respond to written requests from the Agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by submitting a letter to the Radiation Control Program and provide written justification as to why it cannot comply.
- (l) shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.
- (m) (i) shall register, in accordance with C.6.C.(3)(m)(ii) and (iii), devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, 3.7 megabecquerels (0.1 millicurie) of radium-226, or 37 MBq (1 mCi) of americium-241 or any other transuranic ((i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under paragraph C.6.C.(3)(m)(iii)(d), represents a separate general licensee and requires a separate registration and fee.
- (ii) If in possession of a device meeting the criteria of C.6.C.(3)(m)(i), shall register these devices annually with the Agency and shall pay the required fee. Registration must be done by verifying, correcting and/or adding to the information provided in a request for registration received from the Agency. The registration information must be submitted to the Agency within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general license holding devices meeting the criteria of C.6.C.(3)(m)(i) is subject to bankruptcy notification requirement in Part C.
- (iii) In registering devices, shall furnish the following information and any other information specifically requested by the Agency:
 - (a) Name and mailing address of the general licensee.
 - (b) Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label).
 - (c) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under paragraph C.6.C.(3)(l). of this section.

- (d) Address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage.
- (e) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.
- (f) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.
- (iv) Persons generally licensed by an Agreement State with respect to devices meeting the criteria in paragraph C.6.C.(3)(m)(i) this section are not subject to registration requirements if the devices are used in areas subject to Agency jurisdiction for a period less than 180 days in any calendar year. The Agency will not request registration information from such licensees.
- n. shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Radiation Control Program Manager within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.
- o. shall not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by C.6.C(3)(c) need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.
- (4) The general license in C.6.B(1) does not authorize the manufacture of devices containing radioactive material.
- (5) The general license provided in C.6.B(1) is subject to the provisions of A.4 through A.9., C.14., C.21., C.22. and Part L of these regulations.

C.6.I General License to Install Devices Generally Licensed in C.6.C.

- (1) Any person who holds a specific license issued by an Agreement State authorizing the holder to manufacture, install, or service a device described in C.6.B(1) within such Agreement State is hereby granted a general license to install and service such device in any non-Agreement State and a general license to install and service such device in offshore waters, as defined in Part A of these regulations; provided that:
 - (a) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the Agreement State.
 - (b) Such person assures that any labels required to be affixed to the device under regulations of the Agreement State which licensed manufacture of the device bear a statement that removal of the label is prohibited.

12. Special Requirements for Issuance of Specific Licenses for Source Material Milling. *Reserved.*

13. Issuance of Specific Licenses.

- A. Each license issued pursuant to the these regulations in this part shall be subject to all provisions of the Act, now or hereafter in effect, and to all valid rules, regulations and orders of the Agency.
- B. No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, now or hereafter in effect and to all valid rules, regulations and orders of the Agency and shall give its consent in writing.
- C. Each person licensed by the Agency pursuant to the regulations in this Part shall confine his possession and use of the radioactive material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the regulations in this part shall carry with it the right to receive, possess, and use radioactive material. Preparation for shipment and transport of radioactive material shall be in accordance with Part L of these regulations.
- D. The Agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this part as it deems appropriate or necessary in order to:
 - (1) minimize danger to public health and safety or property;
 - (2) require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary;
 - (3) prevent loss or theft of material subject to this part; and
 - (4) protect restricted data