

**Methodology to Indicate Changes to
DPH-07-002 – General License Requirements**

The proposed changes for comment that are the subject of this notice are indicated as follows:

- Deletions from the proposed text presented during the second 15-day public comment period are indicated by a shaded double strike-through (~~strike through~~).
- Additions to the proposed text presented during the second 15-day public comment period are indicated by a shaded double underline (underline).

(1) Amend Section 30192.1 to read as follows:

§ 30192.1. General Licenses—Gauging and Controlling.

~~(a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and government agencies to 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, qualitative or quantitative chemical composition or for producing light or an ionized atmosphere when such devices are manufactured pursuant to a specific license authorizing distribution to general licensees provided that each such device:~~

~~(1) Is labeled in accordance with the provisions of the specific license which authorizes distribution of the device;~~

~~(2) Bears a label containing the following or substantially similar statement:~~

~~"The receipt, possession, use and transfer of this device, Model _____, Serial No. _____, are subject to a general license or equivalent and the regulations of the United States Nuclear Regulatory Commission or of a state with which the United States Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. Removal of this label is prohibited.~~

~~CAUTION--RADIOACTIVE MATERIAL~~

~~_____

(Name of Supplier)"~~

~~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; and~~

~~(3) Is installed on the premises of the general licensee by a person having a specific license which authorized installation of such devices when required by the label on the device.~~

~~(b) Persons who possess a device pursuant to the general license contained in Section 30192.1(a) shall:~~

~~(1) Within 30 days of the receipt of any such device, register with the Department and within 30 days of transfer of any such device, notify the Department in accordance with the provisions of Group 1.5 of this subchapter (Registration of Radiation Sources).~~

~~(2) Not transfer, abandon or dispose of the device, except by transfer to a person holding a specific license to receive such device.~~

~~(3) Transfer the device to another general licensee only;~~

~~(A) Where the device remains in use at a particular location. In such case the transferrer shall give the transferee a copy of this section and any safety documents identified in the label of the device, or;~~

~~(B) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by the general licensee.~~

~~(4) 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 comply with all instructions contained in such labels.~~

~~(5) 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 radioactive material on the premises of the general licensee and thereafter at no longer than six month intervals or at such longer intervals as may be specified in the specific license which authorized distribution of the device to general licenses. Devices containing only krypton need not be tested for leakage. Devices containing only tritium or not more than 100 uCi of other beta and/or gama emitting material or 10 uCi of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any reason.~~

~~(6) Have the test required by Section 30192.1(b)(5) and all other services involving the radioactive material, its shielding and containment performed:~~

~~(A) In accordance with the instructions provided by the label; or~~

~~(B) By a person holding an appropriate license therefor.~~

~~(7) Maintain records of all tests performed on the devices as required under this section, including the dates and results of these tests and the names and addresses of the persons conducting the test.~~

~~(8) Upon 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 of the on-off mechanism or indicator, immediately suspend operation of the device until it has been repaired by or disposed of to a person holding a specific license therefor.~~

~~(9) Within 30 days after the occurrence of a failure of or damage to the shielding or containment of radioactive material or the on-off mechanism or indicator or upon the detection of 0.005 microcuries or more of removable radioactive material, furnish to the Department a complete description of the device (manufacturer, type, serial number) and a brief description of the event and the remedial action taken.~~

~~(c) Persons who possess a device pursuant to the general license contained in Section 30192.1(a) shall with respect thereto be exempt from the requirements of Group 3 of this subchapter except for Sections 30253, 30254, and 30293(a).~~

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

(b) The general license issued pursuant to subsection (a) applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the provisions of:

(1) A specific license, which authorizes distribution of the device, issued by the Department pursuant to section 30195(d);

(2) An equivalent specific license issued by an Agreement State other than this State; or

(3) A specific license issued by the United States Nuclear Regulatory Commission (NRC) under section 32.51 of title 10, Code of Federal Regulations (10 CFR), Part 32.

(c) Devices described in subsection (a) shall have been received from one of the specific licensees described in subsection (b), or through a transfer made pursuant to subsection (d)(12).

(d) Persons who acquire, receive, possess, use or transfer a device under the general license issued pursuant to subsection (a) shall:

(1) Register and renew registration pursuant to section 30108.1 any devices containing at least 10 millicuries (mCi) of cesium-137, 0.1 mCi of strontium-90, 1 mCi of cobalt-60, 0.1 mCi of radium-226, or 1 mCi of americium-241 or any other transuranic (i.e., an element with atomic number greater than uranium (92)), based on the activity indicated on the label. The licensee shall be subject to the reporting requirement in section 30108.1(c) for such devices;

(2) Ensure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon, and comply with all instructions and precautions provided by such labels;

(3) Ensure that the device is tested for leakage of radioactive material and that the on-off mechanism and indicator, if any, operate as designed. These tests shall be performed at intervals no longer than six months or at such other intervals as are specified in the device's label. However:

(A) Devices containing only krypton need not be tested for leakage; and

(B) Devices containing only tritium, or not more than 100 microcuries (uCi) of other beta and/or gamma emitting material or 10 uCi 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;

(4) Ensure that the tests required by subsection (d)(3) and any testing, installation, servicing, and removal from installation involving the radioactive material, its shielding, or containment, are performed:

(A) In accordance with the instructions provided by the device's labels; or

(B) By a person holding a specific license issued by the Department or an Agreement State other than this State, authorizing the licensee to perform those activities;

(5) Maintain records showing compliance with the requirements of subsections (d)(3) and (d)(4), to include the results of tests, the dates of performance of tests, and the names of the persons performing testing, installing, servicing, and removing from the installation radioactive material, its shielding, or containment. The licensee shall retain records of tests required by:

(A) Subsection (d)(3) for three years after the next required test for leakage and test of the on-off mechanism and indicator is performed, or until the sealed source is transferred or disposed of; and

(B) Subsection (d)(4) for three years from the date of the recorded event or other test, or until the device is transferred or disposed of;

(6) Immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 uCi or more of removable radioactive material. The device shall not be operated until it has been repaired by the manufacturer or a person holding a specific license issued by the Department, the NRC, or an Agreement State other than this State, authorizing the licensee to repair the device. The device, and any radioactive material from the device, may only be disposed of in accordance with subsection (d)(10);

(7) Within 30 calendar days of an event specified in subsection (d)(6), submit a report to the Department containing:

(A) A brief description of the event and the remedial action taken; and

(B) If removable radioactive material greater than or equal to 0.005 uCi has been detected, or failure of or damage to a sealed source is likely to result in contamination of

the premises or the environs, a plan to ensure that the premises and environs are acceptable for unrestricted use;

(8) Not abandon the device;

(9) Not export the device except in accordance with an export license issued by the NRC pursuant to 10 CFR, Part 110. This provision shall not be construed to incorporate by reference 10 CFR, Part 110;

(10) Transfer or dispose of the device only:

(A) By export as provided by subsection (d)(9);

(B) By transfer to a specific licensee authorized to receive such device or another general licensee as authorized in subsection (d)(12); or

(C) After obtaining written Department approval authorizing transfer or disposal to any other specific licensee not specifically identified in subsection (d)(10)(A) or (B), except that 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:

1. Verifies that the specific license authorizes the possession and use, or pursuant to section 30194.2 applies for and obtains an amendment to the license authorizing the possession and use;

2. Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by subsection (d)(2)), so that the device is labeled in compliance with section 20.1904 of 10 CFR, Part 20, incorporated by reference in section 30253; however, the manufacturer, model number, and serial number shall be retained;

3. 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

4. Reports the transfer under subsection (d)(11);

(11) Within 30 calendar days after transfer of a device pursuant to subsection (d)(10), submit a report to the Department containing the:

(A) Identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;

(B) Name, address, and license number of the person receiving the device (license number not applicable if exported); and

(C) Date of the transfer;

(12) Transfer the device to another general licensee only if:

(A) The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of this section, sections 30108.1, 30254, 30257 and 30293(a) of this subchapter, sections 20.2201 and 20.2202 of 10 CFR, Part 20, incorporated by reference in section 30253, and any safety documents identified in the label of the device. Within 30 calendar days of the transfer, the transferor shall submit a report to the Department containing:

1. The manufacturer's (or initial transferor's) name;

2. The model number and the serial number of the device transferred;

3. The transferee's name and mailing address for the location of use; and

4. The name, title, and phone number of the responsible individual identified by the transferee pursuant to subsection (d)(15); or

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

(13) Comply with sections 20.2201 and 20.2202 of 10 CFR, Part 20, incorporated by reference in section 30253, for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from other requirements in Group 3 of this subchapter, except for sections 30257 and 30293(a);

(14) Upon Department request, 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 is unable to provide the requested information within the allotted time, a request for extending that time shall be submitted prior to the end of the allotted time, and the request for an extension of time shall include a written justification as to why the allotted time should be extended;

(15) Appoint an individual responsible for having knowledge of required actions and authority for taking required actions, so as to comply with this section and all sections cited or referenced within this section. Appointment of the responsible individual does

not relieve the general licensee of any of its own responsibility for complying with the Act and this subchapter; and

(16) Not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter shall be locked in the closed position. The testing required by subsection (d)(3) need not be performed during the period of storage. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they shall 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.

(e) The general license issued pursuant to this section does not authorize the manufacture or import of devices containing radioactive material.

Note: Authority cited: Sections ~~100275~~ and 114975, 115000 and 131200, Health and Safety Code. Reference: Sections 114965, 114970, 114985(g), 115060, 115165, 115230, ~~and~~ 115235, 131050, 131051 and 131052, Health and Safety Code.

(2) Amend Section 30192.3 to read as follows:

§ 30192.3. General Licenses—Calibration or Reference Sources.

(a) A general license is hereby issued to persons who hold either a specific license issued by the Department for any radioactive material, or a specific license issued by the United States Nuclear Regulatory Commission for any ~~special nuclear radioactive~~ material, to possess americium-241, ~~or~~ plutonium, or radium-226 in the form of calibration or reference sources. Calibration or reference sources shall be manufactured in accordance with the specifications contained in an appropriate specific license, which authorizes distribution under a general license. Each source possessed pursuant to the general license or its storage container shall bear a label, which includes the information required in the following statement:

"The receipt, possession, use and transfer of this source, Model_____, Serial No._____, are subject to a general license or its equivalent, and are further subject to the regulations of the United States Nuclear Regulatory Commission or ~~of~~ a state with which the United States Nuclear Regulatory 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 ~~-241, OR~~ PLUTONIUM, ~~OR~~ RADIUM-226, whichever is appropriate). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

"_____
(Name of Manufacturer or Importer)

(b) Persons who possess a source pursuant to under the general license ~~contained in Section 30192.3~~ issued pursuant to subsection (a) shall:

(1) Not have, at any one time, at any one location of storage or use, more than 5 microcuries of americium-241, ~~and~~ 5 microcuries of plutonium, or 5 microcuries of radium-226 contained in such sources.

(2) Not transfer, abandon or dispose of such sources, except by transfer to a person authorized by a license to receive the source.

(3) With respect to each such source when not in use, store the source in a closed container adequately designed and constructed to contain any of the radioactive material in ~~case~~the event the source is ruptured or leaks.

(4) Not use such source for any purpose other than calibration of radiation detectors or standardization of other sources.

(c) Persons who possess a source pursuant to under the general license contained in ~~Section 30192.3~~issued pursuant to subsection (a) shall, with respect thereto, be exempt from the requirement of Group 3 of this subchapter, except for sections 30253, 30254, 30255, 30275(a) and (b), and 30293(a), and 30295 of this subchapter and sections 20.2201 and 20.2202 of title 10, Code of Federal Regulations, Part 20, incorporated by reference in section 30253 Sections 30253, 30254, and 30293(a).

(d) The general license ~~issued pursuant to~~ in paragraph subsection (a) of this section does not authorize the manufacture, import, or export of calibration or reference sources containing americium-241, or plutonium, or radium-226 or the introduction of americium-241, plutonium, or radium-226 into any product or material.

Note: Authority cited: Sections ~~100275 and~~ 114975, 115000 and 131200, Health and Safety Code. Reference: Sections 114965, 114970, 114985(g), 115000, 115060, 115165, 115230, ~~and~~ 115235, 131050, 131051 and 131052, Health and Safety Code.