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California Department of Public Health



GAVIN NEWSOM
 Governor

August 26, 2024

Ms. Theresa V. Clark, Deputy Director
 Division of Materials Safety, Security, State, and Tribal Programs (MSST)
 Office of Nuclear Material Safety and Safeguards (NMSS)
 U.S. Nuclear Regulatory Commission (NRC)
 Washington, D.C. 20555-0001

Dear Ms. Clark:

Subject: Review of Agreement State Legally Binding Requirements (LBR)

Enclosed for review are proposed or amended LBRs corresponding to the following equivalent amendments to NRC’s regulations or to existing NRC regulations, as applicable.

RATS ID	Title	State LBR
Not applicable (NA)	Pool Irradiators Leak Testing	I-37
NA	Teletherapy Co-60 Leak Tests	M-2
NA	Teletherapy Installation/Removal/Replacement	M-7
NA	RIA Kits Manufacturer and Distributor	GLR-4
NA	General License Device Manufacturer	GLD-3

We believe that adoption of these legally binding requirements satisfies the compatibility and health and safety categories established in the Office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-200.



If you have any questions, please contact me at (916) 440-7976 or ira.schneider@cdph.ca.gov , or Robert Custodio, Supervising Health Physicist, Radioactive Materials Licensing at (916) 650-0561 or Robert.custodio@cdph.ca.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Ira Schneider', with a long horizontal flourish extending to the right.

Ira Schneider, Chief
Radiologic Health Branch

Enclosures

Cc: Solomon Sahle, Allyce Bolger

Attachments

1. Excerpts from Title 17, California Code of Regulations (17 CCR)
2. LBR I-37
3. LBR M-2
4. LBR M-7
5. LBR GLR-4
6. LBR GLD-3

Excerpts
Title 17, California Code of Regulations
Division 1, Chapter 5
Subchapter 4. Radiation

§ 30100. General Definitions.

As used in subchapter 4:

(a) "Act" means the "Radiation Control Law," Health and Safety Code, Division 104, Part 9, chapter 8, sections 114960 et seq.

(b) "Agreement State" means any state with which the United States Atomic Energy Commission or Nuclear Regulatory Commission has entered into an effective agreement under section 274b of the Atomic Energy Act of 1954, Title 42, United States Code, section 2021(b) (formerly section 274(b)).

(c) "Decommission" means to remove safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the license.

(d) "Department" means the California Department of Public Health.

(e) "Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

(f) "Hazardous radioactive material," as used in section 33000 of the California Vehicle Code and 114820(d) of the Health and Safety Code means any "highway route controlled quantity" of radioactive material as such material is defined in title 49, Code of Federal Regulations, section 173.403.

(g) "Human use" means the internal or external administration of radiation or radioactive materials to human beings.

(h) "Installation" means the location where one or more reportable sources of radiation are possessed.

(i) "License," except where otherwise specified, means a license issued pursuant to group 2, Licensing of Radioactive Material.

(j) "Other official agency specifically designated by the Department" means an agency with which the Department has entered into an agreement pursuant to section 114990 of the Health and Safety Code.

(k) "Person" means any individual, corporation, partnership, limited liability company, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, other than the United States Nuclear Regulatory Commission, the United States Department of Energy, or any successor thereto, and other than Federal Government agencies licensed by the United States Nuclear Regulatory Commission, under prime contract to the United States Department of Energy, or any successor thereto.

(l) "Personnel monitoring equipment" means devices designed to be worn or carried by an individual for the purpose of measuring the dose received by that individual (e.g., film badges, pocket chambers, pocket dosimeters, film rings, etc.).

(m) "Possess" means to receive, possess, use, transfer or dispose of radioactive material pursuant to this regulation.

(n) "Possessing a reportable source of radiation" means having physical possession of, or otherwise having control of, a reportable source of radiation in the State of California.

(o) "Radiation" (ionizing radiation) means gamma rays and X-rays; alpha and beta particles, high-speed electrons, neutrons, protons, and other nuclear particles; but not sound or radio waves, or visible, infrared, or ultraviolet light.

(p) "Radiation machine" means any device capable of producing radiation when the associated control devices are operated, but excluding devices which produce radiation only by the use of radioactive material.

(q) "Radioactive material" means any material which emits radiation spontaneously.

(r) "Registrant" means any person who is registering or who has registered with the Department pursuant to group 1.5, Registration of Sources of Radiation.

(s) "Reportable sources of radiation" means either of the following:

(1) Radiation machines, when installed in such manner as to be capable of producing radiation.

(2) Radioactive material contained in devices possessed pursuant to a general license under provisions of sections 30192.1 and 30192.6.

(t) "Research and development" means theoretical analysis, exploration, experimentation or the extension of investigative findings and scientific or technical theories into practical application for experimental or demonstration purposes, including the experimental production and testing of models, prototype devices, materials and processes; but shall not include human use.

(u) "Sealed source" means any radioactive material that is permanently encapsulated in such manner that the radioactive material will not be released under the most severe conditions likely to be encountered by the source.

(v) "Source of radiation" means a discrete or separate quantity of radioactive material or a single radiation machine.

(w) "Special nuclear material" means:

(1) Plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Department declares by rule to be special nuclear material after the United States Nuclear Regulatory Commission, or any successor thereto, has determined the material to be such, but does not include source material; or

(2) Any material artificially enriched by any of the foregoing, but does not include source material.

(x) "Specific license" means a license or the equivalent document issued to a named person by the Department or by the Nuclear Regulatory Commission or by any other Agreement State.

(y) "This regulation" means: California Code of Regulations, Title 17, Division 1, Chapter 5, Subchapter 4.

(z) "User" means any person who is licensed to possess radioactive material or who has registered as possessing a reportable source of radiation pursuant to groups

1.5 and 2 of this subchapter, or who otherwise possesses a source of radiation which is subject to such licensure or registration.

(aa) "Worker" means any individual engaged in activities subject to this regulation and controlled by a user, but does not include the user.

Note: Authority cited: Sections 114975, 115000 and 131200, Health and Safety Code.
Reference: Sections 114965, 114970, 114985, 115060, 131050, 131051 and 131052, Health and Safety Code.

§ 30192.1 General Licenses - Gauging and Controlling

(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 30196;
- (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 114975, 115000 and 131200, Health and Safety Code.
Reference: Sections 114965, 114970, 114985(g), 115060, 115165, 115230, 115235, 131050, 131051 and 131052, Health and Safety Code.

§ 30196 Special Requirements for Issuance of Specific Licenses to Manufacture or Transfer Certain Items Containing Radioactive Material

(a) The regulations governing manufacturing or initially transferring items containing radioactive material for sale or distribution in Title 10, Code of Federal Regulations (10 CFR), Part 32 (10 CFR 32) (January 1, 2021) are hereby incorporated by reference with the following exceptions:

(1) Title 10, Code of Federal Regulations, sections 32.1, 32.3, 32.8, 32.11, 32.12, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.21 a, 32.22, 32.23, 32.25, 32.26, 32.27, 32.28, 32.29, 32.101, 32.102, 32.103, 32.110, 32.301, and 32.303 and NRC Form 653 referenced in section 32.52 are not incorporated by reference.

(2) Any reference to "byproduct material" in 10 CFR 32 is replaced by the term "radioactive material" as defined in section 30100.

(3) Any reference to the United States Nuclear Regulatory Commission (NRC) or any component thereof shall be deemed to be a reference to the Department as defined in section 30100.

(4) Any reference to the term "Agreement State" shall be deemed to be a reference to the term "Agreement State" as defined in section 30100.

(5) Any reference to the below identified federal regulation cited within 10 CFR 32 shall be deemed to be a reference to the below identified Department regulation in this subchapter:

Federal regulation cited within 10 CFR 32	Department regulation within this subchapter
§ 30.34(h)	§ 30257
§ 30.33	§ 30194
§ 30.36	§ 30256
§ 30.51	§ 30293
§ 31.2	§ 30190
§ 31.5	§ 30192.1
§ 31.7	§ 30192.2
§ 31.8	§ 30192.3
§ 31.10	§ 30192.4
§ 31.11	§ 30192.5
10 CFR 20 (any section)	§ 30253

(6) Any reference within 10 CFR 32 to sections found in 10 CFR 35 shall be deemed to be a reference to section 30195(a) except that 10 CFR 35.65(a) (January 1, 2021) cited within 10 CFR 32.74(a)(3) is incorporated by reference in this section for the purpose of issuing a specific license pursuant to this section. Section 35.65(a) of 10 CFR is not incorporated by reference for purposes of issuing a specific license pursuant to section 30195(a).

Note: Authority cited: Sections 114975, 115000, 115091 and 131200, Health and Safety Code. Reference: Sections 114965, 114970, 115060, 115091, 115092, 115235, 131050, 131051 and 131052, Health and Safety Code.

§ 30275 Survey and Tests

(a) Each user shall make or cause to be made such surveys as are necessary for compliance with all provisions of this regulation.

(b) Upon instruction from the Department or other official agency specifically designated by the Department, each user shall perform or cause to have performed, and shall permit the Department or said agency to perform, such reasonable tests as the Department or said agency deems necessary for the protection of life, health, or property, including, but not limited to, tests of:

- (1) Sources of radiation.
- (2) Facilities wherein sources of radiation are used or stored.
- (3) Radiation detection and monitoring instruments.
- (4) Other equipment and devices used in connection with utilization or storage of sources of radiation.

(c) Each sealed source other than sources listed below, shall be tested for contamination prior to initial use and for leakage at least every six months:

- (1) Hydrogen-3 or krypton-85 sources.
- (2) Sealed sources containing licensed radioactive material in gaseous form.
- (3) Source material.
- (4) Sources containing radioactive material with a half life of 30 days or less.
- (5) Sources of beta- and/or gamma-emitting radioactive material with an activity of 100 microcuries or less.
- (6) Sources of alpha and/or neutron-emitting radioactive material with an activity of 10 microcuries or less.

In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source shall not be put into use until tested. If there is reason to suspect that a source might have been damaged, it shall be tested for leakage before further use.

Contamination and leak tests shall be capable of determining the presence of 0.005 microcuries of removable contamination. When any contamination or leak test reveals the presence of 0.005 microcuries or more of removable contamination the user shall immediately withdraw the source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with applicable provisions of Group 2 of this subchapter. Two copies of a report shall be filed, within 5 days of the test, with the Department or other official agency specifically designated by the Department, describing the source involved, the test results, and the corrective action taken.

(d) The test sample shall be taken from the surface of the source, or source holder, or from the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate. Where sealed sources are permanently mounted in devices or equipment, alternate tests for contamination and leakage may be approved by the Department.

(e) Tests for contamination and leakage, decontamination, and repair of sealed sources shall be performed only by persons specifically authorized by the Department to do so in accordance with provisions of Group 2 of this subchapter.

(f) Records of leak tests shall be maintained as specified in United States, title 10, Code of Federal Regulations, part 20, subpart L as incorporated by reference in section 30253.

Note: Authority cited: Sections 114975, 115000, 115060 and 131200, Health and Safety Code. Reference: Sections 114965, 114970, 114980, 115060, 115230, 115235, 131050, 131051 and 131052, Health and Safety Code.

Note:

- Unknown if NRC has reviewed LBR.
- 10 CFR 35.59(b)
- Used for program codes:
 - 03521

Proposed:

Notwithstanding Title 17, California Code of Regulations, Section 30275 (c) and (d), after sources are placed in a pool irradiator, the sources must be tested for leakage by testing the pool water for contamination each day the irradiator operates. The test may be done either by using a radiation monitor on the pool water circulating system or by laboratory analysis of a pool water sample. The results of the pool water sample analysis must be available within 24 hours. If a radiation monitor on the pool water circulating system is used, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures. Detection of a leaking source shall be reported to the California Department of Public Health, Radiologic Health Branch, MS 7610, P.O. Box 997414, Sacramento, CA 95899-7414 within five days of the test. This report shall include a description of the defective source and/or device, the results of the test, and the corrective action taken.

M-2

Notes:

- Unknown if NRC has reviewed LBR.
- Used for program codes:
 - 02110
 - 02300

Proposed:

Tests for leakage and/or contamination of teletherapy sealed sources shall be performed in accordance with Title 17, California Code of Regulations, Section 30275 (c) except that Cobalt-60 sources may be tested at intervals not exceeding two years, provided that the tests performed at the time of installation of the source, and six months thereafter, do not reveal leakage and/or contamination in excess of the specified limit.

M-7

Note:

- Unknown if NRC has reviewed LBR.
- Used for program codes:
 - 02110
 - 02300

Proposed:

At least 30 days prior to the initiation of any of the actions listed below , the licensee shall submit an application to the Department for a license amendment authorizing the proposed action. The application shall include drawings and other information as may be necessary for evaluation of radiation safety. Such actions are:

- (a) Installation, removal, or replacement of a radioactive teletherapy source.
- (b) Installation, removal, or replacement of a partially shielded container, such as a drawer, containing a radioactive teletherapy source.
- (c) Installation or replacement of a complete teletherapy unit or of a teletherapy unit head which provides complete shielding of the radioactive source.
- (d) Relocation or reorientation of a teletherapy unit for use within a shielded room.
- (e) Any other change in the teletherapy unit, treatment room, or shielding, or in the manner of use of the unit, or in the occupancy or use of any adjacent area, which could produce radiation levels or exposures of individuals in excess of those indicated in previous applications or radiation survey reports.

GLR-4

Notes:

- Unknown if NRC has reviewed LBR.
- Used for program codes:
 - 03244

Proposed:

The authorization to distribute radioimmunoassay (RAI) kits stated in Item 9 of this license shall not be valid unless the licensee possesses a currently valid license issued by the Department for manufacture of drugs or devices, in accordance with the California Sherman Food, Drug, and Cosmetic Law (commencing at Section 109875 of the California Health and Safety Code).

GLD-3

Notes:

- Unknown if NRC has reviewed LBR.
- Applicable to 10 CFR 32.51 for 31.5 GLDs.
- 17 CCR 30196 incorporates Part 32.
- 31.5 = 17 CCR 30192.1.
- Used for program codes:
 - 03240

Proposed:

[Each Model _____ device/Each generally licensed device] distributed under this license shall bear a durable, clearly visible label containing the radiation caution symbol of purple, magenta, or black on a yellow background, the words "Caution—Radioactive Material", the quantity and isotope contained, the date of assay, the manufacturer's name and address, the model and serial number of the device head, and statements as follows:

- (a) "The receipt, possession, use and transfer of this device are subject to a general license or equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority."
- (b) "Operation of this device shall be immediately suspended until necessary repairs have been made if there is any indication of a possible failure of or damage to the shielding or containment of radioactive material, or the on-off mechanism indicator."
- (c) "This device shall be tested for proper operation of the on-off mechanism or indicator at intervals not to exceed six months."
- (d) "The sealed radioactive source contained in this device shall be tested at installation and every [six (6) months/three (3) years] thereafter for leakage of radioactive material."
- (e) "Maintenance, tests or other service involving the radioactive material, its shielding and containment, shall be performed by persons holding a specific radioactive material license to provide these services."
- (f) "Installation, relocation, maintenance, repair and initial radiation survey of this device, and leak testing, installation, replacement, and disposal of sealed sources containing radioactive material used in this device shall be performed only by persons holding a specific radioactive material license to provide these services."
- (g) "This device shall not be transferred, abandoned, or disposed of except by transfer to a person holding a specific radioactive material license to receive this device."
- (h) "Removal of this label is prohibited."