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**California Department of Public Health**



**GAVIN NEWSOM**  
*Governor*

December 21, 2021

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.

<b>RATS ID</b>	<b>Title</b>	<b>State LBR</b>
Not applicable (NA)	Exemption, if requested, from DFP for possession/use of Ge-68/Ga-68 medical use generators – 10 CFR 30.35(a)	Q-12
NA	Listing of authorized devices for distribution – 10 CFR 32.51(a)(2)	GLD-1
NA	Documentation provided to transferee prior to transfer of device – 10 CFR 32.51a	GLD-4
NA	Labels & Statements on prepackaged units for distribution – 10 CFR 32.71(c)	GLR-1
NA	Labels & Statements on prepackaged units for distribution – 10 CFR 32.71(d)	GLR-2



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We believe that the submitted LBRs satisfy 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) 440-7942, or Phillip Scott, Chief, Regulations Unit at (916) 440-7978.

Sincerely,

*Signature on file*

Gonzalo L. Perez,  
Branch Chief  
Radiologic Health Branch

Attachments

cc: Michelle Beardsley

## **Attachments**

1. Title 17, California Code of Regulations (17 CCR)
2. LBR Q-12
3. LBR GLD-1
4. LBR GLD-4
5. LBR GLR-1
6. LBR GLR-2

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

A copy of Subchapter 4 is attached.

## Q-12

### Notes:

- Addresses exemption from 10 CFR 30.35(a)(1) DFP for Ge-68/Ga-68 generators as discussed in NRC's July 13, 2017 letter (ML17075A487) and RCPD-18-006.
- 10 CFR 30.35(a) is compatibility category H&S.
- 17 CCR 30195.1 informs all licensees and applicants they are subject to financial surety.
- 17 CCR 30197(a)(1) specifically addresses 10 CFR 30.35(a)(1).
- NRC deemed state provisions compatible with 10 CFR 30.35, 40.36, and 70.25 under RATS ID 2011-1 (ML19066A318) on March 28, 2019.

### **Current Q-12:**

Notwithstanding the requirements of Title 17, California Code of Regulations, Section 30195.1(a), the licensee is exempt from the requirement to have a decommissioning funding plan needed for the possession and use of Ge-68/Ga-68 medical use generators (Eckert and Ziegler Radiopharma, Inc. GalliaPharm™), based on the commitments between the licensee and manufacturer (Eckert and Ziegler Radiopharma, Inc.), described in the letter dated [*specify date of letter*].

### **Proposed Q-12:**

Notwithstanding the requirements of Title 17, California Code of Regulations, Section ~~30195.1(a)~~30197(a)(1), the licensee is exempt from the requirement to have a decommissioning funding plan ~~needed~~ for the possession and use of Ge-68/Ga-68 medical use generators (~~Eckert and Ziegler Radiopharma, Inc. GalliaPharm™~~ make/model # of generators), based on the commitments between the licensee and manufacturer (~~Eckert and Ziegler Radiopharma, Inc.~~ name of manufacturer/distributor), described in the letter dated [*specify date of letter*]. The licensee shall return the generators to the manufacturer/distributor in accordance with the generator return agreement described in the letter/application dated [*specify date of letter*].

## GLD-1

### Notes:

- Unknown if NRC has reviewed this LBR.
- Applicable to 10 CFR 32.51.
  - Compatibility category B.
- 17 CCR section 30196 incorporates by reference 10 CFR 32.51, Jan. 1, 2013 edition.
  - Section 30196 is proposed to be amended to incorporate the 2021 edition of 10 CFR 32.
    - CDPH proposal submitted to NRC for review on Oct. 22, 2021. Per November 3, 2021 letter (ML21307A028), NRC had no comments on proposal.
    - CDPH to submit final adopted regulation upon completion of state rulemaking procedures.

### **Proposed GLD-1:**

The licensee is authorized to distribute the following devices pursuant to the terms and conditions of this license.

Device Model	Sealed Source Manufacturer/Model No.	Maximum Activity
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(a) [Specify Device Model, Sealed Source Manufacturer/Model No., Maximum Activity]

## GLD-4

### Notes:

- Unknown if NRC has reviewed this LBR.
- Applicable to 10 CFR 32.51a for 10 CFR 31.5 GLDs.
  - 10 CFR 32.51a is compatibility category B.
  - 10 CFR 31.5 is compatibility category C.
- 17 CCR 30196 incorporates by reference 10 CFR 32.51a, Jan. 1, 2013 edition.
  - Section 30196 is proposed to be amended to incorporate the 2021 edition. CDPH proposal submitted to NRC for review on Oct. 22, 2021. Per November 3, 2021 letter (ML21307A028), NRC had no comments on proposal.
  - CDPH to submit final adopted regulation upon completion of state rulemaking procedures.
- 17 CCR 30192.1 addresses 10 CFR 31.5.
  - NRC deemed provision compatible on Feb. 9, 2015 (ML15012A465) for RATS ID 2001-1; 2007-2; 2007-3; 2012-1; and 2012-4.
- Any future changes to cited California regulatory sections or websites will not be submitted for NRC approval, except that any substantive change to provisions within cited regulatory sections will be submitted for NRC review in accordance with current NRC procedures.

### **Proposed GLD-4:**

In accordance with Title 10, Code of Federal Regulations (10 CFR) section 32.51a, incorporated by reference in Title 17, California Code of Regulations (17 CCR) section 30196, the licensee, prior to transferring a device, shall furnish each licensee to whom he transfers a device by authorization of this license with the following items. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person.

(a) Operating Procedures Manual.

(b) Radiation rules and regulations applicable to the customer's system for the State in which it will be operated. For the State of California, the regulations to be provided are: 17 CCR sections 30190, 30192.1, and 30293; and 10 CFR sections 20.2201 and 20.2202.

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

(d) Information on acceptable disposal options including estimated costs of disposal.

(e) Registration forms and instructions for the registration of radiation sources in the particular State (if applicable). For the State of California, the registration form and instructions (form CDPH-8240) are available at <https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/cdph8240.pdf> or by contacting [RHBGLicensingInfo@cdph.ca.gov](mailto:RHBGLicensingInfo@cdph.ca.gov).

(f) The name, or title, address and telephone number of the contact at the State or Federal agency from which additional information may be obtained.

## GLR-1

### Notes:

- Unknown if NRC has reviewed this LBR.
- Addresses 10 CFR 32.71(c) for § 31.11 GLDs.
  - 32.71 is compatibility category B.
  - 31.11 is compatibility category D.
- 17 CCR section 30196 incorporates by reference 10 CFR 32.51, Jan. 1, 2013 edition.
  - Section 30196 is proposed to be amended to incorporate the 2021 edition. CDPH proposal submitted to NRC for review on Oct. 22, 2021. Per November 3, 2021 letter (ML21307A028), NRC had no comments on proposal.
  - CDPH to submit final adopted regulation upon completion of state rulemaking procedures.
- 17 CCR 30192.5 addresses 10 CFR 31.11

### **Proposed GLR-1:**

Each prepackaged unit of radioactive materials distributed under this license shall bear a durable, clearly visible label:

(a) Identifying the radioactive contents as to chemical form and radionuclides, and indicating that the amount of radioactivity does not exceed 10 microcuries [*\*of iodine-131, iodine-125, selenium-75, carbon-14, or cobalt-57; or 50 microcuries of hydrogen-3 (tritium); or 20 microcuries of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each*]; and

(b) Displaying the radiation caution symbol described in the Title 10, Code of Federal Regulations, Part 20, Section 20.1901 incorporated by reference in Title 17, California Code of Regulations section 30253, and the words, "Caution, Radioactive Material", and "Not for Internal or External Use in Humans and Animals."

**\*NOTE to reviewer: Use appropriate radionuclide and maximum radioactivity for which the licensee is authorized. See 17 CCR 30192.5.**



## GLR-2

### Notes:

- Unknown if NRC has reviewed this LBR.
- Addresses 10 CFR 32.71(d) for § 31.11 GLDs.
  - 32.71 is compatibility category B.
  - 31.11 is compatibility category D.
- 17 CCR section 30196 incorporates by reference 10 CFR 32.51, Jan. 1, 2013 edition.
  - Section 30196 is proposed to be amended to incorporate the 2021 edition. CDPH proposal submitted to NRC for review on Oct. 22, 2021. Per November 3, 2021 letter (ML21307A028), NRC had no comments on proposal.
  - CDPH to submit final adopted regulation upon completion of state rulemaking procedures.
- 17 CCR 30192.5 addresses 10 CFR 31.11

### **Proposed GLR-2:**

The following statement, or a substantially similar statement that contains the information called for in the following statement, shall appear either on a label affixed to each unit of radioactive material distributed under this license or in a leaflet or brochure which accompanies each package of such units:

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

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Name of manufacturer