

## FINAL STATEMENT OF REASONS

The information contained in the Initial Statement of Reasons (ISR) at the time of Public Notice remains unchanged with the exception of the following modifications:

### Section 30181:

- Subsection (c)(5)(A) and (B): The date of manufacturing is deleted for consistency with the equivalent NRC provision in 10 CFR 40.13(c)(5). NRC designates these provisions as compatibility category B, requiring the provisions to be essentially identical.
- Subsection (e)(1): Due to comments, the phrase "or mirrors" is added for consistency with NRC's provision in 10 CFR 40.13(c)(7).

### Section 30191:

- Subsection (a): Due to comments, the word "receipt" (noun form of "receive") is added for consistency with NRC's provision in 10 CFR 40.22(a).
- Subsection (c): Due to comments, the second sentence is revised as recommended. As revised, the Department believes the proposal meets NRC's designated compatibility category C criteria because it is more restrictive, which is allowed under that criteria. These provisions would require the general licensee (GL) to:
  - After notification, consult only with the Department, whereas 10 CFR 40.22(c) allows the GL to either not consult with anyone, or consult with NRC or others of the licensee's choosing. Thus, the revised proposal ensures the Department is consulted with and is the only consultant.
  - Comply with the cited provisions. Under those provisions, the GL must:
    - Ensure radioactive material is properly disposed. Disposal is then verified by the Department. This is more restrictive than 10 CFR 40.22(c) since that provision does not require verification of disposal.
    - Demonstrate that their efforts to eliminate residual contamination were reasonable. Such demonstration is not required under 10 CFR 40.22(c); and
    - Demonstrate, through a submitted radiation survey, that the site is suitable for release, whereas 10 CFR 40.22(c) does not require such demonstration.

Thus, the revised proposal ensures the Department is consulted with and is the only consultant, has verified the material is properly disposed, has determined the GL's efforts are reasonable, and has confirmed through a documented survey that the site is releasable.

- Subsection (d): Due to comments, the provision is revised to cite to the equivalent procedures and provisions. The Department believes the revision is now essentially identical to NRC's provision because the action (i.e., comply with the cited provisions to the extent necessary to meet the other cited provisions), for both the proposed revision and 10 CFR 40.22(d), is the same regardless of the version that is read.

**Public Notice:**

An error in the Public Notice, as published in the California Regulatory Notice Register, dated December 21, 2018, No. 51-Z, was identified after publication. The fiscal impact contained in the Public Notice was incorrect. A Notice of Correction was published in the California Regulatory Notice Register, dated January 18, 2019, No. 3-Z. No comments regarding the error were received during any public comment period.

**SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE INITIAL NOTICE PERIOD OF DECEMBER 21, 2018 THROUGH FEBRUARY 4, 2019, AND THE 15-DAY ADDITIONAL PUBLIC COMMENT PERIOD OF MARCH 22, 2019 THROUGH APRIL 8, 2019.**

Following is the list of persons who commented on the initial proposed regulations (DPH-16-001) during the 45-day public comment period beginning on December 21, 2018 and ending at 5:00 p.m. on February 4, 2019. The Department received two letters of comment as identified below. A request to hold a public hearing was not received so no public hearing was held. A 15-day public comment period was conducted beginning on March 22, 2019 and ending at 5:00 p.m. on April 8, 2019. The Department received one comment letter during the 15-day public comment period.

**List of Commenters during Initial 45-day Proceeding held from December 21, 2018 through February 4, 2019.** (Written testimony)

1. Jim DeVoll, CTNM, Lead Technologist, Nuclear Medicine, Enloe Medical Center
2. Linda Howell, Acting Deputy Director, Division of Materials Safety, Security, State and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission (NRC).

**List of Commenters during the 15-day Proceeding held from March 22, 2019 through April 8, 2019.** (Written testimony)

3. Kevin Williams, Deputy Director, Division of Materials Safety, Security, State and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission.

**Summary of comments and responses**

Note: The digit or digit and letter before the decimal point designation identifies the Commenter as listed above. The digit(s) after the decimal point indicate the identified comment from that commenter.

- 1.0 Requested a copy of the proposed regulation text.

Response: A copy of the proposal was sent as requested.

**2.1. California needs to add the phrase "or mirror" to section 30181(e)(1) to meet the Compatibility Category B designation assigned to 10 CFR 40.13(c)(7).**

Response: The comment was accepted and an additional 15-day public comment period was conducted. A comment letter stating the commenter had no comments was received.

**2.2. California needs to add the word "receive" to 30191(a) to meet the Compatibility Category B designation assigned to 10 CFR 40.22(a).**

Response: The comment was accepted and an additional 15-day public comment period was conducted. A comment letter stating the commenter had no comments was received.

**2.3. California omits the phrase "where source material was used under this general license is not likely to result in exposures that exceed the limits in § 20.1402 of this chapter."; and replaces it with text that states, "... reasonable effort is made to eliminate the contamination or residual source material." California needs to add an equivalent provision that meets the essential objectives of 10 CFR 40.22(c) as indicated above to meet the Compatibility Category C designation assigned to 10 CFR 40.22(c).**

Response: The comment was accepted and an additional 15-day public comment period was conducted. A comment letter stating the commenter had no comments was received.

**2.4. California omits the phrase, "except that such person shall comply with the provisions of §§ 20.1402 and 20.2001 of this chapter to the extent necessary to meet the provisions of paragraphs (b)(2) and (c) of this section." from section 30191(d). California needs to include this phrase in section 30191(d), substituting their equivalent procedures (in the case of 20.1402); and sections/regulations to the NRC parts/sections cited within. California needs to revise section 30191(d) as indicated above to meet the Compatibility Category B designation assigned to 10 CFR 40.22(d).**

Response: The comment was accepted and an additional 15-day public comment period was conducted. A comment letter stating the commenter had no comments was received.

**3.0 Commenter had no comments on the revised proposal.**

Response: The Department appreciates the review.

ALTERNATIVES DETERMINATION: In accordance with Government Code Section 11346.9(a)(4), the Department has determined that no alternative would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

#### IMPOSITION OF LOCAL MANDATE

The Department has determined that the regulation would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code, nor are there any other nondiscretionary costs imposed.

#### IMPACT ON BUSINESS

The Department has made a determination that the regulations would not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.