

SECOND SUPPLEMENTAL STATEMENT OF REASONS Reference 10

The California Department of Public Health (Department) has instituted additional changes to these proposed regulations which are discussed below. These changes are made in response to comments or initiated by the Department. Additional discussion to the Initial Statement of Reasons (ISR) and documents relied upon, identified below, are added to the rulemaking file.

Documents relied upon: The following documents are added to the rulemaking file as documents relied upon for purposes of Government Code section 11347.1:

- The document “Supplemental Statement of Reasons” dated May 10, 2018 is deemed a document relied upon and designated as **Reference 5**.
- Regarding section 30373, the following document, designated as **Reference 6**, is added as a document relied upon. The acronym “FRN” as found in that document means “Federal Register Notice”:
 - Email dated April 26, 2018, forwarded to Phillip Scott, from Michelle Beardsley, Health Physicist/State Regulation Review Coordinator, Agreement States Program Branch, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission (NRC)
- Regarding section 30220, NRC’s “10 CFR Part 37, Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material, Implementation Plan,” found at <https://www.nrc.gov/docs/ML1132/ML113290229.pdf> (accessed October 1, 2018) is hereby deemed a document relied upon and designated as **Reference 7**.
- The letter dated April 19, 2018 from the NRC is hereby deemed a document relied upon and designated as **Reference 8**.
- The letter from CDPH to NRC dated November 1, 2018 is hereby deemed a document relied upon and designated as **Reference 9**.
- This document “Second Supplemental Statement of Reasons” is hereby deemed a document relied upon and designated as **Reference 10**.

ISR: Additional discussion to the ISR is provided as follows:

- **Page 4:** Regarding the presentation of the NRC Compatibility Categories, the cited reference material for the following sentence is to the material indicated in footnote 4 (p. 7) (Reference 3):
 - “[] = A bracket around a category (e.g. [B]) means that the Section may have been adopted elsewhere and it is not necessary to adopt it again.”
- **Section 30192.6:**
As indicated in the ISR (p. 6), section 30192.6(c)(6), as redesignated, is proposed to be amended for consistency with 10 CFR 40.25(d)(3). This section addresses the

possession of depleted uranium (DU) contained in industrial products or devices to provide a concentrated mass in a small volume of the product or device, under a general license (GL). As defined in H&S Code section 114985(g), a GL is “a license, pursuant to regulations promulgated by the department, effective without the filing of an application, to transfer, acquire, own, possess or use quantities of, or devices or equipment utilizing, byproduct, source, or special nuclear materials or other radioactive material occurring naturally or produced artificially.”

The NRC has designated 10 CFR 40.25(d)(3) as Compatibility Category C, requiring Agreement States to adopt regulations meeting the essential objective of NRC’s provision. To ensure consistency with NRC’s provisions addressing transfer of DU, this proposal requires the transferor to provide a copy of sections 30192.6 and 30108.1 to the transferee. This accomplishes consistency with NRC’s provision, other Agreement States, and, since the general licensee need not apply for a specific license (H&S Code § 114985(h); 17 CCR 30190(c)), ensures the general licensee is aware they remain subject to other requirements, including providing copies of the specific regulation sections when transferring DU under the GL.

- **Section 30210(b)(7):**

As discussed in the ISR (pp. 7-8), section 30210 is revised for consistency with 10 CFR 30.41 and 40.51. Proposed section 30210(b)(7) corresponds, and is equivalent to, 10 CFR 30.41(b)(7) and 40.51(b)(7), both of which are designated by NRC as compatibility category C provisions. Section 30210 specifies to whom a licensee may transfer material. Subsection (b)(7), verbatim to NRC’s provisions, allows a licensee to transfer the material if the Department has authorized the transfer in writing, but the provision does not clarify when such transfer would be authorized.

The Department is not specifying when authorization would be given or the types of events that would warrant granting such authorization. An event triggering such an authorization would be an extremely rare unanticipated event. It informs licensees that the Department has discretion as it pertains to whom radioactive material may be transferred. Specifying when authorization would be given would constrain our discretion or imply we will or must grant the authorization if the requester merely meets the added language. Also, because state licensees may also hold an NRC license, the Department prefers to maintain consistency with NRC’s provision.

- **Section 30293:**

Currently, the existing provision applies to users, as defined in 17 CCR 30100(z), of both radiation machines and radioactive materials. Because the NRC does not regulate radiation machines, subsection (a)(2) is revised for consistency with 10 CFR 40.61(a)(2) by providing an exception specific to source material, a subset of radioactive material as defined in 17 CCR 30100(q). NRC has designated 10 CFR

40.61(a)(2) as compatibility category C, requiring agreement states to adopt the essential objectives.

Additionally, because the existing provision applies to all users of radioactive materials, 10 CFR 30.51(a)(2) was reviewed, and the existing provision deemed equivalent, to ensure the proposal did not change the regulatory effect for radioactive material users not possessing source material.

However, this proposal excludes reference to “byproduct material,” defined in 10 CFR 40.4 as follows, found within 10 CFR 40.61(a)(2):

Byproduct Material means the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by such solution extraction operations do not constitute “byproduct material” within this definition.

With the exception of “byproduct material” as defined in section 11e. of the [Atomic Energy] Act, other terms defined in section 11 of the Act shall have the same meaning when used in the regulations in this part.

That phrase is excluded because California has no licensees possessing that defined material. Under NRC’s policy, a State need not adopt a specific regulation if the State has no licensees that would be subject to the regulation. (Reference 3a: Appendix E, footnote 4.)

The section’s reference note is amended to include section 115230, to fully identify where California’s legal agreement with the NRC is found; namely, Health and Safety Code sections 115230 and 115235.

Regulation text: Additional changes, if so indicated, to the proposed regulation text are as follows:

Section 30210:

- Subsections (a) and (b), (b)(1) & (b)(2): No additional changes are proposed.
- Subsection (b)(3) is revised for consistency with NRC’s provisions found in 10 CFR 30.41(b)(2) and 40.51(b)(2), and to present federal language from the States’ perspective, not the NRC’s. The presented language is based on NRC’s provision and 17 CCR 30100(b).
- Subsection (b)(4) is revised to clarify where exemptions to licensing requirements are located.
- Subsection (b)(5): No additional changes are proposed.

- Subsection (b)(6) is revised to delete unneeded duplication of a defined acronym's meaning.
- Subsections (b)(7), (c) and (d): No additional changes are proposed.

Section 30220:

- Subsections (a) and (a)(1): No additional changes are proposed.
- Due to comments, subsection (a)(2) is revised so that the term "fingerprint orders" is adopted by reference in subsection (a). The term "government agency," designated by NRC as compatibility category D, remains as initially proposed to not be adopted.
- Subsection (a)(3): No additional changes are proposed.
- Due to the revision of subsection (a)(2), subsection (a)(4) is revised for clarity by:
 - Adding new subparagraphs (A) and (B) to address references to the NRC in the cited provisions. Subparagraph (B) is needed to clarify that "security orders," as defined in the cited CFR, refers only to orders issued by NRC under its authority to protect the common defense and security (ISR: pp. 9 & 10; Reference 7, pp. 1-6);
 - Recodifying initially proposed subparagraphs (A) and (B) to subparagraphs (C) and (D), respectively, to maintain a coherent structure; and
 - Deleting reference to paragraph (9) in subparagraph (C), as recodified, since it is proposed to be deleted.
- Subsection (a)(5): No additional changes are proposed.
- Subsection (a)(6) is revised to clarify that the terms in the presented table are for purposes of the material incorporated by reference in subsection (a).
- Subsections (a)(7) and (a)(9) are deleted due to the revision of subsection (a)(2) that would result in adoption by reference of the term "fingerprint orders" in subsection (a).
- Subsection (a)(8) is deleted due to adoption of the term "fingerprint orders" and the reference clarification in newly proposed paragraph (4)(B) regarding the term "security orders."
- Subsection (a)(10) is recodified to subsection (a)(7) due to the deletion of subsections (a)(7), (a)(8) and (a)(9).

Section 30293:

- Due to comments regarding subsection (a)(2), subsection (a)(2) is amended for consistency with NRC's provision in 10 CFR 40.61(a)(2). However, the phrase "byproduct material" found within 10 CFR 40.61(a)(2), and defined in 10 CFR 40.4, is excluded because California has no licensees possessing that defined material. Under NRC's policy, a State need not adopt a specific regulation if the State has no licensees that would be subject to that regulation. (Reference 3a: Appendix E, footnote 4.)
- No changes to subsections (a)(1), (a)(3), and (b) through (g) are proposed.

Section 30373:

- Subsection (a): No additional changes are proposed.
- Due to comments, the following revisions are proposed:
 - Due to comments, subsection (a)(1) is revised to remove 10 CFR 71.8 and 71.13 from those provisions not being incorporated to clarify that the equivalent provisions are located as specified in newly proposed subsections (a)(7) and (a)(8), respectively.
 - Additionally, subsection (a)(1) lists provisions that are not incorporated by reference in subsection (a). Title 10, CFR 71.103(a), designated by NRC as compatibility category C, is removed. Thus, as initially proposed, 10 CFR 71.103(a) would be adopted under subsection (a).
 - Subsection (a)(2): The initially proposed text identified this existing provision as one not being amended by use of the phrase “no change to text.” Due to comments, this provision is revised to identify those provisions for which the reference to the NRC must remain a reference to the NRC. Comments, in part, indicated that the reference to NRC in 10 CFR 71.101(c)(1) should remain a reference to NRC since that provision contained “certificate of compliance (CoC), certificate holder, and applicant for a CoC.” However, it appears the commenter intended 71.101(c)(2), not 71.101(c)(1) since 71.101(c)(1) does not contain those terms. Because 71.101(c)(2) is designated as compatibility category NRC, agreement states may not adopt that provision. Thus, the reference to NRC in 71.101(c)(1) should be adopted by replacing “NRC” with the Agreement State’s applicable department name. Only those provisions being incorporated by reference in subsection (a) to which the reference to NRC must so remain are identified.
 - Subsections (a)(3) and (a)(4): No additional changes are proposed.
 - Subsections (a)(5) and (a)(6): Due to additionally proposed provisions, the word “and” is deleted and the punctuation at the end of this provision is revised for consistency with existing regulatory structure, resulting in no regulatory effect.
 - Subsection (a)(7) is newly added to clarify where the equivalent provision to 10 CFR 71.8 is found.
 - Subsection (a)(8) is newly added to clarify where the equivalent provision to 10 CFR 71.13 is found.
- Subsections (b) and (c): The initially proposed text identified these existing provisions as not being amended by use of the phrase “no change to text.” The existing provisions are now displayed for the reader’s convenience. No changes are proposed.