

SUPPLEMENTAL STATEMENT OF REASONS

The California Department of Public Health (Department) has instituted additional changes to these proposed regulations which are discussed below. These changes are either initiated by the Department or in response to comments that were received during the 45-day public comment period, which ended on September 15, 2010.

Section 30192: Due to comments received from the U.S. Nuclear Regulatory Commission (NRC), subsection (a) is amended for consistency with title 10, Code of Federal Regulations (10 CFR), section 31.3.

Section 30192.1(d)(1): Due to public comments, an additional review of title 10, Code of Federal Regulations (10 CFR), section 31.5(c)(13)(i) shows that radium-226 is included as a registration-triggering isotope and quantity. However, as proposed, subsection (d)(1) did not include the radioisotope. Therefore, to address the comment and to ensure consistency with NRC's provision, the phrase "0.1 mCi of radium-226" is added.

Section 30192.2: Due to comments received from NRC, the following changes are made:

- Subsection (a) is amended for consistency with 10 CFR 31.7.
- Language is amended and added in subsection (b) for consistency with 10 CFR 31.7.

Section 30192.3: An additional review of proposed changes in this section indicates that the proposal was inconsistent with NRC's 10 CFR 31.8. Therefore, the following changes are made:

- Subsection (a): a nonsubstantial capitalization change is made regarding the label statement. The word "or" found between "plutonium" and "radium-226" is changed to "OR".
- Subsection (c): Corrections are made for consistency with 10 CFR 31.8(c) to identify those sections to which the general licensee is subject. NRC's provision identifies other provisions the general licensee must comply with. The corresponding California regulation is listed after the federal provision referenced in 10 CFR 31.8(c) and further discussed:
 - 10 CFR 30.14(d); see below discussion of subsection (d).
 - 10 CFR 30.34(a) to (e); Sections 30210, 30210.1 and, in general, Health and Safety Code section 115165. 10 CFR 30.34(a), (b), & (c) are compatibility category B and 10 CFR 30.34(d) & (e) are compatibility category NRC. Amendment of the proposed regulation is not necessary because the general license is already required to meet the law and sections 30210 and 30210.1 as indicated in section 30190(d). The phrase "this regulation" as found in section 30190(d) is defined in section 30100(z) to mean California Code of Regulations, title 17, Division 1, chapter 5, subchapter 4.0. Thus, the general licensee is already subject to sections 30210 and 30210.1.
 - 10 CFR 30.50; section 30295. 10 CFR 30.50(a), (b), and (c) through (c)(2) are compatibility category C and subdivision (c)(3) is category D. Thus, section 30295 is added for consistency with 10 CFR 31.8(c).

- 10 CFR 30.51; section 30293. The proposal includes section 30293(a), however, it fails to encompass all NRC provisions in 10 CFR 30.51. Therefore, to maintain consistency, section “30293(a)” is to “30293” to ensure all provisions apply.
- 10 CFR 30.53; section 30275(a) & (b). Though 10 CFR 30.53 is a compatibility category D, it is proposed it be included to maintain consistency with NRC’s provision. Section 30275(a) and (b) only are being added as the other provisions of section 30275 do not apply to the types of devices for which the general license is issued.
- 10 CFR 30.55; no equivalent. 10 CFR 30.55 is a compatibility category NRC meaning that an agreement state may not adopt it. Therefore, it is not included in this proposal.
- 10 CFR 30.61; section 30205. 10 CFR 30.61 is a compatibility category D. Though the provision is not required to meet compatibility with NRC, existing section 30192.3 is nearly identical to the NRC’s provision. The proposed changes were to ensure section 30192.3 was essentially identical to 10 CFR 31.8. However, as proposed, section 30192.3 is not amended to address 10 CFR 30.61 because the general license is already required to meet section 30205 as specified in section 30190. The phrase “this regulation” as found in section 30190(d) is defined in section 30100(z) to mean California Code of Regulations, title 17, Division 1, chapter 5, subchapter 4.0. Thus, the general license is already subject to section 30205.
- 10 CFR 30.62 & 30.63; generally, Health and Safety Code sections 115095, 115150, 115160, 115165, 115170, and 115175. Further, the compatibility category for both provisions is D. Therefore, because the law already applies to the general license and the compatibility category is D, the proposal is not amended.
- 10 CFR Parts 19, 20, and 21; section 30253, 30254, and 30255. The proposal is amended to include the equivalent sections to maintain consistency with NRC’s provisions. Section 30253 incorporates by reference 10 CFR Part 20. Sections 30254 and 30255 contain provisions equivalent to 10 CFR Part 19. 10 CFR Part 21 is compatibility category NRC and is solely reserved to NRC and agreement states are not authorized to adopt it.
- Subsection (d): a phrase is added to clarify that the issued general license does not authorize the introduction of the specified radioactive material into a product or material so as to be consistent with 10 CFR 30.14(d) referenced in 10 CFR 31.8(c). 10 CFR 30.14(d) is compatibility category B and the equivalent Agreement State provision is required to be essentially identical to the NRC’s provision.

Section 30192.4: Due to comments received from NRC and further evaluation of the proposal, the section is amended to maintain consistency with NRC’s provision in 10 CFR 31.10. Nonsubstantial changes, including creating the “10 CFR 20” acronym in subsection (b)(2) instead of subsection (c), are made for consistency.

Section 30192.6: Due to comments received from NRC, the section is amended for consistency with 10 CFR 40.25.

Section 30257: Due to comments received from NRC, subsection (a)(2) is amended for consistency with 10 CFR 30.34(h)(1)(ii).