

Initial Statement of Reasons

Summary of Proposed Regulatory Action

This proposal amends, adopts, or repeals regulations pertaining to radioactive material (RAM) as encompassed in the following 12 topics to ensure the regulations are compatible with those of the U.S. Nuclear Regulatory Commission (NRC). Nonsubstantial changes are also proposed in existing regulations.

Topic	Sections Affected
1. Exempt persons, products, concentrations and quantities.	Amend: 30180. Adopt: 30180.1, 30180.2, 30180.3, 30180.4, 30180.5, 30180.6, 30180.7 and 30181.
2. General licenses regarding: (a) static elimination or ion generation devices; and (b) gauging and controlling devices; and (c) authorizing any person to acquire, receive, possess, use, or transfer, radium-226 contained in certain products manufactured prior to November 30, 2007.	Amend: 30190 and 30192.1. Adopt: 30192.7.
3. Requirements for applicants submitting transfer of license requests.	Amend: 30194.
4. Special Requirements for issuance of Specific Licenses. Applies to: (a) medical use licensees; (b) all applicants wishing to use RAM in the form of a sealed source or in a device containing a sealed source; and (c) medical facilities or educational institutions wishing to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium.	Amend: 30195.
5. Emergency Plans: Licensees required to have an Emergency Plan.	Amend: 30195.2 and 30195.3.
6. Additional Requirements for Specific Licenses authorizing production of PET radioactive drugs for noncommercial transfer to licensees in its consortium.	Adopt: 30195.4.

7. Manufacturing/Distribution: Licensees authorized for Manufacturing and Distribution.	Adopt: 30196. Repeal: 30210.2.
8. Schedules A and C: Quantities and concentrations of RAM that may require possession of a specific license.	Amend: 30235 and 30237.
9. Standards for Protection Against Radiation: All licensees.	Amend: 30253.
10. Inspections and Investigations: nonsubstantial correction of an erroneous reference.	Amend: 30254.
11. Industrial Radiography: Licensees authorized to use RAM in Industrial Radiography.	Amend: 30330, 30332.5, 30332.6, 30332.8, 30333, 30333.1, 30336, 30336.1 and 30336.5. Adopt: 30332.9.
12. Well Logging: Licensees authorized to use RAM in Well-logging.	Amend: 30346, 30346.2, 30348.1 and 30350.

This proposal further:

- Updates the incorporation by reference of Title 10, Code of Federal Regulations Part 35 (10 CFR 35)¹ “Medical Use of Byproduct Material,” in section 30195(a) from January 1, 2008 to January 1, 2013.
- Updates the incorporation by reference of 10 CFR 30.32(i) and 30.72, pertaining to when an Emergency Plan is required pursuant to section 30195.2, from January 1, 1994 to January 1, 2013.
- Updates the incorporation by reference of 10 CFR 20 pertaining to Standards for Protection Against Radiation in section 30253 from January 1, 2008 to January 1, 2013.
- Incorporates by reference the January 1, 2013 version of 10 CFR 32 “Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material,” in proposed section 30196.
- For purposes of proposed section 30196, incorporates by reference the January 1, 2013 version of 10 CFR 35.65 in proposed section 30196.

¹ This short format “10 CFR 35” for a given Part of NRC’s regulation will be used throughout this document for brevity. For example, “10 CFR 39.33” means Title 10, Code of Federal Regulations, Part 39, section 39.33.

This proposal also corrects inconsistencies in existing regulations that correspond to NRC provisions. Nonsubstantial changes are made in each section to correct grammar, spelling, and capitalization, include the use of acronyms to reduce the physical size of the regulations or to maintain consistency with proposed changes.

Authority and Reference

The Department is proposing to adopt, amend, or repeal, as applicable, the regulation sections identified in the table on page one under the authority provided in sections 100110, 100275, 114970, 114975, 115000, 115091, and 131200 of the Health and Safety Code. This proposal implements, interprets and makes specific sections 114960, 114965, 114970, 114985, 114990, 115000, 115060, 115091, 115105, 115110, 115120, 115165, 115230, 115235, 131050, 131051, 131052, and 131055 of the Health and Safety Code.

Policy Statement Overview

Problem Statement: Existing California Department of Public Health (CDPH) regulations pertaining to radioactive material are not compatible with those of the U.S. Nuclear Regulatory Commission (NRC), contain provisions that are out-of-date, and contain unclear references, inconsistencies, and grammatical and capitalization errors.

Objectives: Broad objectives of this proposed regulatory action are to:

- Ensure CDPH regulations are compatible with those of the NRC.
- Address comments from NRC regarding past regulatory adoptions and existing regulations.
- Update and clarify existing regulations.

Benefits: Anticipated benefits, including nonmonetary benefits, from this proposed regulatory action are:

- Continued protection of the public health and safety, worker safety, and the environment, as established by the Legislature in the following provisions:
 - Health and Safety (H&S) Code sections 114705, 114740, 114755, 114965, 114970, 115000, 115230, and 115235.
- Compatibility with the standards and regulatory programs of the NRC, as specified in H&S Code 114965(a)², 115000(b) and 115235(article V).
- Consistency with the regulatory programs of other states, as specified in H&S Code 114965(c).
- Orderly regulatory pattern within the State, among the states and between the federal government and the State, as specified in H&S Code 114965(b).
- Address comments from NRC regarding past regulatory adoptions and existing regulations.

² This short format "H&S Code 114705" for a given Health and Safety Code section will be used throughout this document for brevity. For example, "H&S Code 114705" means California Health and Safety Code section 114705.

- Update and clarify existing regulations and delete unnecessary regulations.

Evaluation as to whether the proposed regulations are inconsistent or incompatible with existing state regulations: CDPH evaluated this proposal to determine whether the proposed regulations are inconsistent or incompatible with existing state regulations. This evaluation included a review of CDPH's existing general regulations and those regulations specific to the regulatory control of radioactive material. Some inconsistencies in those specific regulations were found, and are addressed in this proposal. An internet search of other state agency regulations was also performed. It was determined that no other state regulation addressed the same subject matter, and that this proposal was not inconsistent or incompatible with other state regulations. Therefore, CDPH has determined that this proposal, if adopted, would not be inconsistent or incompatible with existing state regulations.

Program Background

RAM is widely used in many industries, including: the healing arts, for diagnostic and therapeutic purposes; industrial radiography, for nondestructive testing of objects to ensure structural integrity; well logging, for the purpose of obtaining information about the well or adjacent formations which may be used in oil, gas, mineral, groundwater, or geological exploration; and manufacturing and distribution, for designing, building, and supplying radioactive sources for use by the medical, industrial, and other industries. CDPH issues licenses authorizing such uses and conducts inspections of users to ensure compliance with applicable laws and regulations.

RAM is regulated and controlled by both the NRC and each of the 50 states within the United States. The regulatory scheme is structured to allow acquisition, receipt, possession, use, or transfer of RAM in the following ways:

- Specific licenses: H&S Code 114985(h) defines "Specific license" as "a license, issued after application, to use, manufacture, produce, transfer, receive, acquire, own, or possess quantities of, or devices or equipment utilizing, byproduct, source, or special nuclear materials, or other radioactive material occurring naturally or produced artificially."
- General Licenses: H&S Code 114985(g) defines "general license" as 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." Regulations (17 CCR 30190 – 30192.6³) clarify and specify particular types of existing general licenses.
- Exempt products and concentrations: Specific types of products manufactured and distributed by authorized specific licensees may be possessed and used by persons without that person being subject to regulatory requirements, provided

³ The short format "17 CCR 30190" for a given regulation found within title 17, California Code of Regulations will be used throughout this document for brevity.

the product is used as labeled. Exempt concentrations may be possessed by persons without that person being subject to regulatory requirements, provided a certain amount is not exceeded or certain activities are not performed. H&S Code 115060(c) authorizes CDPH to create such exemptions.

Thus, depending on the particular radionuclide, quantity, or activity, a person may be required to obtain a specific license, may only be subject to requirements under a particular general license, or may be exempt from both specific and general license requirements.

Authority

The Radiation Control Law (RCL) (H&S Code sections 114960 – 115273) requires CDPH to develop programs for licensing and regulating radioactive materials. (H&S Code 115000(b).) The CDPH is the successor of the California Department of Health Services and has the authority to license and regulate radioactive material under the California Public Health Act of 2006 (Stats. 2006, ch. 241 (Senate Bill (SB) 162, Ortiz)).

In 1962, the State of California ratified and approved an agreement with the United States Atomic Energy Commission, the predecessor of the United States Nuclear Regulatory Commission (NRC), by which the federal agency discontinued its regulatory authority over certain radioactive materials. (H&S Code 115230.) By such action California became an "Agreement State."

California, as an Agreement State, has regulatory authority over the possession and use of RAM by any person subject to state jurisdiction. A person, defined in H&S Code 114985(c), is "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."

A provision of the agreement between California and the NRC specifies that the State "will use its best efforts to maintain continuing compatibility between its program and the program of the [United States Atomic Energy] Commission for the regulation of like materials." (H&S Code 115235, art. V.) NRC's stated policy is "to evaluate Agreement State programs established pursuant to Section 274 of the Atomic Energy Act (AEA) of 1954, as amended, to ensure they are adequate to protect public health and safety and compatible with NRC's regulatory program."⁴

⁴ "Adequacy and Compatibility of Agreement State Programs," Management Directive 5.9, page 1. The document is available at the Nuclear Regulatory Commission, Office of Federal and State Materials and Environmental Programs website: <http://nrc-stp.ornl.gov/procedures.html> (Reference 1).

To determine a state's compatibility, the NRC uses Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs, Handbook 5.9*.⁵ This handbook describes the specific criteria and process that are used to determine which NRC program elements should be adopted and implemented by an Agreement State for purposes of compatibility, and which NRC program elements have a particular health and safety significance. The NRC rates the elements on the degree of compatibility required. Thus, the NRC requires that some elements be adopted by the states in a form identical to the NRC's, while adoption of others need not be identical, but are still required to meet the essential objective of the program element. The overall determination of adequacy and compatibility for an Agreement State is made pursuant to Management Directive 5.6, *The Integrated Materials Performance Evaluation Program (IMPEP)*.⁶ The NRC evaluates Agreement States every four years to determine if a state's radiation safety program meets the adequacy and compatibility criteria. If California fails to meet those criteria the NRC may revoke California's status as an Agreement State and re-invoke federal authority over RAM.

In conjunction with NRC's IMPEP review every four years, NRC procedures (SA-200⁷) require Agreement States, when adopting regulations required for meeting the adequacy and compatibility determinations, to submit proposed regulations to NRC for review. NRC reviews the proposal to ensure the proposed regulations meet the applicable NRC compatibility categories. The categories are defined as follows:

NRC Compatibility Categories⁸ (underlined words are defined below)

Category A: Basic radiation protection standard, or related definitions, signs, labels or terms that are necessary for a common understanding of radiation protection principles. The State program element should be essentially identical to that of NRC.

Category B: Program element with significant direct trans-boundary implications. The State program element should be essentially identical to that of NRC.

Category C: Program element, the essential objectives of which should be adopted by the State to avoid conflicts, duplications or gaps. The manner in which the essential objectives are addressed need not be the same as NRC provided the essential objectives are met.

⁵ Ibid.

⁶ "Integrated Materials Performance Evaluation Program (IMPEP)," Management Directive 5.6. The document is available at the Nuclear Regulatory Commission, Office of Federal and State Materials and Environmental Programs website: <http://nrc-stp.ornl.gov/procedures.html> by clicking on "MD-5.6." (Reference 2).

⁷ SA-200 is available at <http://nrc-stp.ornl.gov/procedures.html> by clicking on "SA-200" (Reference 3).

⁸ Volume 5, Governmental Relations and Public Affairs, Adequacy and Compatibility of Agreement State Programs, February 27, 1998, Handbook 5.9, Part II, pp. 4-7 (Handbook 5.9 is included within Reference 1).

Category D: Not required for purposes of compatibility.

Category NRC: Not required for purposes of compatibility. These are NRC program elements that address areas of regulation that cannot be relinquished to Agreement States pursuant to the AEA or provisions of Title 10 of the Code of Federal Regulations. The State should not adopt these program elements.

Category Health & Safety (H&S): Program elements identified as H&S are not required for purposes of compatibility; however, they do have particular health and safety significance. The State should adopt the essential objectives of such program elements in order to maintain an adequate program.

[] = A bracket around a category (e.g. [B]) means that the Section may have been adopted elsewhere so that it is not necessary to adopt it again.

Definitions⁹

Conflict means that the essential objectives of regulations or program elements are different and an undesirable consequence is likely to result in another jurisdiction or in the regulation of agreement material on a nationwide basis.

Duplication means that identical regulations or program elements apply to the same material at the same time. Note: this definition applies primarily to review of Agreement State regulations.

Essentially Identical means the interpretation of the text must be the same regardless of the version (NRC or Agreement State) that is read.

Essential objective of a regulation or program element means the action that is to be achieved, modified or prevented by implementing and following the regulation or program element. In some instances, the essential objective may be a numerical value (e.g., restriction of exposures to a maximum value) or it may be a more general goal (e.g., access control to a restricted area).

Gaps means that the essential objectives of NRC regulations or program elements are absent from the Agreement State program, and an undesirable consequence is likely to result in another jurisdiction or in the regulation of agreement materials on a nationwide basis.

The regulations that implement, interpret and make specific the provisions of the Radiation Control Law are in title 17, California Code of Regulations, sections 30100 through 30395.

Changes to the authority and reference citations note found at the end of sections:

⁹ Ibid, pg. 17.

- 30254, 30346, 30346.2, and 30348.1 that are proposed to be amended reflect the numbering system implemented by the 1995 recodification of the Health and Safety Code; and
- 30180, 30194, 30195.2, 30235, 30237, 30350 that are proposed to be amended reflect the reorganization of the Department of Health Services into the Department of Health Care Services and the California Department of Public Health, pursuant to SB 162. (Stats. 2006, ch. 241.)

These changes are nonsubstantial pursuant to 1 CCR 100.

Specific Discussion of Proposed Changes

The changes to existing state regulations are explained as follows:

Existing **Section 30180** applies to all persons, with regard to who is not required to hold a license and what products, concentrations and quantities of RAM can be possessed without obtaining a license. The title is proposed to be amended from “Exempt Persons, Products, Concentrations and Quantities” to “Carriers, Federal Licensees and Prime Contractors” to reflect the contents of the section as revised. Also, the section is proposed to be broken into additional sections that more closely correspond to NRC’s equivalent provisions.

The problem with existing section 30180 is that it contains a large number of provisions relating to a number of different types of users and products and is difficult to cross-reference with federal regulations. By presenting the provisions in separate new sections, anticipated benefits include making it easier to find particular subject matter, making it easier to cross-reference state regulations with NRC provisions, and making it easier to ensure regulations maintain compatibility with NRC regulations. See cross-reference table at the end of this document providing a detailed cross-reference to existing section 30180, NRC provisions, and proposed sections. Each particular section proposed to be adopted as identified in the below table (and the detailed cross-reference table) is intended to realize those benefits.

Section 30180 is proposed to be amended to ensure compliance with the NRC agreement, and the compatibility of State regulations. This proposal amends section 30180 to address those changes made by the NRC, as noted in the following federal registers and during a review of existing NRC provisions as found in 10 CFR 30, 40, and 150:

- 72 Fed.Reg. 55864 (Oct. 1, 2007);
- 72 Fed.Reg. 58473 (Oct. 16, 2007); and
- 77 Fed.Reg. 43666 (July 25, 2012).

Existing Section 30180 (subsection)	10 CFR Section	Compatibility Category	Description & Rationale NE = No Equivalent, I = Identical, EI = Essentially Identical

Existing Section 30180 (subsection)	10 CFR Section	Compatibility Category	Description & Rationale NE = No Equivalent, I = Identical, EI = Essentially Identical
(a)	30.12 30.13 40.11 40.12 150.15	B B B (a) – B, (b) – NRC NRC	<p>Subsection (a) is amended to maintain consistency with NRC’s provisions. Existing subsections (a)(1), (a)(2), and (a)(3) are redesignated to subsections (a), (b), (c) and (d), respectively.</p> <p>As redesignated, the subsections correspond to NRC’s provisions as follows:</p> <ul style="list-style-type: none"> • Subsection (a) corresponds to 10 CFR 30.13 and 40.12(a). 10 CFR 40.12(b) is not adopted as it is reserved to NRC. • Subsection (b) corresponds to 10 CFR 150.15. • Subsections (c) and (d) corresponds to 10 CFR 30.12 and 40.11.
(b) through (e)	<p>These existing subsections are proposed to be redesignated to the following proposed sections as discussed in those sections, or deleted as discussed below:</p> <ul style="list-style-type: none"> • Subsections (c)(1), (c)(3) and (e) are redesignated to section 30180.1, equivalent to 10 CFR 30.14. That portion of subsection (c)(1) pertaining to naturally occurring radioactive material is redesignated to section 30180.1. That portion of subsection (c)(1) pertaining to source material is redesignated to section 30181. • The following subsections are redesignated to section 30180.2, equivalent to 10 CFR 30.15: <ul style="list-style-type: none"> ○ Subsections (b)(1), (b)(17), (b)(19), (b)(22), (b)(24), (b)(28), and (d)(1). • Subsections (c)(4) and (e) are redesignated to section 30180.3, equivalent to 10 CFR 30.18. • Subsections (b)(27) and (d)(1) are redesignated to section 30180.4, equivalent to 10 CFR 30.19: • Subsections (b)(26) and (d)(1) are redesignated to section 30180.5, equivalent to 10 CFR 30.20: • The following subsections are redesignated to section 30180.6, equivalent to 10 CFR 30.21: <ul style="list-style-type: none"> ○ Subsections (b)(30), (d)(1) and (e). • The following subsections are redesignated to section 30181, equivalent to 10 CFR 40.13: <ul style="list-style-type: none"> ○ Subsections (b)(3)-(b)(16), (b)(21), (b)(25), (c)(1), (c)(2), (d)(1), (d)(4) and (d)(6). That portion of subsection (c)(1) pertaining to naturally occurring radioactive material is redesignated to section 30180.1. That portion of subsection (c)(1) pertaining to source material is 		

Existing Section 30180 (subsection)	10 CFR Section	Compatibility Category	Description & Rationale NE = No Equivalent, I = Identical, EI = Essentially Identical
			<p>redesignated to section 30181.</p> <ul style="list-style-type: none"> • The following subsections are deleted: <ul style="list-style-type: none"> ○ Subsections (b)(2), (b)(18), (b)(20), (b)(23), and (b)(29). These subsections are deleted because NRC has repealed the allowance of such products to be manufactured as an exempt product. NRC has informed Agreement States that exemption of such products must be removed from the state's regulations. These subsections correspond to the following NRC provisions deleted by NRC: <ul style="list-style-type: none"> ▪ (b)(2) = 10 CFR 30.15(a)(2) ▪ (b)(18) = 10 CFR 30.15(a)(4) ▪ (b)(20) = 10 CFR 30.15(a)(6) ▪ (b)(23) = 10 CFR 30.16 ▪ (b)(29) = 10 CFR 30.15(a)(10) ○ Subsections (d)(2), (d)(3), and (d)(5). Subsection (d)(2) is deleted because it is addressed in proposed section 30180.2. Subsection (d)(3) is deleted because NRC has informed Agreement States that exemption of such products must be removed from the state's regulations. Subsection (d)(5) is deleted because it is addressed in proposed section 30180.6. <p>As noted above, some subsections appear to be redesignated to more than one section. This means that the subsection's broad content is placed into and addressed in the proposed section. For example, subsection (e)'s content is addressed in three proposed sections; namely, sections 30180.1, 30180.3, and 30180.6, as it pertains to the equivalent NRC provision.</p>

Section 30180.1, Exempt Concentrations is proposed to be adopted to both address the problems and realize the benefits as stated regarding this proposed regulatory action, and for consistency and compatibility with 10 CFR 30.14, which is compatibility category B. The section is essentially identical to 10 CFR 30.14 except that the proposal references the Department's NRC-equivalent provisions to ensure the applicable provisions can be located. Referenced section 30237 corresponds to 10 CFR 30.70, which is compatibility category B.

Because this proposed section is part of the restructuring of existing section 30180, existing section 30180(c)(1) pertaining to naturally occurring radioactive material is redesignated to proposed subsection (b) in this proposed section (i.e. section 30180.1). That portion of existing section 30180(c)(1) pertaining to source material is redesignated to section 30181.

Prior to NRC's changes to 10 CFR 30.14(c) and (d) (72 Fed.Reg. 58476 (Oct. 16, 2007)), NRC's regulations allowed Agreement State licensing of the introduction of exempt concentrations into products or materials. However, NRC, in 2007, amended its regulations so that the licensing of introduction of exempt concentrations is limited to NRC and not Agreement States. Thus, subsections (d) and (e) are proposed to be adopted essentially identical to NRC's provision by not including any implication that the Department issues a license authorizing the introduction of exempt concentrations. The sentence "This provision shall not be constructed to incorporate by reference 10 CFR 32, section 32.11" found in subsection (f) is needed to clarify that NRC's provision is not incorporated by reference. Section 32.11 of 10 CFR 32 is designated compatibility category NRC, so Agreement States are not authorized to issue such licenses.

Section 30180.2, Certain Items Containing Radioactive Material, is proposed to be adopted to both address the problems and realize the benefits as stated regarding this proposed regulatory action, and for consistency and compatibility with 10 CFR 30.15, which is compatibility category B. This proposal (subsection (b)) also addresses NRC's recent amendment of 10 CFR 30.15(a)(2) (77 Fed.Reg. 43666 (July 25, 2012)). That amendment includes the date of October 23, 2012, which is NRC's regulation effective date. Because this date does not correspond to the establishment of NRC's regulations adopted under the federal Energy Policy Act of 2005, Agreement States may adopt a different date for purposes of the state's regulation adoption. However, because the effective date of this proposal cannot be determined, the Department proposes to authorize the Office of Administrative Law (OAL) to insert the date for clarity.

NRC has informed Agreement States that the dates found in 10 CFR 30.15(a)(1), (a)(3) and (a)(5) may not be changed as they correspond to the establishment of NRC's regulations adopted under the federal Energy Policy Act of 2005. The section is essentially identical to 10 CFR 30.15 except that the proposal references the Department's NRC-equivalent provisions to ensure that the applicable provisions can be located, and reworded in order to make the section more readable.

Section 30180.3, Exempt Quantities is proposed to be adopted to both address the problems and realize the benefits as stated regarding this proposed regulatory action, and for consistency and compatibility with 10 CFR 30.18, which is compatibility category B. The section is essentially identical to 10 CFR 30.18 except as discussed below, and has been reworded for readability:

- Subsection (a) references the NRC-equivalent section that specifies the applicable radionuclides and quantities. The proposal also references the Department's NRC-equivalent provisions to ensure that the applicable provisions can be located.
- Subsection (b), equivalent to 10 CFR 30.18(b), addresses possession of radioactive material under prior regulations. In 1968, NRC proposed to amend its general license provision, formerly codified in 10 CFR 31.4, to allow a person to possess certain sources under an exemption instead of a general license. (33 Fed.Reg. 11414 (Aug. 10, 1968).) NRC adopted that proposed rule, effective September 25, 1971. The Department followed suit and amended its equivalent

regulations (former section 30192(a)(2)), effective November 12, 1972 (Cal. Code Register 72, No. 42), and codified the exemption into section 30180(c)(4) (formerly section 30180(c)(24); Cal. Code Register 86, No. 28). Therefore, the Department's effective date of November 12, 1972 is used in lieu of the NRC's date.

- Subsection (d) is essentially identical to 10 CFR 30.18(d), except that it references NRC's regulations relating to a license for transferring certain quantities of radioactive material to persons exempt from license requirements for clarity and consistency. The sentence "This provision shall not be constructed to incorporate by reference 10 CFR 32, section 32.18" is needed to clarify that NRC's provision is not incorporated by reference. Section 32.18 of 10 CFR 32 is compatibility category NRC, so Agreement States are not authorized to issue such licenses.

Subsection (c) is essentially identical to 10 CFR 31.18(c), to maintain uniformity and consistency with NRC.

The date found in subsection (e), equivalent to 10 CFR 30.18(e), may not be changed as it is the date of NRC's Generic Letter 99-01 (Reference 6) that addressed bundling of exempt quantities. As stated by NRC (72 Fed.Reg. 58477 (Oct. 16, 2007)), the date and exclusion are intended to avoid imposing a regulatory burden on those persons who otherwise might be impacted by this rule change, and who are continuing to use devices which were in use before the generic letter was issued.

Section 30180.4, Self-Luminous Products Containing Tritium, Krypton-85, or Promethium-147 is proposed to be adopted to both address the problems and realize the benefits as stated regarding this proposed regulatory action and for consistency and compatibility with 10 CFR 30.19, which is compatibility category B. The section is essentially identical to 10 CFR 30.19, except that subsection (a) references the Department's NRC-equivalent provisions to ensure the applicable provisions can be located and is reworded for readability. The sentence "This provision shall not be constructed to incorporate by reference 10 CFR 32, section 32.22" is needed to clarify that NRC's provision is not incorporated by reference. Section 32.22 of 10 CFR 32 is compatibility category NRC so Agreement States are not authorized to issue such licenses.

Section 30180.5, Gas and Aerosol Detectors Containing Radioactive Material, is proposed to be adopted to both address the problems and realize the benefits as stated regarding this proposed regulatory action and for consistency and compatibility with 10 CFR 30.20, which is compatibility category B. This proposal also addresses NRC's recent amendment of 10 CFR 30.20 (77 Fed.Reg. 43666 (July 25, 2012)). The section is essentially identical to 10 CFR 30.20, except that the proposal addresses the provision from the States' perspective instead of NRC's perspective. The November 30, 2007 date is the effective date of the Energy Policy Act of 2005, which expanded NRC's authority to regulate certain naturally and artificially produced radioactive material (NARM) and certain discrete sources of radium-226. Prior to that date, NARM was

regulated only by the States, which could issue licenses authorizing the transfer of NARM to exempt persons. The proposal also references the Department's NRC-equivalent provisions, to ensure that the applicable provisions can be located. The sentence "This provision shall not be constructed to incorporate by reference 10 CFR 32, section 32.26" is needed to clarify that NRC's provision is not incorporated by reference. Section 32.26 of 10 CFR 32 is compatibility category NRC, so Agreement States are not authorized to issue such licenses.

Section 30180.6, Radioactive Drug: Capsules Containing Carbon-14 Urea for "In Vivo" Diagnostic Use for Humans, is proposed to be adopted to both address the problems and realize the benefits as stated regarding this proposed regulatory action and for consistency and compatibility with 10 CFR 30.21(a), (b) and (d), which is compatibility category B; and subdivision (c), which is compatibility category NRC. The section is essentially identical to 10 CFR 30.21, except that it is reworded for readability, and subsection (b) references the Department's NRC-equivalent provisions to ensure that the applicable provisions can be located. Regarding subsection (c) as it relates to the activities found in 10 CFR 30.21(c), NRC does not authorize Agreement States to license such manufacturers or activities, as indicated by the compatibility category of NRC for 10 CFR 30.21(c). Thus, CDPH is not adopting a provision reserved to NRC, but proposes to clearly state that the exemption shall not be deemed to authorize the specific activities.

Section 30180.7, Certain Industrial Products, is proposed to be adopted to both address the problems and realize the benefits as stated regarding this proposed regulatory action, and for consistency and compatibility with 10 CFR 30.22, which is compatibility category B. NRC recently adopted 10 CFR 30.22 (77 Fed.Reg. 43666 (July 25, 2012) to establish a new class exemption for certain industrial devices. The proposal also references the Department's NRC-equivalent provisions to ensure that the applicable provisions can be located. The sentence "This provision shall not be construed to incorporate by reference 10 CFR 32, section 32.30" is needed to clarify that NRC's provision is not incorporated by reference. Section 32.30 of 10 CFR 32 is compatibility category NRC, so Agreement States are not authorized to issue such licenses.

Section 30181, Products and Quantities of Source Material, is proposed to be adopted to both address the problems and realize the benefits as stated regarding this proposed regulatory action and for consistency and compatibility with 10 CFR 40.13, which is compatibility category B. The section is essentially identical to 10 CFR 40.13, except that the proposal references the Department's NRC-equivalent provisions to ensure that the applicable provisions can be located.

Because this proposed section is part of the restructuring of existing section 30180, existing section 30180(c)(1) pertaining to source material is redesignated to this section (i.e. section 30181). Existing section 30180(c)(1) pertaining to naturally occurring radioactive material is redesignated to proposed section 30180.1(b).

Section 30190, Types of Licenses, is proposed to be amended to both address the problems and realize the benefits stated regarding this proposed regulatory action, and to ensure clarity and consistency with other proposed changes. Subsection (c) is amended to include the new sections being added as discussed regarding section 30180.

Subsection (c) is further amended to include the section reference to the proposed new general license in section 30192.7. Both of these changes fall in topic 2 as listed in the table on page one. The reference to section 30192 is proposed to be deleted as discussed regarding that section. These changes are without regulatory effect.

Section 30192, General Licenses – Static Elimination or Ion Generation Devices, equivalent to 10 CFR 31.3, is proposed to be deleted because NRC now limits the licensing of introduction of exempt concentrations of RAM to the NRC. NRC has directed Agreement States that this general license should be removed from the state's regulations. (77 Fed.Reg. 43687 (July 25, 2012).)

Section 30192.1, General Licenses – Gauging and Controlling, is proposed to be amended to both address the problems and realize the benefits stated regarding this proposed regulatory action, and to achieve compatibility with 10 CFR 31.5(b)(1)(i) and consistency with other proposed changes. Section 30192.1(b)(1) references section 30195(d). However, section 30195(d) does not exist; the correct reference is section 30195(c) as pointed out by NRC. (Reference 7, comment 18.) Section 30195(c) is proposed to be deleted and addressed in proposed 30196. Therefore, subsection (b)(1) is amended for compatibility with NRC, consistency with other proposed changes, and for clarity.

Section 30192.7, General Licenses – Items and Self-Luminous Products Containing Radium-226, is proposed to be added to both address the problems and realize the benefits stated regarding this proposed regulatory action, and to achieve compatibility with 10 CFR 31.12, which is compatibility category C. NRC adopted that provision as published in the October 1, 2007 publication of the Federal Register. (72 Fed.Reg. 55927 (Oct. 1, 2007).) Though the Department need only meet the essential objective of the provision, it is proposed that the provision be adopted essentially identical, except as discussed below. This provides uniformity between California, the federal government, and other states, as specified by the Legislature in H&S Code 114965.

Subsection (a) is essentially identical to 10 CFR 31.12(a), to maintain consistency and uniformity with NRC's provision. The specific date is maintained, as NRC has informed the Agreement States that the date may not be changed as it is the effective date of the regulations adopted pursuant to the federal Energy Policy Act of 2005 [Pub.L. 109-58]. (72 Fed.Reg. 55927 (Oct. 1, 2007).)

Subsection (b) is essentially identical to 10 CFR 31.12(b), except that the proposal references the Department's NRC-equivalent provisions to ensure that the applicable provisions can be located.

Subsection (c) is essentially identical to 10 CFR 31.12(c) except that:

- Subsections (c)(1) and (c)(5) substitutes the Department for NRC as it relates to submission of a report when required, as found in 10 CFR 31.12(c)(1) and (c)(5), respectively.
- Subsection (c)(2) excludes the reference to 10 CFR 20.2008, as found in 10 CFR 31.12(c)(2). Under NRC's compatibility category C, agreement states may be more restrictive than NRC. CDPH proposes to be more restrictive because under current State law, RAM may only be disposed of at a facility holding a Department-issued specific license authorizing disposal. (H&S Code 114715, 114985(m), 115010, & 115165; 17 CCR 30470 et seq.)
- Subsection (c)(3) includes the sentence "This provision shall not be constructed to incorporate by reference 10 CFR 110" as it is needed to inform licensees that 10 CFR 110 is not incorporated by reference.
- Subsection (c)(4) excludes the reference to federal or state hazardous waste law and the Energy Policy Act of 2005 as found in 10 CFR 31.12(c)(4). Under NRC's compatibility category C, Agreement States may be more restrictive than NRC. CDPH proposes to be more restrictive because under current state law, RAM may only be disposed of at a facility holding a specific license authorizing its disposal. (H&S Code 114715, 114985(m), 115010, & 115165; 17 CCR 30470 et seq.)

Subsection (d) is essentially identical to 10 CFR 31.12(d), to maintain uniformity and consistency with NRC.

RAM can be in the form of a solid, liquid, or gas. A "sealed source" is 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. (17 CCR 30100(v).) RAM is often used within a device to utilize the emitted radiation for a particular purpose, such as determining the thickness or density of certain materials. As a liquid or gas, RAM as a radioactive drug can be used for medical diagnosis or cancer treatment.

Section 30194, Approval of Applications and Specific Terms and Conditions for Licenses, is proposed to be amended to both address the problems and realize the benefits stated regarding this proposed regulatory action, and to achieve compatibility with NRC's regulations found in 10 CFR 30.34(b)(2), as adopted by NRC in the June 17, 2011 publication of the Federal Register. (76 Fed.Reg. 35512 (June 17, 2011).)

Subsection (c) is amended to address NRC's changes as specified in 10 CFR 30.34(b)(2), which is compatibility category C, requiring adoption of a regulation that meets the essential objective of the NRC's regulation. Though the Department need only meet the essential objective of the provision, it is proposed that the provision be adopted essentially identical, except that it is revised to cite the Department's applicable regulation. This provides uniformity between California, the federal government, and other states, as intended by the Legislature's policy specified in H&S Code 114965.

Subsection (g), second sentence, is proposed to be deleted to remove an obsolete provision used to implement a regulatory change in 1995. This is a nonsubstantial change.

Section 30195, Special Requirements for Issuance of Specific Licenses, is proposed to be amended to both address the problems and realize the benefits stated regarding this proposed regulatory action, and to achieve compatibility with the updated NRC medical use regulations found in 10 CFR 35 and 10 CFR 30.32(g) and (j), as amended by NRC in the October 1, 2007 publication of the Federal Register. (72 Fed.Reg. 55927 (Oct. 1, 2007).) This proposal also addresses NRC's recent amendment of 10 CFR 30.32(g) (77 Fed.Reg. 43666 (July 25, 2012)).

Subsection (a) is amended to incorporate by reference those changes that were made to 10 CFR 35 from January 1, 2008 to January 1, 2013. By changing the date, the incorporated material will include the changes made by the NRC in the following federal registers that are available at <http://www.gpoaccess.gov/fr/index.html>:

- 74 Fed.Reg. 33901 (Jul. 14, 2009).

The following 10 CFR 35 sections, all of which are compatibility category B, were amended between January 1, 2008 and January 1, 2013:

- 10 CFR 35.50 - Training for Radiation Safety Officer.
- 10 CFR 35.51 - Training for an authorized medical physicist.
- 10 CFR 35.57 - Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.
- 10 CFR 35.190 - Training for uptake, dilution, and excretion studies.
- 10 CFR 35.290 - Training for imaging and localization studies.
- 10 CFR 35.390 - Training for use of unsealed byproduct material for which a written directive is required.
- 10 CFR 35.392 - Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).
- 10 CFR 35.394 - Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).
- 10 CFR 35.396 - Training for the parenteral administration of unsealed byproduct material requiring a written directive.
- 10 CFR 35.490 - Training for use of manual brachytherapy sources.
- 10 CFR 35.491 - Training for ophthalmic use of strontium-90.
- 10 CFR 35.690 - Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Subsection (a)(14)(A) is amended to address NRC's comment on the original adoption of this provision, equivalent to 10 CFR 35.57. (Reference 4, comment 1.) The proposal

follows NRC's recommendation to ensure the provision is compatible with the federal regulation.

Existing subsection (c) is deleted as unnecessary due to proposed section 30196 addressing the content being deleted. See section 30196 for additional discussion.

Proposed subsection (c) is added to achieve compatibility with NRC's regulations found in 10 CFR 30.32(g), which is compatibility category C, as adopted at 77 Fed.Reg. 43666 (July 25, 2012). Though the Department need only meet the essential objective of the provision, it is proposed that the provision be adopted essentially identical, except that it is revised to cite the Department's applicable source or device registration regulation. This provides uniformity between California, the federal government, and other states, as intended by the Legislature's policy specified in H&S Code 114965.

Subsection (d) is added to achieve compatibility with NRC's regulations found in 10 CFR 30.32(j), which is compatibility category B, and is essentially identical, except that it is revised to cite the Department's applicable source or device registration regulation to ensure that the applicable provisions can be located. Though different, under NRC's review procedures (Reference 3a, Appendix B), such a difference is not significant since the difference does not result in Department licensees being subject to a requirement different from the equivalent NRC requirement.

Section 30195.2, Special Requirements for Issuance of Specific Licenses - Emergency Plans, is amended to both address the problems and realize the benefits stated regarding this proposed regulatory action by updating the date of incorporation of 10 CFR 30.32(i) and 30.72 found in subsection (a) (redesignated to subsection (b)) from January 1, 1994 to January 1, 2013, to achieve compatibility with NRC's regulations. NRC has made no changes to 10 CFR 30.32(i). However, section 30195.2 also incorporates 10 CFR 30.72, which was amended at the October 1, 2007 publication of the federal register (72 Fed.Reg. 55926) to include radium-226, and designated by NRC as compatibility category H&S. Updating the incorporation date makes it easier for licensees who are subject to this section to obtain the incorporated document and addresses the addition of radium-226 to 10 CFR 30.72. Nonsubstantial changes related to acronym usage, deletion of unnecessary verbiage, and capitalization in subsections (a), (a)(1), and (b) are made.

Section 30195.3, Special Requirements for Issuance of Specific Licenses for Use of Sealed Sources in Industrial Radiography, is proposed to be amended to both address the problems and realize the benefits stated regarding this proposed regulatory action by making grammatical corrections in subsection (b)(6). This change is without regulatory effect.

Section 30195.4, Additional Requirements for Specific Licenses Authorized Pursuant to Section 30195(d), is proposed to be adopted to both address the problems and realize the benefits stated regarding this proposed regulatory action, and to achieve compatibility with NRC's regulations found in 10 CFR 30.4 for the term "consortium" and

10 CFR 30.34(j) as adopted by NRC in the October 1, 2007 publication of the Federal Register. (72 Fed.Reg. 55927 (Oct. 1, 2007).)

Subsection (a) is adopted to achieve compatibility with NRC's regulations found in 10 CFR 30.34(j), which is compatibility category B. The proposal is essentially identical to NRC's provision, except that the proposal references the Department's NRC-equivalent provisions to ensure the applicable provisions can be located.

Subsection (b) is adopted to achieve compatibility with NRC's regulations found in 10 CFR 30.4, for the term "consortium", which is compatibility category C. Though the Department need only meet the essential objective of the provision, it is proposed that the provision be adopted essentially identical for clarity with NRC's regulation, and to maintain uniformity between California, the federal government, and other states, as intended by the Legislature's policy specified in H&S Code 114965.

Section 30196, Special Requirements for Issuance of Specific Licenses to Manufacture or Transfer Certain Items Containing Radioactive Material, is proposed to be adopted to both address the problems and realize the benefits stated regarding this proposed regulatory action, and to achieve compatibility with NRC's regulations found in 10 CFR 32. Subsection (a) is adopted to incorporate by reference the NRC's regulations governing the manufacture or transfer of certain items containing byproduct material in 10 CFR 32, January 1, 2013, with exceptions. California, as an Agreement State, has regulatory authority over the manufacture and distribution of items containing radioactive material within the state. This incorporation is necessary to ensure California's compatibility with federal regulations.

This proposal also addresses NRC's changes to 10 CFR 32 as found in the July 25, 2012 publication of the Federal Register. (77 Fed.Reg. 43666 (Jul. 25, 2012).)

Subsection (a)(1) lists those NRC provisions not being incorporated because the specific section either may not be required for compatibility or adequacy, may be reserved only to the NRC, may be addressed in existing regulations, or may be removed by NRC as follows:

- 10 CFR 32.1(a), (b) & (c)(2) are compatibility category D and (c)(1) is compatibility category NRC.
- 10 CFR 32.3, 32.8, 32.301, & 32.303 are compatibility category D.
- 10 CFR 32.11, 32.12, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.21a, 32.22, 32.23, 32.25, 32.26, 32.27, 32.28, & 32.29 are compatibility category NRC.
- 10 CFR 32.101, 32.102, 32.103, 32.110 were removed by NRC. (77 Fed.Reg. 43687 (Jul. 25, 2012).)
- NRC Form 653 referenced in 10 CFR 32.52. That form merely duplicates the provisions in section 32.52 and, by not incorporating it, clarity and consistency are maintained.

Thus, the following sections of 10 CFR 32 are being incorporated by reference:

- 10 CFR 32.2:
 - Terms “committed dose” and “Sealed source and device registry” are compatibility category D. Though these terms are not required for compatibility, they are being adopted to maintain uniform and consistent interpretation of those provisions proposed to be adopted in this section.
 - Term “dose commitment” is compatibility category [A];
 - Terms “lot tolerance percent defective” and “nationally tracked source” are compatibility category B.
- 10 CFR 32.24 is compatibility category B.
- 10 CFR 32.51 through 32.74 are compatibility category B.
- 10 CFR 32.201 and 32.211 are compatibility category B for Agreement States that perform sealed source and device (SS&D) evaluations, and compatibility category D for those states that do not. NRC’s amendment (77 Fed.Reg. 43666 (Jul. 25, 2012)) of 10 CFR 32.210 added subdivision (g), which is compatibility category B for Agreement States that perform SS&D evaluations, and added subdivision (h), which is compatibility category C for Agreement States that perform SS&D evaluations. California performs SS&D evaluations; therefore, these sections are proposed to be adopted. Though the Department need only meet the essential objective of 10 CFR 32.210(h), it is proposed that the provision be adopted essentially identical for clarity with NRC’s regulation, and to maintain uniformity between California, the federal government, and other states, as intended by the Legislature’s policy specified in H&S Code 114965.

Subsection (a)(2) is needed to clarify that any reference to a “byproduct material” is a reference to “radioactive material” because, within the State, CDPH has regulatory authority over types of material not subject to federal law. By directing the reference for “byproduct material” to “radioactive material”, accelerator produced isotopes used in positron emission tomography (PET) are included – and CPDH already has jurisdiction over their use.

Subsection (a)(3) is needed to clarify that CDPH, not the NRC, is the organization responsible for radiological health in California. As an Agreement State, California has regulatory authority over the possession and use of radioactive material.

Subsection (a)(4) is needed to clarify that any reference to “Agreement State” is a reference to the term “Agreement State,” as defined in section 30100. The term is not defined within the federal regulations being incorporated, but is defined in other Parts of 10 CFR, and is written from NRC’s perspective and applies nationally. The State’s definition is written from California’s perspective, and the clarification is needed since this proposal applies only to this State’s jurisdiction. Further, it prevents duplication of the term’s definition.

Subsection (a)(5) is needed to clarify that reference to a particular section found in 10 CFR 32 is a reference to the provided State regulation section. As it relates to 10 CFR 20, the referenced State regulation incorporates all 10 CFR 20 sections that are cited within that portion of 10 CFR 32 being incorporated, as follows:

10 CFR 32 section	10 CFR 20 sections cited within 10 CFR 32	Discussion
32.2 – Nationally Tracked Source	10 CFR 20, Appendix E.	All cited sections of 10 CFR 20, including Appendix E, are incorporated in section 30253.
32.51(a)(2)(ii) & (c)	10 CFR 20.1201(a)	
32.51(a)(4) & (a)(5), 32.54, 32.61(d), & 32.71(c)(2)	10 CFR 20.1901 or 20.1901(a)	
32.51a(a)(2) & (b)(1)	10 CFR 20.2201 & 20.2202	
32.71(e)	10 CFR 20.2001	

Subsection (a)(6) is needed to clarify that references within 10 CFR 32 to sections found in 10 CFR 35 are references to section 30195(a), with one exception as specified in the below table. Because section 30195(a) does not incorporate 10 CFR 35.65 as cited by section 32.74(a)(3), it is necessary to clarify the relationship between this proposed section and section 30195(a). A specific license issued pursuant to 10 CFR 32, and this proposed section, allows the licensee to commercially manufacture and distribute certain sources throughout the United States. A specific license issued pursuant to 10 CFR 35, and section 30195(a), does not authorize the licensee to manufacture or distribute sources for commercial distribution. A licensee under section 30195(a) may only use radioactive material for medical use as authorized in the license, at the specific use locations identified in the license. As it relates to the labeling requirement in 10 CFR 32.74(a)(3), the manufacturer/distributor must affix a label, as prescribed, to the source or device, and the medical use licensee may only use the source or device as stated on the label. Thus, the exception language of proposed subsection (a)(6) is necessary to clarify that the manufacturer/distributor licensee can be authorized to distribute the source or device to certain persons for the use specified in the 10 CFR 35 sections cited in 10 CFR 32.74(a)(3), since they can distribute the product to licensees in other states, but a medical use licensee cannot be so authorized. Further, this clarification maintains consistency with the NRC compatibility categories of 10 CFR 35.65 (compatibility category D, meaning it is not necessary to adopt it for compatibility) and 10 CFR 32.74 (compatibility category B, meaning it must be adopted in an essentially identical manner).

10 CFR 32 section	10 CFR 35 sections cited within 10 CFR 32	Discussion
32.72	10 CFR 35.2, 35.27, 35.55 & 35.59	Section 30195(a) incorporates by reference all cited 10 CFR 35 sections except 35.65.
32.74	10 CFR 35.65, 35.400, 35.500, 35.600, & 35.1000	

Section 30210.2, Labeling Requirements for the Manufacture, Preparation or Transfer for Commercial Distribution of Drugs Containing Radioactive Material for Human Use as Authorized by a Specific License, is proposed to be deleted because it is duplicative of 10 CFR 32.72(a)(4), which is being incorporated by reference in proposed section 30196.

Section 30235, Schedule A. Exempt Quantities, is proposed to be amended to both address the problems and realize the benefits stated regarding this proposed regulatory action by including certain radionuclides. This section was compared with its federal equivalent, 10 CFR 30.71 (compatibility category B). The following changes are made to ensure the section is essentially identical to NRC's provision, as recommended by NRC (Reference 7, comment 17):

- The following radionuclides, and the indicated quantity, are added:
 - Germanium 68 (Ge 68), 10 microcuries;
 - Gold 195 (Au 195), 10 microcuries;
 - Indium 115 (In 115), 10 microcuries;
 - Thallium 202 (Tl 202), 100 microcuries; and
 - Yttrium 88 (Y 88), 10 microcuries.
- Sodium 22 (Na 22): quantity is changed from one microcurie to 10 microcuries.
- Beryllium 7 (Be 7) and Lead 210 (Pb 210) are deleted as required by NRC.

Section 30237, Schedule C, Exempt Concentrations is proposed to be repealed and adopted to both address the problems and realize the benefits stated regarding this proposed regulatory action by ensuring it is equivalent to its federal equivalent, 10 CFR 30.70 (compatibility category B). A review of this section with 10 CFR 30.70 indicated a large number of differences in isotope acronyms and concentration values. Thus, the section is repealed entirely and readopted to present the table information accurately and more clearly. The proposal is identical to 10 CFR 30.70 except that the concentration values are presented in "E notation" where the letter "E" represents "times ten raised to the power of," thus, replacing the "x 10", followed by the value of the exponent. (e.g. $1 \times 10^2 = 1E2$; $1 \times 10^{-2} = 1E-2$.) This notation allows for easier preparation and presentation of the table information for electronic output devices.

Section 30253, Standards for Protection Against Radiation, is proposed to be amended to both address the problems and realize the benefits stated regarding this proposed regulatory action, and to achieve compatibility with NRC's radiation protection standards amended at the June 17, 2011 publication of the Federal Register (76 Fed.Reg. 35512).

Subsection (a) is amended to incorporate by reference changes that were made to 10 CFR 20 from January 1, 2008 to January 1, 2013. (76 Fed.Reg. 35512 (June 17, 2011).) By changing the date, the incorporated material will include the change made to 10 CFR section 20.1501, which is compatibility category H&S. The NRC's changes to 10 CFR sections 20.1403, 20.1404, and 20.1406 are not included because those sections remain not incorporated by reference, as indicated in subsection(a)(1). It is

necessary to not incorporate those sections, in order to maintain compliance with a trial court order issued May 16, 2002, in *Committee to Bridge the Gap, et al. v. Diana M. Bonta*, Director, California Department of Health Services, Sacramento County Superior Court No. 01CS01445.

Subsection (a)(11) is proposed to be added to reference the Department's NRC-equivalent provisions, instead of those NRC provisions that are cited to within 10 CFR 20.1501. This ensures the applicable provisions can be located. The references to 10 CFR sections 50.75(g) and 72.30(d) as cited in 20.1501 are not incorporated by reference because both sections are compatibility category NRC and cannot be adopted by Agreement States.

Section 30254, Inspection, is proposed to be amended to both address the problems and realize the benefits stated regarding this proposed regulatory action by correctly identifying a section reference. Subsection (d) is amended to correctly identify the referenced section. Section 30280 was redesignated to section 30255 in 1994 (Cal. Code Register 94, No. 9). This is a nonsubstantial change.

Section 30330, Definitions Specific to Industrial Radiography, is proposed to be amended to both address the problems and realize the benefits stated regarding this proposed regulatory action, by addressing NRC's comment on this provision, equivalent to 10 CFR 34.3 for the terms "Industrial Radiography" and "Radiographer Certification." (Reference 5, comments 1 & 2.) Both terms are compatibility category B. Subsections (b)(13) and (b)(18) are amended as recommended by NRC, to ensure the provision is compatible with the federal regulation.

Section 30332.5, Quarterly Inventory of Sealed Sources, is proposed to be amended to both address the problems and realize the benefits stated regarding this proposed regulatory action by addressing NRC's comment on this provision, which is equivalent to 10 CFR 34.29 and is compatibility category C. (Reference 5, comment 3.) The section is amended to be identical to 10 CFR 34.29, to ensure that the provision is compatible with the federal regulation. Though the compatibility category is C, the department proposes that the regulation be identical because industrial radiography is performed throughout the country. Identical regulations allow for more consistent compliance and reduce a user's regulatory burden, by not requiring the user to meet a different standard in different jurisdictions.

Section 30332.6, Utilization Logs, is proposed to be amended to both address the problems and realize the benefits stated regarding this proposed regulatory action by addressing NRC's comment on this provision, equivalent to 10 CFR 34.71, which is compatibility category B. (Reference 5, comment 8.) Subsection (a)(1) is amended as recommended by NRC, to ensure the provision is compatible with the federal regulation.

Section 30332.8, Reporting Requirements, is proposed to be amended to both address the problems and realize the benefits stated regarding this proposed regulatory action by addressing NRC's comment on this provision, equivalent to 10 CFR 34.101,

which is compatibility category C. (Reference 5, comment 11.) Subsection (c) is added as recommended by NRC to ensure the provision is compatible with the federal regulation. Though the compatibility category is C, CDPH proposes that the regulation be identical because industrial radiography is performed throughout the country. Identical regulations allow for more consistent compliance and reduce a user's regulatory burden by not requiring the user to meet a different standard in different jurisdictions. Existing subsection (c) is redesignated to subsection (d) to maintain a coherent structure.

Pursuant to Government Code section 11346.3(d), the Department finds that the reports required by proposed subsection (c) are necessary for the health, safety, and welfare of the people of this state. This finding is based on NRC's federal statutory authority for protection of the public health and safety, as identified in NRC's comments. (Reference 7, comment 11.)

Section 30332.9, Labeling, storage, and transportation, is proposed to be adopted to both address the problems and realize the benefits stated regarding this proposed regulatory action by addressing NRC's comment regarding an equivalent regulation to 10 CFR 34.35, which is compatibility category B. (Reference 5, comment 4.) The proposed section is essentially identical to NRC's provision, except that subsections (a) and (b) cite the Department's NRC-equivalent regulation pertaining to the standard radiation symbol and transportation requirements. Though different, under NRC's review procedures (Reference 3a, Appendix B), such a difference is not significant, since the difference does not result in Department licensees being subject to a requirement different from the equivalent NRC requirement.

Section 30333, Training and Supervision for Radiographers and Radiographers' Assistants Using Sealed Sources, is proposed to be amended to both address the problems and realize the benefits stated regarding this proposed regulatory action by addressing NRC's comment on this provision, which is equivalent to 10 CFR 34.79, and is compatibility category C. (Reference 5, comment 9.) Subsection (f) is amended as recommended by NRC to ensure the provision is compatible with the federal regulation. Though the compatibility category is C, the department proposes that the regulation be identical because industrial radiography is performed throughout the country. Identical regulations allow for more consistent compliance and reduce a user's regulatory burden by not requiring the user to meet a different standard in different jurisdictions.

The section's title is amended for grammatical correction. This is a change without regulatory effect.

Section 30333.1, Operating and Emergency Procedures, is proposed to be amended to both address the problems and realize the benefits stated regarding this proposed regulatory action by addressing NRC's comment on this provision, equivalent to 10 CFR 34.81, which is compatibility category C. (Reference 5, comment 10.) Subsection (b) is added as recommended by NRC, to ensure the provision is compatible with the federal regulation. Though the compatibility category is C, the department proposes that the

regulation be identical because industrial radiography is performed throughout the country. Identical regulations allow for more consistent compliance and reduce a user's regulatory burden by not requiring the user to meet a different standard in different jurisdictions.

Section 30336, Requirements for Shielded-Room Radiography, is proposed to be amended to address the following problems and realize the following benefits. This is a change without regulatory effect.

Problem: The note at the end of the section, as identified by an asterisk (*), incorrectly implies that "Global Engineering Documents" is part of the American National Standards Institute, Inc. (ANSI). Further, the mailing address for ANSI is outdated.

Objective: Correctly identify the mailing address for ANSI and delete "Global Engineering Documents."

Benefits: Anticipated benefits, including nonmonetary benefits, from this proposal are:

- Identification of the correct mailing address for ANSI;
- Clarification that "Global Engineering Documents" is related to the indicated Internet website, not ANSI; and
- Reduction of postage costs for persons trying to obtain a copy of the incorporated document due to using the wrong mailing address for ANSI.

The note at the end of the section is amended to update ANSI's mailing address and to clarify that the phrase "Global Engineering Documents" is not an entity within ANSI but is associated with the specified internet website address. That phrase is deleted and the website's name is inserted; namely, IHS Standards Store.

Section 30336.1, Requirements for Field Radiography, is proposed to be amended to both address the problems and realize the benefits stated regarding proposed section 30336 by making grammatical corrections to subsections (p) and (p)(3) and updating the note on how to obtain a copy of the document incorporated by reference in this section. This is a change without regulatory effect. The note at the end of the section is amended to update the mailing address of the American National Standards Institute, Inc. (ANSI) and to clarify that the phrase "Global Engineering Documents" is not an entity within ANSI but is associated with the specified internet website address. That phrase is deleted and the website's name is inserted; namely, IHS Standards Store.

Section 30336.5, Requirements for Radiation Machine Radiographers' Assistants, is proposed to be amended to both address the problems and realize the benefits stated regarding proposed section 30336 by making grammatical corrections in the section's title and the authority and reference note. These changes are without regulatory effect.

Section 30346, Agreement with Well Owner or Operator, is proposed to be amended to both address the problems and realize the benefits stated regarding this proposed regulatory action, and to achieve consistency with NRC's regulation found in 10 CFR

39.15, which is compatibility category C. A review and comparison of this section to NRC's provision indicated a number of inconsistencies. All proposed changes are nonsubstantial.

Subsection (a)(2) is amended to clearly prohibit the attempt to recover a sealed source that could result in the source's rupture. Subsection (a)(5)(B) is amended for consistency with NRC's provision. The reference to section 30278 found in subsection (a)(5)(C) is changed to correctly identify the provision specifying the radiation symbol and color requirements of the symbol. Prior to 1994, the symbol was found in section 30278. However, in 1994, the Department repealed that section and incorporated by reference NRC's provisions specifying the symbol and color requirements.

Subsections (a)(3) and (c) are amended for consistency with capitalization usage in other existing regulations. Subsections (c) and (d) are amended for consistency with wording referring to specific provisions within the section (e.g. paragraph, subsection).

Section 30346.2, Radiation Detection Instruments, is proposed to be amended to both address the problems and realize the benefits stated regarding this proposed regulatory action, and to achieve compatibility with NRC's regulation found in 10 CFR 39.33, which is compatibility category C and D. Subsection (a) is amended to delete the reference to survey instruments acquired prior to the regulation effective date of December 4, 1991. The Department is unaware of any such instruments that are still in use; it is unlikely that such an instrument would still be in use since the instrument would be more than 20 years old. Nonsubstantial changes are also made.

Section 30348.1, Training Requirements, is proposed to be amended to both address the problems and realize the benefits stated regarding this proposed regulatory action, and to achieve consistency with NRC's regulation found in 10 CFR 39.61, which is compatibility category B. A review and comparison of this section to NRC's provision indicated a number of inconsistencies with terminology. All proposed changes are nonsubstantial.

Subsection (a)(2)(A) is amended to shorten the reference to where the specified regulations are found. Subsections (a)(2)(C) and (b)(2) are amended for consistency with capitalization usage in other existing regulations. Subsections (a)(4), (b)(3), and (e) are amended for consistency with wording referring to specific provisions within the section (e.g. paragraph, subsection).

Section 30350, Security, is proposed to be amended to both address the problems and realize the benefits stated regarding this proposed regulatory action, and by correcting an inadvertent change made in a prior rulemaking regarding NRC's provision 10 CFR 39.71, which is compatibility category C. The term "controlled area" found in subsection (b) is changed to "restricted area." Prior to the change made in November of 1994 (Cal. Code Register 1994, No. 9), the term "controlled area" was defined, in part, as "any area access which is controlled by the user for purposes of radiation safety pursuant to the provisions of this regulation." In 1994, CDPH adopted by reference the NRC's

provisions (10 CFR 20 published Jan. 1, 1993), which included the term “restricted area” but not the term “controlled area” and deleted certain terms from section 30100. That rulemaking resulted in inconsistencies. In 2010 (Cal. Code Register 2010, No. 46 regarding section 30253), CDPH adopted the 2008 version of 10 CFR 20 that included the terms “controlled area” and “restricted area” but failed to reference the correct corresponding federal term. Thus, this proposal corrects the terminology, so that the regulations are compatible with the NRC’s provisions.

Statements of Determinations

CDPH has determined that the proposed regulatory action would have no significant adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

CDPH 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.

CDPH has determined that there would be an effect on small business because they will be legally required to comply with the regulation and may incur a detriment from the enforcement of the regulation.

CDPH has determined that the regulations will have no impact on housing costs.

Consideration of Reasonable Alternatives

Alternatives have been considered in those areas not subject to or specifically limited by the adequacy and compatibility criteria applicable under the State of California agreement with the United States Atomic Energy Commission, the predecessor to the United States Nuclear Regulatory Commission (Health & Saf. Code, § 115230). Such areas are discussed within the specific discussion of each section proposed to be amended, adopted or repealed.

Economic Impact Analysis

CDPH analyzed whether and to what extent this proposal affects the following:

A. The creation or elimination of jobs within the State of California. The proposal will not impact the creation or elimination of jobs because it only addresses compatibility with NRC regulations through restructuring, clarifying and updating existing regulation, and making a number of nonsubstantial changes.

B. The creation of new businesses or the elimination of existing businesses within the State of California. The proposal will not impact the creation or elimination of businesses because it only addresses compatibility with NRC regulations through restructuring, clarifying and updating existing regulation, and making a number of nonsubstantive changes.

C. The expansion of businesses currently doing business within the State of California. The proposal will not impact the expansion of businesses because it only addresses compatibility with NRC regulations through restructuring, clarifying and updating existing regulation, and making a number of nonsubstantial changes.

D. The benefits of the regulation to the health and welfare of California residents, worker safety, and the state's environment. The proposal increases and strengthens the health and welfare of California residents, worker safety, and protection of the State's environment because it addresses compatibility with NRC regulations through restructuring, clarifying and updating existing regulation as intended by the Legislature. The following benefits specifically demonstrate:

- Continued protection of the public health and safety, worker safety, and the environment, as established by the Legislature in the following provisions:
 - Health and Safety (H&S) Code sections 114705, 114740, 114755, 114965, 114970, 115000, 115230, and 115235.
- Compatibility with the standards and regulatory programs of the NRC, as specified in H&S Code sections 114965(a), 115000(b) and 115235(article V).
- Consistency with the regulatory programs of other states, as specified in H&S Code section 114965(c).
- Evidence of orderly regulatory pattern within the State, among the states and between the federal government and the State, as specified in H&S Code section 114965(b).
- Initiation and administration programs of surveillance and control of those activities that could lead to the introduction of radioactive materials into the environment, as specified in H&S Code section 114705.
- Demonstrate CDPH' commitment to protection of the public by:
 - Addressing comments from NRC regarding past regulatory adoptions and existing regulations.
 - Updating and clarify existing regulations and delete unnecessary regulations.

CDPH – NRC			
Regulation Cross-Reference Table			
for			
Existing Section 30180 & Proposed Sections 30180.1 – 30181			
(NRC compatibility category indicated in table is listed at end of table.)			
Existing Section 30180 (subsection)	10 CFR 30 or 150 (section) – (compatibility category)	10 CFR 40 (section) – (compatibility category)	Proposed Section or deleted
Subsection (a)			
(a)(1)	30.13 – B	40.12(a) – B 40.12(b) – NRC	30180(a)
(a)(2)	150.15 – NRC		30180(b)
(a)(3)	30.12 – B	40.11 – B	30180(c) & (d)
Subsection (b)			
(b)(1)	30.15(a)(1) – B		30180.2(a)(1)
(b)(2)	30.15(a)(2) [reserved]		Deleted
(b)(3)		40.13(c)(1)(vi) – B	30181(c)(1)(C)
(b)(4)		40.13(c)(2)(i) – B	30181(c)(2)(A)
(b)(5)		40.13(c)(2)(iii) – B	30181(c)(2)(C)
(b)(6)		40.13(c)(2)(iv) – B	30181(c)(2)(D)
(b)(7)		40.13(c)(3) – B	30181(c)(3)
(b)(8)		40.13(c)(1)(i), (ii), & (iii) – B	30181(c)(1)(A)
(b)(9)		40.13(c)(4) – B	30181(c)(4)
(b)(10)		40.13(c)(7)(i) – B	30181(c)(7)(A)
(b)(11)		40.13(d) – B	30181(d)
(b)(12)		40.13(c)(1)(iv) – B	30181(c)(1)(A)
(b)(13)		40.13(c)(1)(v) – B	30181(c)(1)(B)
(b)(14)		40.13(c)(1)(vii) – B	30181(c)(1)(D)
(b)(15)		40.13(c)(6) – B	30181(c)(6)
(b)(16)		40.13(c)(5) – B	30181(c)(5)
(b)(17)	30.15(a)(3) – B		30180.2(a)(2)
(b)(18)	30.15(a)(4) [reserved]		Deleted
(b)(19)	30.15(a)(5) – B		30180.2(a)(3)
(b)(20)	30.15(a)(6) [reserved]		Deleted
(b)(21)		40.13(c)(8) – B	30181(c)(8)
(b)(22)	30.15(a)(8) – B		30180.2(a)(5)
(b)(23)	30.16 [reserved]		Deleted
(b)(24)	30.15(a)(1)(viii) – B		30180.2(a)(1)(H)

CDPH – NRC Regulation Cross-Reference Table for Existing Section 30180 & Proposed Sections 30180.1 – 30181 (NRC compatibility category indicated in table is listed at end of table.)			
Existing Section 30180 (subsection)	10 CFR 30 or 150 (section) – (compatibility category)	10 CFR 40 (section) – (compatibility category)	Proposed Section or deleted
(b)(25)		40.13(c)(2)(ii) – B	30181(c)(2)(B)
(b)(26)	30.20 – B		30180.5
(b)(27)	30.19 – B		30180.4
(b)(28)	30.15(a)(9) – B		30180.2(a)(6)
(b)(29)	30.15(a)(10) [reserved]		Deleted
(b)(30)	30.21 – B for (a), (b) & (d), NRC for (c)		30180.6
Subsection (c)			
(c)(1)		40.13(b) – B	30180.1(b) & 30181(b)
(c)(2)		40.13(a) – B	30181(a)
(c)(3)	30.14 – B		30180.1
(c)(4)	30.18 – B		30180.3(d)
Subsection (d)			
(d)(1)	30.15(b) – B 30.19(b) – B 30.20(b) – B 30.21(c) – NRC	40.13(c)(9) – B	30.15 = 30180.2(b) 30.19 = 30180.4(a) 30.20 = 30180.5 30.21 = 30180.6(c) 40.13 = 30181(d)
(d)(2)	30.15(b) – B		30180.2(b)
(d)(3)	30.15(a)(2) [reserved] and 30.15(b) – NRC		Deleted
(d)(4)		40.13(c)(4) – B	30181(c)(4)
(d)(5)	30.21(c) – NRC		Deleted
(d)(6)		40.13(c)(5)(iv) – B	30181(c)(5)(D)
Subsection (e)			

CDPH – NRC Regulation Cross-Reference Table for Existing Section 30180 & Proposed Sections 30180.1 – 30181 (NRC compatibility category indicated in table is listed at end of table.)			
Existing Section 30180 (subsection)	10 CFR 30 or 150 (section) – (compatibility category)	10 CFR 40 (section) – (compatibility category)	Proposed Section or deleted
(e)	30.14(c) & (d) – B 30.18(c) & (d) – B 30.21(b) & (c) – B		30180.1(d) & (e) 30180.3(c) & (d) 30180.6(b) & (c)
<p>NRC Compatibility Categories:</p> <p>Category B: Program element with significant direct trans-boundary implications. The State program element should be essentially identical to that of NRC.</p> <p>Category NRC: Not required for purposes of compatibility. These are NRC program elements that address areas of regulation that cannot be relinquished to Agreement States pursuant to the AEA or provisions of Title 10 of the Code of Federal Regulations. The State should not adopt these program elements.</p>			

Documents Relied Upon

Adequacy and Compatibility of Agreement State Programs, Directive and Handbook 5.9 as published in Volume 5: Governmental Relations and Public Sector Affairs, February 27, 1998, page 1; Part II, pp. 4-7; and Part IV, page 17. The document is available at the Nuclear Regulatory Commission, Office of Federal and State Materials and Environmental Programs website: <http://nrc-stp.ornl.gov/procedures.html> by clicking on "MD-5.9." Accessed on October 16, 2012.

Integrated Materials Performance Evaluation Program (IMPEP), Management Directive 5.6 as published in Volume 5: Governmental Relations and Public Affairs, November 5, 1999 (Revised: February 26, 2004). The document is available at the Nuclear Regulatory Commission, Office of Federal and State Materials and Environmental Programs website: <http://nrc-stp.ornl.gov/procedures.html> by clicking on "MD-5.6." Accessed on October 16, 2012.

NRC Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements – SA – 200*, June 5, 2009. This document is available at: <http://nrc-stp.ornl.gov/procedures.html> by clicking on "SA-200." Accessed on October 16, 2012.

NRC Procedure SA-201, *Review of State Regulatory Requirements – SA – 201*, July 27, 2007, Appendix B. This document is available at: <http://nrc-stp.ornl.gov/procedures.html> by clicking on "SA-201." Accessed on October 16, 2012.

NRC letter dated January 5, 2011, comment 1. This document is available at: <http://nrc-stp.ornl.gov/special/regs/caregs110105.pdf>. Accessed on October 16, 2012.

NRC letter dated June 19, 2008, comments 1-4 and 8-10. This document is available at: <http://nrc-stp.ornl.gov/special/regs/caregs080619.pdf>. Accessed on October 16, 2012.

NRC Generic Letter 99-01 dated May 3, 1999 available at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/gen-letters/1999/gl99001.html>. Accessed on October 16, 2012.

NRC letter dated January 20, 2012, comments 11, 17, and 18. This document is available at: <http://nrc-stp.ornl.gov/special/regs/caregs120120.pdf>. Accessed on October 16, 2012.

NRC Form 653 available at: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc653.pdf>. Accessed on October 16, 2012.