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**NOTICE OF PROPOSED RULEMAKING**  
**Title 17, California Code of Regulations**  
**Radioactive Materials Regulation Amendments, DPH-11-024**

**PUBLIC PROCEEDINGS**

The California Department of Public Health (Department) is conducting a written public proceeding during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in the Informative Digest/Policy Statement Overview section of this notice.

**PUBLIC HEARING**

The Department has not scheduled a public hearing on this proposed action. However, the Department will hold a hearing if it receives a written request for a public hearing from any interested person, or his or her duly authorized representative, no later than 15 days prior to the close of the written comment period.

**WRITTEN COMMENT PERIOD**

Any interested person, or his or her authorized representative, may submit to the Department written comments relevant to the proposed regulatory action. The written comment period closes at 5:00 p.m. on June 23, 2014. The Department will consider only comments received at the Department's Office of Regulations at that time.

Written comments may be submitted as follows:

1. By email to [regulations@cdph.ca.gov](mailto:regulations@cdph.ca.gov). Please place the regulation package identifier "DPH-11-024" in the subject line;
2. By fax transmission to (916) 440-5747;
3. By postal service to Office of Regulations, California Department of Public Health, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377;
4. Hand-delivered to Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All comments, including email or fax transmissions, should include the author's name and U.S. Postal Service mailing address.

**AUTHORITY AND REFERENCE**

The Department is proposing to adopt, amend, or repeal, as applicable, the proposed regulation 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.

**INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW**

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.

<b>Topic</b>	<b>Sections Affected</b>
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)<sup>1</sup> “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.

<sup>1</sup> 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.

- 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.

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.

*Problem Statement:* Existing Department regulations pertaining to radioactive material are not compatible with those of the 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 Department 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)<sup>2</sup>, 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.
- Update and clarify existing regulations and delete unnecessary regulations.

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<sup>2</sup> 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.

### 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. The Department 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." Title 17, California Code of Regulations section 30190-30192.6 (17 CCR 30190 – 30192.6<sup>3</sup>) 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 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 the Department 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 114960 – 115273) requires the Department to develop programs for licensing and regulating radioactive materials (H&S Code 115000(b)). The Department is the successor of the California Department of

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<sup>3</sup> 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.

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 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." <sup>4</sup>

To determine a state's compatibility, the NRC uses Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs, Handbook 5.9*. <sup>5</sup> 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

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<sup>4</sup> "Adequacy and Compatibility of Agreement State Programs," Management Directive 5.9, Volume 5: Governmental Relations and Public Sector Affairs, February 27, 1998, 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>.

<sup>5</sup> "Adequacy and Compatibility of Agreement State Programs," Directive and Handbook 5.9, Volume 5: Governmental Relations and Public Sector Affairs, February 27, 1998. 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>.

to Management Directive 5.6, *The Integrated Materials Performance Evaluation Program (IMPEP)*.<sup>6</sup> 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-200<sup>7</sup>) 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 Categories<sup>8</sup> (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.

**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

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<sup>6</sup> "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>.

<sup>7</sup> SA-200 is available at <http://nrc-stp.ornl.gov/procedures.html>.

<sup>8</sup> "Adequacy and Compatibility of Agreement State Programs," Handbook 5.9, Volume 5: Governmental Relations and Public Sector Affairs, February 27, 1998, Part II, pp. 4-7. 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>.

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.

#### Definitions<sup>9</sup>

**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 RCL are in 17 CCR 30100 through 30395.

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

- 30254, 30346, 30346.2, and 30348.1 that are proposed to be amended reflect the numbering system implemented by the 1995 recodification of the H&S 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).

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<sup>9</sup> "Adequacy and Compatibility of Agreement State Programs," Handbook 5.9, Volume 5: Governmental Relations and Public Sector Affairs, February 27, 1998, 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>.

These changes are nonsubstantial pursuant to 1 CCR 100.

The Department proposes to make the following changes:

**Section 30180, Exempt persons, products, concentrations and quantities**, is proposed to be amended to both address the problems and realize the benefits as stated regarding this proposed regulatory action and to achieve compatibility with applicable NRC provisions in 10 CFR 30, 40, and 150. Existing section 30180 contains a large number of provisions relating to a number of types of users and products. The section is restructured by proposing to adopt sections 30180.1 through 30181 to treat the different categories of users and products in separate sections as opposed to one long section.

**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.

**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.

**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.

**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.

**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.

**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 are compatibility category B, and subdivision (c), which is compatibility category NRC.

**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.

**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.

**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.

**Section 30192, General Licenses – Static Elimination or Ion Generation Devices**, equivalent to 10 CFR 31.3, is proposed to be deleted for the reasons stated regarding section 30180 as it relates to NRC's regulatory amendments that limit the licensing of introduction of exempt concentrations of RAM to the NRC.

**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 30192.7, 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.

**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)).

**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 at the October 1, 2007 publication of the Federal Register (72 Fed. Reg. 55927 (Oct. 1, 2007)). The date of incorporation of 10 CFR 30.35 is changed from January 1, 1994 to January 1, 2013 to achieve compatibility with NRC's regulations.

**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 from January 1, 1994 to January 1, 2013 to achieve compatibility with NRC's regulations.

**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)).

**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. The January 1, 2013 publication of 10 CFR 32 is incorporated by reference with exceptions.

**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:

- 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 re-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).

**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 achieve compatibility with NRC's radiation protection standards amended at the June 17, 2011 publication of the Federal Register (76 Fed. Reg. 35512). The incorporation date of January 1, 2008 is changed to January 1, 2013 to achieve compatibility with NRC's regulations.

**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.

**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, which is equivalent to 10 CFR 34.3 for the terms "Industrial Radiography" and "Radiographer Certification." Both terms are compatibility category B.

**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.

**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, which is equivalent to 10 CFR 34.71, compatibility category B.

**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, which is equivalent to 10 CFR 34.101, compatibility category C.

**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.

**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. The title's section is also 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, which is equivalent to 10 CFR 34.81, compatibility category C.

**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 that states how to obtain the document incorporated by reference in this section is outdated. Further, the note incorrectly implies that "Global Engineering Documents" is part of the American National Standards Institute, Inc. (ANSI).

**Objective:** Correctly identify the mailing address for ANSI and clarify the business relationships between ANSI and "Global Engineering Documents."

Anticipated 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 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.

**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 categories C and D.

**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.

**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.

### **INCONSISTENT/INCOMPATIBLE WITH EXISTING STATE REGULATIONS**

The Department evaluated this proposal to determine whether the proposed regulations are inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department'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 is not inconsistent or incompatible with other state regulations. Therefore, the Department has determined that this proposal, if adopted, would not be inconsistent or incompatible with existing state regulations.

### **LOCAL MANDATE**

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

### **FISCAL IMPACT ESTIMATE**

- A. Fiscal Effect on Local Government or School District: None.
- B. Fiscal Effect on State Government: None.
- C. Fiscal Effect on Federal Funding of State Programs: None.
- D. Other Nondiscretionary Cost or Savings Imposed on Local Agencies: None.

### **COST IMPACTS ON REPRESENTATIVE PRIVATE PERSON OR BUSINESS**

The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in a reasonable compliance with the proposed action.

### **HOUSING COSTS**

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

### **SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE**

The Department has made an initial determination 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.

### **SMALL BUSINESS**

The Department 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.

### **RESULTS OF THE ECONOMIC IMPACT ANALYSIS**

The Department has determined that the proposed regulatory action would not significantly affect the following:

1. The creation or elimination of jobs within the State of California.
2. The creation of new businesses or the elimination of existing businesses within the State of California.
3. The expansion of businesses currently doing business within the State of California.

The Department has determined that the proposed regulatory action would increase and strengthen 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.

### **BUSINESS REPORTING REQUIREMENT**

The Department finds that the reports required by the proposed regulatory action 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 to the Department.

### **ALTERNATIVES INFORMATION**

The Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. 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 NRC (H&S Code, § 115230). Such areas are discussed within the specific discussion of each section proposed to be amended, adopted or repealed.

### **CONTACT PERSON**

Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Phillip L. Scott of the Radiologic Health Branch, at (916) 440-7978 or Brandy Pena of the Radiologic Health Branch, at (916) 440-7961.

All other inquiries concerning the action described in this notice may be directed to Linda M. Cortez, Office of Regulations, at (916) 440-7807.

**In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-11-024.**

### **AVAILABILITY STATEMENTS**

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you, please call (916) 440-7807 (or the California Relay Service at 711), send an email to [regulations@cdph.ca.gov](mailto:regulations@cdph.ca.gov), or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audiocassette, or computer disk.

The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

**INTERNET ACCESS**

Materials regarding the action described in this notice (including this public notice, the regulation text of the proposed regulations, and the initial statement of reasons) are available via the Internet and may be accessed at [www.cdph.ca.gov](http://www.cdph.ca.gov) by clicking on these links, in the following order: Decisions Pending & Opportunity for Public Participation, Proposed Regulations.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH



Ron Chapman, MD, MPH  
Director & State Health Officer

Date: APR 29 2014