



**TITLE 17. CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
NOTICE OF PROPOSED RULEMAKING
Compatibility Maintenance with NRC Regulations (DPH-13-001)
Notice published February 23, 2018**

NOTICE IS HEREBY GIVEN that the California Department of Public Health (Department) intends to amend the regulations described below after considering all comments, objections, and recommendations regarding the proposed action.

SUMMARY OF THE PROPOSED REGULATION

The Department proposes to amend sections of title 17 of the California Code of Regulations (CCR) that address radioactive material (RAM), in accordance with the United States Nuclear Regulatory Commission's (NRC) adoption of title 10, Code of Federal Regulations, part 37 (10 CFR 37), Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material, and part 71 (10 CFR 71), Transportation of Licensed Material. These proposed regulations also address the NRC's provisions in 10 CFR parts 30, 40, and 70.

These proposed regulations incorporate by reference the January 2016 versions of 10 CFR 37 and 10 CFR 71, and the U.S. Department of Transportation's (DOT) provisions in 49 CFR parts 107, 171 through 180, and 390 through 397 - which are referenced in 10 CFR 71's provisions - effective as of January 1, 2016. These proposed regulations also correct inconsistencies in existing regulations that correspond to the NRC's provisions, and make other nonsubstantial corrections.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action described in this notice to:

California Department of Public Health
Office of Regulations
1415 L Street, 5th Floor, Suite 500
Sacramento, CA 95814

Comments may be submitted by facsimile (FAX) at (916) 440-5747 or by e-mail to Regulations@cdph.ca.gov. The written comment period closes at **5:00 p.m. on April 9, 2018**. The Department will consider only comments received at the Department by that time. **Please include the package identifier DPH-13-001.**

Written comments should include the author's contact information so that the Department can provide notification of any further changes to the regulation proposal.



A public hearing has not been scheduled for this rulemaking. However, the Department will conduct a hearing if a written request for a public hearing is received 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: April 9, 2018 at 5:00 p.m.

The Department will consider all comments received regarding the proposal equally, whether submitted in writing or through oral testimony at a public hearing.

ASSISTIVE SERVICES

The Department can provide assistive services such as the conversion of written materials into Braille, large print, audiocassette, and computer disk. For public hearings, assistive services can include sign-language interpretation, real-time captioning, note takes, reading or writing assistance. To request these assistive services, please call (916) 558-1710 (or California Relay at 711 or 1-800-735-2929), email Regulations@cdph.ca.gov or write to the Office of Regulations at the address noted above. Note: The range of assistive services available may be limited if requests are received less than 10 business days prior to a public hearing.

AUTHORITY AND REFERENCE

The Department proposes to adopt, amend, or repeal, as applicable, sections 30108.1, 30192.6, 30194, 30210, 30210.1, 30220, 30257, 30295, and 30373 of 17 CCR, under the authority provided in sections 114820, 114970, 114975, 115000, 115091, and 131200 of the Health and Safety Code (H&S Code). This proposal implements, interprets and makes specific sections 114740, 114765, 114960, 114965, 114970, 114985, 114990, 115000, 115060, 115065, 115091, 115105, 115110, 115120, 115165, 115175, 115205, 115230, 115235, 131050, 131051, and 131052 of the H&S Code.

INFORMATIVE DIGEST/ POLICY STATEMENT OVERVIEW

Problem Statement: Existing Department regulations that address radioactive material do not address recent NRC regulatory changes, contain provisions that are out-of-date, and contain incorrect addresses, inconsistencies, and grammatical and capitalization errors.

Anticipated Benefits of the Proposed Regulation:

Objectives: The broad objectives of this proposed regulatory action are to:

- Ensure that the Department's regulations are compatible with those of the NRC and the DOT.
- Update and clarify existing regulations.

Benefits: Anticipated benefits from this proposed regulatory action are:

- Continued protection of the public health and safety, worker safety, and the environment, as provided for by the Legislature in the following provisions:
 - H&S Code sections 114705, 114740, 114755, 114965, 114970, 115000, 115230, and 115235.
- Continued compatibility with the standards and regulatory programs of the NRC, as specified in H&S Code sections 114965(a),¹ 115000(b), and 115235 (article V).

¹ This short format "H&S Code section 131055" for a given Health and Safety Code section will be used throughout this document for brevity.

- Consistency with the regulatory programs of other States, as specified in H&S Code section 114965(c).
- Continued maintenance of an 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).
- An updating and clarification of existing regulations, and a deletion of unnecessary regulations.

EVALUATION AS TO WHETHER THE PROPOSED REGULATIONS ARE INCONSISTENT OR 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 both 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 was 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.

PROGRAM BACKGROUND/AUTHORITY

Radioactive Material (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 that may be used in oil, gas, mineral, groundwater, or geological exploration; and, manufacturing and distribution, for designing, building, and supplying radioactive sources for use in medicine and by other industries. The Department issues licenses authorizing such uses, and conducts inspections of users to ensure compliance with applicable laws and regulations.

The Radiation Control Law (RCL) (H&S Code §§ 114960 through 115273) requires that the Department develop programs for licensing and regulating radioactive materials. (H&S Code § 115000(b).) The Department is the successor of the California Department of Health Services and as such has the authority to license and regulate radioactive material under the California Public Health Act of 2006. (Chapter 241, Statutes of 2006; 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, as defined in H&S

Code section 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 requires that the State “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.) The 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.”²

To determine a state's compatibility, the NRC uses Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*, Handbook 5.9. (Reference 1.) 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 maintaining compatibility, and which NRC program elements have a particular health and safety significance. The NRC rates the elements according to the degree of compatibility required. The NRC requires that some elements be adopted by the States in a form identical to the NRC's. Other elements need not be adopted in identical form, but are still required to meet the “essential objective” of the program element. The NRC's overall determination of the adequacy and compatibility of an Agreement State's program is made pursuant to Management Directive 5.6, *The Integrated Materials Performance Evaluation Program (IMPEP)*.³ The NRC evaluates Agreement States' programs 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 assume direct regulation and control of byproduct, source, and special nuclear material within the State.

In conjunction with the NRC's IMPEP review every four years, the NRC procedures (SA-200⁴) require that Agreement States, when adopting regulations required for meeting the adequacy and compatibility determinations, submit proposed regulations to the NRC for review. The NRC then reviews the proposal to ensure that the proposed regulations meet the applicable NRC compatibility category, defined as follows:

² [Adequacy and Compatibility of Agreement State Programs, Management Directive 5.9](#), page 1. The document is available at the Nuclear Regulatory Commission, Office of State, and Tribal Programs website: <https://scp.nrc.gov/procedures/md0509.pdf> (Reference 1.)

³ [Integrated Materials Performance Evaluation Program \(IMPEP\), Management Directive 5.6](#). The document is available at the Nuclear Regulatory Commission, Office of State, and Tribal Programs website: <https://scp.nrc.gov/procedures/md0506.pdf> (Reference 2).

⁴ [SA-200](#) is available at <https://scp.nrc.gov/procedures/sa200.pdf> (Reference 3).

NRC Compatibility Categories⁵ (underlined words are defined below)

Category A: Basic radiation protection standard, or related definitions, signs, labels or terms that is 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 transboundary 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 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 and it is not necessary to adopt it again.

Definitions⁶

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.

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).

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

Gap means that the essential objectives of NRC regulations or program elements are absent from the Agreement State program and an undesirable consequence is

⁵ 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, available at: <https://scp.nrc.gov/procedures/md0509.pdf> (Reference 1).

⁶ *Ibid*, pg. 17.

likely to result in another jurisdiction or in the regulation of agreement materials on a nationwide basis.

To ensure compliance with the NRC agreement and to maintain compatibility of State regulations, this proposal amends existing regulations relating to radioactive material and addresses those changes made by the NRC, as noted in the following volumes of the Federal Register (FR):

- 77 FR 34194 (June 11, 2012)⁷
- 77 FR 39899 (July 6, 2012)
- 78 FR 16922 (March 19, 2013)
- 79 FR 58664 (September 30, 2014)
- 80 FR 33987 (June 12, 2015)
- 80 FR 45841 (August 3, 2015)

The authority and reference citations of sections being amended, resulting in no regulatory effect pursuant to 1 CCR section 100, reflect the:

- Numbering system implemented by the 1995 recodification of the Health and Safety Code, and
- Reorganization of the Department of Health Services into the Department of Health Care Services and the Department of Public Health, pursuant to SB 162. (Stats. 2006, ch. 241.)

The regulations that implement, interpret, and make specific the provisions of the Radiation Control Law are identified in title 17, California Code of Regulations, sections 30100 through 30395. The proposed changes to existing state regulations are explained as follows:

Amend Section 30108.1, Registration, and General Provisions for Persons Possessing Devices Under Sections 30192.1 and 30192.6. This section is amended for consistency with proposed changes to section 30192.6. These changes are without regulatory effect.

Amend Section 30192.6, General Licenses - Depleted Uranium. This section is amended to ensure consistency with 10 CFR 40.25.

Amend Section 30194, Approval of Applications and Specific Terms and Conditions for Specific Licenses. This section is amended to provide citations to other provisions that may apply to applicants.

Amend Section 30210, Transfer of Radioactive Material. This section is amended to maintain compatibility with NRC's provisions found in 10 CFR 30.41 and 40.51.

Repeal Section 30210.1, Verification Required. This section is repealed and the content redesignated to section 30210.

The title of **Article 6** of Group 2 of subchapter 4.0 is proposed to be amended to clearly identify the contents of the article.

⁷ The citation format 77 FR 34194 (June 11, 2012) means the June 11, 2012 publication of Volume 77, commencing at page 34194, of the Federal Register. This short format for any given federal register will be used throughout this document for brevity.

Adopt Section 30220, Special Requirements for Issuance of Specific Licenses—Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material. This section is adopted to achieve compatibility with the new NRC physical protection standards found in 10 CFR 37. The January 1, 2016, version of 10 CFR 37 is proposed to be incorporated by reference with exceptions.

Amend Section 30257, Bankruptcy Notification. This section is amended for consistency with changes proposed regarding section 30192.6. These changes are without regulatory effect.

Amend Section 30295, Notification of Incidents. This section is amended for consistency and compatibility with NRC's reporting requirements specified in 10 CFR 30.50, 40.60, and 70.50.

Amend Section 30373, Transportation Regulations. This section is amended for consistency and compatibility with 10 CFR 71. Subsection (a) is amended to incorporate by reference those changes that were made to 10 CFR 71 from January 1, 2007 to January 1, 2016. Subsection (a)(5) is also amended to incorporate by reference those changes made by the federal Department of Transportation (DOT) regulations, as referenced in 10 CFR 71.5, by changing the date of incorporation from January 1, 2007 to January 1, 2016.

MANDATED BY FEDERAL LAW OR REGULATIONS - Not applicable.

FORMS INCORPORATED BY REFERENCE - Not applicable.

OTHER STATUTORY REQUIREMENTS - Not applicable.

REPORTING REQUIREMENTS: The Department has determined that this proposed regulation would require businesses to submit a report and that the report is necessary for the health, safety, and welfare of the people of this state.

LOCAL MANDATE: The Department has determined that this regulatory action would not impose a mandate on local agencies or school districts, nor are there any costs that require state reimbursement pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

DISCLOSURES REGARDING THE PROPOSED ACTION

The Department has made the following initial determinations:

FISCAL IMPACT ESTIMATES

Cost to any local agency or school district requiring reimbursement in accordance with Government Code sections 17500 through 17630: None.

Cost or savings to any state agency: None.

Other non-discretionary costs or savings imposed on local agencies: None.

Cost or savings in federal funding to the state: None.

Cost impacts on a 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 reasonable compliance with the proposed action.

Significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states: There is no impact because the proposal only addresses compatibility with the NRC through restructuring, clarifying and updating existing regulations, making a number of nonsubstantial changes, and that State licensees already comply with the proposal.

Significant effect on housing costs: The Department has determined that the proposed regulations will not have an impact on housing costs.

Effect on Small Business: There would be an affect on small business because they will be legally required to comply with the regulations, and may incur a detriment from the enforcement of the regulation.

CONSIDERATION OF REASONABLE ALTERNATIVES

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 agency 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 made applicable under the State of California agreement with the United States Atomic Energy Commission, the predecessor to the United States Nuclear Regulatory Commission (NRC). (H&S Code § 115230.) The NRC categories A and B require that the State be “essentially identical” to the NRC; category C requires that the “essential objectives” are met; category D is not required for purposes of compatibility; and category H&S is not required for purposes of compatibility, but does have health and safety significance and requires adoption of regulations meeting the essential objectives for an adequate program. According to the agreement, the state is to 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.) 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.

The Department invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations or during the written comment period.

RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

The Department 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 the NRC through restructuring, clarifying and updating existing regulations, 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 the NRC through restructuring, clarifying and updating existing regulations, and making a number of nonsubstantial 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 the NRC through restructuring, clarifying and updating existing regulations, 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 the NRC through restructuring, clarifying, and updating existing regulations, as intended by the Legislature, as follows:

- Continues protection of the public health and safety, worker safety, and the environment, as established by the Legislature in the following provisions:
 - H&S Code sections 114705, 114740, 114755, 114965, 114970, 115000, 115230, and 115235.
- Maintains 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).
- Maintains consistency with the regulatory programs of other states, as specified in H&S Code section 114965(c).
- Maintains an 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).
- Initiates and administers 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.
- Updates and clarifies existing regulations, and deletes unnecessary regulations.

CONTACT PERSONS

Inquiries concerning the subject matter in this notice may be directed to Phillip Scott of the Department's Radiologic Health Branch, at (916) 440-7978. For inquiries related to the regulatory process, to Laurel Prior, Office of Regulations, at (916) 440-7673.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF REGULATIONS, AND RULEMAKING FILE

The Department will have the entire rulemaking file available for inspection and copying throughout the rulemaking process at its office at the above address. As of the date this notice is published in the Notice Register, the rulemaking file consists of this notice, the proposed text of the regulations, and the initial statement of reasons. Copies may be

obtained by contacting the Office of Regulations at Regulations@cdph.ca.gov or by phone at (916) 558-1710.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments received, the Department may adopt the proposed regulations substantially as described in this notice. If the Department makes modifications that are sufficiently related to the originally proposed text, it will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before the Department adopts the regulations as revised. Please send requests for copies of any modified regulations to the Office of Regulations at Regulations@cdph.ca.gov. The Department will accept written comments on the modified regulations for 15 days after the date on which they are made available.

AVAILABILITY OF THE FINAL STATEMENT OF REASONS

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

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the regulations in underline and strikeout are available via the Internet by clicking [here](http://www.cdph.ca.gov) (www.cdph.ca.gov.)

ATTACHMENTS

1. *Order to Implement Increased Controls Over Certain Radioactive Sources*, November 15, 2005, California Department of Public Health.
2. *Order to implement Fingerprinting and Criminal History Record Checks for Unescorted Access to Radioactive Material in Quantities of Concern*, June 8, 2008, California Department of Public Health.

DOCUMENTS RELIED UPON

Reference 1. [*Adequacy and Compatibility of Agreement State Programs, Management Directive 5.9*](#) as published in Volume 5: Governmental Relations and Public Affairs. <https://scp.nrc.gov/procedures/md0509.pdf>. Accessed on November 7, 2017.

Reference 2. [*Integrated Materials Performance Evaluation Program \(IMPEP\), Management Directive 5.6*](#) as published in Volume 5: Governmental Relations and Public Affairs. <https://scp.nrc.gov/procedures/md0506.pdf>. Accessed on November 7, 2017.

Reference 3.
NRC Procedure SA-200, [*Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements – SA – 200*](#). <https://scp.nrc.gov/procedures/sa200.pdf> Accessed on November 7, 2017.

Reference 3a.
NRC Procedure SA-201, [*Review of State Regulatory Requirements – SA – 201*](#). <https://scp.nrc.gov/procedures/sa201.pdf> Accessed on November 7, 2017.

Reference 4.
Summary of November 26, 2012 meeting with CHP staff.