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NOTICE OF PROPOSED RULEMAKING
Compatibility Maintenance with NRC Regulations (DPH-24-001)
January 24, 2025

Notice is hereby given that the California Department of Public Health (Department) is proposing the regulation described below. This notice of proposed rulemaking commences a rulemaking to make the regulations permanent after considering all comments, objections, and recommendations regarding the regulation.

PUBLIC PROCEEDINGS

The Department is conducting a 45-day 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.

To request copies of the regulatory proposal in an alternate format, please write or call: Jasmine Fullwood, Office of Regulations, 1415 L Street Suite 500, Sacramento, CA 95814, at (916) 558-1710, email Regulations@CDPH.ca.gov or use the California Relay Service by dialing 711.

PUBLIC HEARING

A public hearing has not been scheduled for this rulemaking. However, the Department will conduct a public hearing if a written request for a public hearing is received from any interested person, or his or her authorized representative, no later than 15 days prior to the close of the written comment period, pursuant to Government Code Section 11346.8.

ASSISTIVE SERVICES

For individuals with disabilities, the Department will provide assistive services such as conversion of written materials into Braille, large print, audio format, and computer disk. For public hearings, assistive services can include sign-language interpretation, real-time captioning, note takers, 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 public hearing.

WRITTEN COMMENT PERIOD

Written comments pertaining to this proposal, regardless of the method of transmittal, must be received by the Office of Regulations on March 10, 2025, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely.

Written Comments must be submitted as follows:

1. By email to: regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier “DPH-24-001 Compatibility Maintenance with NRC Regulations” in the subject line to facilitate timely identification and review of the comment.
2. By fax transmission to: (916) 440-5747.
3. By postal service or hand delivered to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All comments, including email or fax transmissions, should include the regulation package identifier, “DPH-24-001 Compatibility Maintenance with NRC Regulations”, along with your name and your mailing address or email address in order for the Department to provide copies of any notices for proposed changes to the regulation text on which additional comments may be solicited.

AUTHORITY AND REFERENCE

The Department proposes to adopt, amend, or repeal, as applicable, sections 30100, 30180.1, 30181, 30195.2, 30196, 30295, 30345.1, 30345.3, 30346.4, 30346.5, 30346.7, 30346.8, 30346.9, 30346.10, 30348.2, 30348.4, 30348.5, 30350.1, and 30350.2 of title 17 of the California Code of Regulations (17 CCR), under the authority provided in sections 114975, 115000, 115091 and 131200 of the Health and Safety Code (HSC). This proposal implements, interprets, and makes specific sections 114965, 114970, 114985, 115000, 115060, 115091, 115092, 115105, 115110, 115165, 115230, 115235, 131050, 131051 and 131052 of the HSC.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Summary of Proposal

The California Department of Public Health (Department) proposes to amend, adopt, or repeal provisions of 17 CCR relating to radioactive material (RAM) to ensure compatibility with the United States Nuclear Regulatory Commission (NRC) by adding an equivalent provision to title 10, Code of Federal Regulations Part 70.50(c)(1)(iii)(D) (10 CFR Part 70.50(c)(1)(iii)(D)), correcting typographical errors, adding the definition of source material and clarifying its use for consistency with NRC, and making non-substantial changes.

Background

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) (HSC §§ 114960 through 115273) requires that the Department develop programs for licensing and regulating radioactive materials. (HSC § 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. (HSC § 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 HSC § 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.” (HSC § 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.”¹

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)*.² 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-200³) 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:

¹ *Adequacy and Compatibility of Agreement State Programs, Management Directive 5.9*. The document is available at the Nuclear Regulatory Commission, Office of State and Tribal Programs website (Reference 1).

² *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 (Reference 2).

³ SA-200 is available at the Nuclear Regulatory Commission website (Reference 3).

NRC Compatibility Categories⁴ (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.

Definitions⁵

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.

⁴ *Adequacy and Compatibility of Agreement State Programs, Management Directive 5.9.* The document is available at the Nuclear Regulatory Commission, Office of State and Tribal Programs website (Reference 1).

⁵ *Ibid*, pg. 14-15.

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 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 NRC's comment regarding reporting requirements, specifically an equivalent provision to 10 CFR 70.50(c)(1)(iii)(D) to meet compatibility category C. It also addresses changes made by the NRC, as noted in the November 21, 2023, publication of volume 88, commencing at page 80947, of the Federal Register ((88 FR 80947 (November 21, 2023)).

The authority and reference citations of sections being amended, resulting in no regulatory effect pursuant to title 1 of the California Code of Regulations § 100, reflect the:

- Numbering system implemented by the 1995 recodification of the HSC, 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.)

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.

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

- Ensure that the Department's regulations are compatible with those of the NRC.

- 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:
 - HSC sections (§§)114705, 114740, 114755, 114965, 114970, 115000, 115230, and 115235.
- Continued compatibility with the standards and regulatory programs of the NRC, as specified in HSC §§114965(a), 115000(b), and 115235(article V)
- Consistency with the regulatory programs of other States, as specified in HSC 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 HSC § 114965(b).
- Clarification of existing 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.

LOCAL MANDATE DETERMINATION

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.

DISCLOSURES REGARDING THE PROPOSED ACTION

FISCAL IMPACT ESTIMATES

- A. FISCAL IMPACT ON LOCAL GOVERNMENT:** As described in Item D.
- B. FISCAL IMPACT ON STATE GOVERNMENT:** For entities subject to the Radiation Control Law, as described in Item D. For the CDPH, absorbable and averted costs.
- C. FISCAL IMPACTS ON FEDERAL FUNDING OF STATE PROGRAMS:** None.
- D. FISCAL IMPACT ON PRIVATE PERSONS OR BUSINESSES DIRECTLY AFFECTED:**
The proposal results in the following estimated cost:
Potentially \$18.65 in a 10-year period for 26 licensees authorized to possess special nuclear materials.
- E. MANDATE ON LOCAL AGENCIES OR SCHOOL DISTRICTS:** None.
- F. OTHER NONDISCRETIONARY COSTS:** None

HOUSING COSTS

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

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

There is no impact because the proposal only addresses compatibility with the NRC through updating existing regulations, making a number of nonsubstantial changes, and that State licensees already comply with the proposal.

STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ASSESSMENT (EIA)

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 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 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 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 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:
 - HSC §§ 114705, 114740, 114755, 114965, 114970, 115000, 115230, and 115235.
- Maintains compatibility with the standards and regulatory programs of the NRC, as specified in HSC §§114965(a), 115000(b), and 115235 (article V).
- Maintains consistency with the regulatory programs of other states, as specified in HSC §114965(c).
- Maintains an orderly regulatory pattern within the State, among the States, and between the federal government and the State, as specified in HSC §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 HSC § 114705.
- Updates and clarifies existing regulations.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS

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

BUSINESS REPORTING REQUIREMENTS

The Department has determined that this proposed regulation would require businesses to add an additional item to the existing reporting requirements and is necessary to maintain compatibility with NRC provisions and that the existing report continues to be necessary for the health, safety, and welfare of the people of this state.

EFFECT ON SMALL BUSINESS

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.

CONSIDERATION OF ALTERNATIVES

The Department must determine that no reasonable alternative it considered 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.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDIES, REPORTS OR 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. Date Approved: April 26, 2018. Accessed on January 8, 2025.

Reference 2.

Integrated Materials Performance Evaluation Program (IMPEP), Management Directive 5.6 as published in Volume 5: Governmental Relations and Public Affairs. Date Approved: July 24, 2019. Accessed on January 8, 2025.

Reference 3.

NRC Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements – SA – 200*. Issue Date August 27, 2020. Accessed on January 8, 2025.

Reference 3a.

NRC Procedure SA-201, *Review of State Regulatory Requirements – SA – 201*. Issue Date August 27, 2020. Accessed on January 8, 2025.

Reference 4.

NRC letter dated July 11, 2022. Accessed on January 8, 2025.

CONTACT PERSON

All inquiries concerning the action described in this notice may be directed to Jasmine Fullwood, Office of Regulations, at Regulations@cdph.ca.gov, or to the designated backup contact person, Michael Boutros at Regulations@cdph.ca.gov.

In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-24-001.

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 custodian of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

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.

FINAL STATEMENT OF REASONS 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 text of the proposed regulations, and the initial statement of reasons) that are available via the Internet may be accessed at www.cdph.ca.gov by clicking on these links, in the following order: I am looking for, Proposed Regulations, Decisions Pending & Opportunities for Public Participation, Proposed Regulations