

## **INITIAL STATEMENT OF REASONS**

### **SUMMARY OF THE PROPOSED REGULATIONS**

The California Department of Public Health (Department) proposes to amend, adopt or repeal provisions of title 17 of the California Code of Regulations (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 nonsubstantial changes.

### **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 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.

### **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regulations that address radioactive material do not address recent NRC regulatory changes, contain provisions that are out-of-date, and contain incorrect addresses, inconsistencies, and grammatical and capitalization errors.

*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.

**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) (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.”<sup>1</sup>

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)*.<sup>2</sup> 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-200<sup>3</sup>) 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:

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<sup>1</sup> *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: <https://www.nrc.gov/docs/ML1808/ML18081A070.pdf> (Reference 1.)

<sup>2</sup> *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://www.nrc.gov/docs/ML1921/ML19213A024.pdf> (Reference 2).

<sup>3</sup> SA-200 is available at <https://www.nrc.gov/docs/ML2018/ML20183A325.pdf> (Reference 3).

**NRC Compatibility Categories<sup>4</sup> (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.

**Definitions<sup>5</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.

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<sup>4</sup> *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: <https://www.nrc.gov/docs/ML1808/ML18081A070.pdf> (Reference 1.)

<sup>5</sup> *Ibid*, pg. 14-15.

**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 (1 CCR) § 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.)

### **SPECIFIC DISCUSSION OF PROPOSED CHANGES**

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

**Amend Section 30100. General Definitions.** This section is amended to define "source material," proposed subsection (v), for consistency with NRC's equivalent provision in 10 CFR 40.4, and to redesignate the subsections to maintain a coherent structure. The term "source material" is currently defined in HSC § 114985(e) as follows:

"Source material" means (1) uranium, thorium, or any other material which the department declares by rule to be source material after the United States Nuclear Regulatory Commission, or any successor thereto, has determined the material

to be such; or (2) ores containing one or more of the foregoing materials, in such concentration as the department declares by rule to be source material after the United States Nuclear Regulatory Commission, or any successor thereto, has determined the material in such concentration to be source material.

Though nearly duplicative of HSC § 114985(e), this proposal is needed to clarify what other materials or concentrations the Department deems are source material. The NRC has made this determination as specified in 10 CFR 40.4, for the term “source material.” The NRC has designated this term and its definition as compatibility category [A], requiring agreement states to adopt an essentially identical provision.

**Amend Section 30180.1. Exempt Concentrations.**

Subsection (f) is amended to connect §§ 30180.1 and 30181 as it relates to source material. During a previous restructure of these provisions (Register 2015, No. 1), the reference to source material was moved out of the original § 30180(c)(1) and placed into § 30181(b) to match both 10 CFR 40.13(b) and “Unrefined and unprocessed ore” in 10 CFR 40.4. This restructuring was intended to move all source material items to § 30181 but failed to connect the provisions, resulting in an unclear overlap.

**Amend Section 30181. Products Containing and Quantities of Source Material.**

Subsection (b) is amended to identify where source material is defined, improving clarity.

**Amend Section 30195.2 Special Requirements for Issuance of Specific Licenses – Emergency Plans.**

Subsection (b)(3) is added to correct an incorporation by reference misspelling of “superceed” to “supersede” for consistency with 88 FR 80947, published November 21, 2023. NRC has designated that provision as category H&S, requiring agreement states to adopt the essential objectives of the provision.

**Amend Section 30196. Special Requirements for Issuance of Specific Licenses to Manufacture or Transfer Certain Items Containing Radioactive Material.**

Subsection (a)(7) is added for consistency and compatibility with NRC’s changes to 10 CFR 32.27(a)(2)(i) specified at 88 FR 57873, published Aug. 24, 2023. NRC amended that provision to correctly identify the U.S. Food and Drug Administration’s regulation. NRC has designated that provision as compatibility category B, requiring agreement states to adopt an essentially identical provision.

**Amend Section 30295. Notification of Incidents.** Subsection (c) is amended for consistency and compatibility with NRC’s reporting requirements specified in 10 CFR 70.50(c)(1)(iii)(D) by adding new paragraph (6) to address the NRC’s comment (Reference 4) to add a provision equivalent to NRC’s regulation. The NRC has designated its provision as compatibility category C, requiring agreement states to adopt regulations that meet the essential objective of the NRC’s regulation. Though the Department’s regulation can be more restrictive, the proposed provision is adopted in

an identical manner to maintain consistency with NRC and other agreement states in accordance with the Legislature's established policies in HSC §§ 114965 and 114970(b).

Subsection (c) is also amended to delete an unnecessary phrase, improving clarity, resulting in a nonsubstantial change.

**Amend Sections 30345.1 through 30350.2.**

The authority and reference citations of the following sections are amended, resulting in no regulatory effect pursuant to 1 CCR §100, to reflect the numbering system implemented by the 1995 recodification of the HSC, and the 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.)

- 30345.1. Scope.
- 30345.3. Specific License for Well Logging.
- 30346.4. Physical Inventory.
- 30346.5. Records of Material Use.
- 30346.7. Inspection, Maintenance and Opening of a Source Holder.
- 30346.8. Subsurface Tracer Studies.
- 30346.9. Radioactive Markers.
- 30346.10. Uranium Sinkers Bars.
- 30348.2. Operating and Emergency Procedures.
- 30348.4. Radiation Surveys.
- 30348.5. Radioactive Contamination Control.
- 30350.1. Documents and Records Required at Field Stations.
- 30350.2. Documents and Records Required at Temporary Jobsites.

The following sections, in addition to the amendments regarding the authority and reference Note citations, are amended as indicated:

- 30346.7(a)
  - Amended to clarify grammatical usage, resulting in no regulatory effect.
- 30350.1(a)(1)
  - Amended to clarify that the cited 17 CCR subchapter is the document the user is reading, resulting in no regulatory effect.
- 30350.2(a)(4) and (5)
  - Amended to correctly identify the structural location of the provisions related to transportation of radioactive materials, and to remove an unnecessary phrase as to the location of § 30225, resulting in no regulatory effect. The cited provisions are located in Subchapter 4 of Chapter 5.

## **STATEMENTS OF DETERMINATIONS**

### **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.

### **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.

### **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.

### **HOUSING COSTS**

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

### **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.

### **CONSIDERATION OF REASONABLE ALTERNATIVES**

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's agreement with the United States Atomic Energy Commission, the predecessor to the NRC (HSC § 115230). The NRC's compatibility 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..." (HSC § 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.

### **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 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.

## **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://www.nrc.gov/docs/ML1808/ML18081A070.pdf> 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. <https://www.nrc.gov/docs/ML1921/ML19213A024.pdf> 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*. <https://www.nrc.gov/docs/ML2018/ML20183A325.pdf> Issue Date August 27, 2020. Accessed on January 8, 2025.

### **Reference 3a.**

NRC Procedure SA-201, *Review of State Regulatory Requirements – SA – 201*. <https://www.nrc.gov/docs/ML2018/ML20183A323.pdf> Issue Date August 27, 2020. Accessed on January 8, 2025.

### **Reference 4.**

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