INITIAL STATEMENT OF REASONS

SUMMARY OF THE PROPOSED REGULATIONS

The California Department of Public Health (Department) proposes to amend, adopt or repeal sections of title 17 of the California Code of Regulations (17 CCR) that:

- Address radioactive material (RAM), in accordance with the United States Nuclear Regulatory Commission's (NRC) regulatory amendments of title 10, Code of Federal Regulations, parts 30; 32; 34; 35; 37; 39; and 71 (10 CFR 30; 32; 34; 35; 37; 39; or 71).
- Allow users of radiation machines (i.e., X-ray machines) for shielded-room radiography and field radiography (non-human uses) to optionally supply equipment operators personnel dosimeters that do not require processing to determine the occupational radiation dose provided the dose is evaluated promptly after replacement of the dosimeter, or at least quarterly, whichever is more frequent.

These proposed regulations incorporate by reference the January 2021 versions of 10 CFR 20; 30.32(i); 30.72; 32; 35; 35.65; 37; and 71. In addition, federal Department of Transportation (DOT) regulations (Title 49, CFR) cited in 10 CFR 71.5, as of January 1, 2021, are proposed to be incorporated by reference. These proposed regulations also make nonsubstantial corrections.

AUTHORITY AND REFERENCE

The Department proposes to adopt, amend, or repeal, as applicable, sections 30194; 30195; 30195.2; 30196; 30220; 30253; 30333.2; 30336; 30348.3; and 30373 of 17 CCR, under the authority provided in sections 100275; 114765; 114820; 114975; 115000; 115060; 115091; 131050; 131051; and 131200 of the Health and Safety Code (HSC). This proposal implements, interprets and makes specific sections 114740; 114765; 114960; 114965; 114970; 114985; 114990; 115000; 115060; 115091; 115092; 115105; 115110; 115120; 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regulations that address radioactive material do not address recent NRC regulatory changes, contain provisions that are out-of-date, and contain incorrect addresses, inconsistencies, and grammatical and capitalization errors.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 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:
    - HSC §§ 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),[1] 115000(b), and 115235(article V).
- 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).
- Consistency with the regulatory programs of other States, as specified in HSC § 114965(c).
- 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

Both RAM and X-ray machines are 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 RAM licenses authorizing, and registers users of X-ray machines for, such uses, and conducts inspections of users to ensure compliance with applicable laws and regulations.

[1] This short format "HSC § 131055" for a given Health and Safety Code section will be used throughout this document for brevity.

The Radiation Control Law (RCL) (HSC §§ 114960 through 115273) requires that the Department develop programs for licensing and regulating radioactive materials, and for evaluation of hazards associated with use of sources of ionizing radiation. (HSC § 115000(a) & (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."[2]

To determine a state's compatibility, the NRC uses Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs,* Directive 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

[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.)

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-200[4]) 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:

NRC Compatibility Categories[5] (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

[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).
[5] Volume 5, Governmental Relations and Public Affairs, *Adequacy and Compatibility of Agreement State Programs,* April 26, 2018, Directive Handbook 5.9, pp. 4-9. (Reference 1).

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[6]

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.

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 adopts, amends or repeals 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):

- 83 FR 30285 (June 28, 2018)[7]
- 83 FR 33046 (July 16, 2018)
- 84 FR 63565 (November 18, 2019)
- 84 FR 65639 (November 29, 2019)

[6] *Ibid*, pp. 14-15.

[7] The citation format 83 FR 30285 (June 28, 2018) means the June 28, 2018 publication of Volume 83, commencing at page 30285, of the Federal Register. This short format for any given federal register will be used throughout this document for brevity.

- 84 FR 66561 (December 5, 2019)
    - This FR changed the effective date from December 30, 2020, specified in 84 FR 65639 (Nov. 29, 2019), to December 30, 2019. The NRC made no regulatory revisions under this FR.
- 85 FR 15347 (March 18, 2020)
- 85 FR 33527 (June 2, 2020)
- 85 FR 36307 (June 16, 2020)
    - This FR confirmed the effective date of June 16, 2020 as specified in 85 FR 15347 (March 18, 2020). The NRC made no regulatory revisions under this FR.
- 85 FR 44685 (July 24, 2020)
    - This FR confirmed the effective date of August 17, 2020 as specified in 85 FR 33527 (June 2, 2020). The NRC made no regulatory revisions under this FR.

This proposal does not adopt any provision designated by the NRC as compatibility category NRC as identified in the above Federal Registers because such provisions are reserved to NRC and may not be adopted by Agreement States.

Pursuant to the RCL, as it pertains to use of X-ray machines in Shield-room Radiography (17 CCR § 30330(b)(25)) and Field Radiography (17 CCR 30330(b)(9)), users register (17 CCR § 30108) with the Department as possessing a reportable source of radiation (17 CCR § 30100(n) & (s)) and are subject to inspection.

Because such use, and its associated hazards, is similar to use of RAM in permanent radiographic installations (17 CCR § 30332.2), industrial radiography (17 CCR § 30330(b)(13)) in general, and outside of such installations (e.g., in the field), this proposal allows, as did the NRC under 85 FR 15347 (March 18, 2020) for Industrial radiography and well logging operations, use of newer, and technologically advanced, personnel dosimeters for shielded-room radiography operations. For field-radiography (17 CCR § 30330(b)(9)), section 30336.1(*l*) cites to, and relies entirely on, section 30333.2 that is being amended. Though section 30336.1 is not proposed to be amended, the amendment of section 30333.2, by virtue of section 30336.1(*l*)), would allow field-radiography operations to use these newer personnel dosimeters.

SPECIFIC DISCUSSION OF PROPOSED CHANGES

The regulations that implement, interpret, and make specific the provisions of the Radiation Control Law are identified in 17 CCR §§ 30100 through 30395. The proposed changes are explained as follows:

Amend Section 30194, Approval of Applications and Specific Terms and Conditions for Specific Licenses. Proposed subsection (g) is added to maintain

compatibility with the NRC's amendment of 10 CFR 30.34(g), designated by the NRC as compatibility category B requiring Agreement States to adopt an essentially identical provision. (83 FR 33095 (July 16, 2018).) Existing subsection (g) is redesignated subsection (h), without change, to maintain a coherent structure, resulting in no regulatory effect.

Amend Section 30195, Special Requirements for Issuance of Specific Licenses. Subsection (a) is amended to update the date of incorporation from Jan. 1, 2013 to Jan. 1, 2021 so as to maintain compatibility with the NRC's changes to 10 CFR 35 made under 83 FR 33095 (July 16, 2018) and 85 FR 33527 (June 2, 2020), and to make nonsubstantial changes. By changing the date of incorporation, this proposal adopts the changes made by the NRC to the following 10 CFR 35 provisions for the indicated reasons:

- 35.2;
    - The NRC designated the following terms as compatibility category B, requiring agreement states to adopt them in an essentially identical manner:
        - Associate Radiation Safety Officer; and
        - Ophthalmic physicist.
    - The NRC designated the term "preceptor" as compatibility category D, a provision not required to be adopted for compatibility. However, the provision is adopted in an essentially identical manner to maintain consistency with other jurisdictions because medical use of radioactive material occurs in every state, and the term is used extensively within 10 CFR 35. Many physicians, physicists, and others in the healthcare industry continuously cross state and federal jurisdictional boundaries. Maintaining uniformity between the several states reduces unnecessary burden on health care.
- The following provisions are designated as compatibility category D and not required to be adopted. Currently, the 2013 edition of 10 CFR 35.24(c) is adopted, and this proposal retains that provision, as amended, even though it need not be adopted. Also, 10 CFR 35.433(c), redesignated from 35.433(b) in the 2013 edition, is currently adopted, and this proposal retains that provision, as redesignated, even though it need not be adopted. Thus, the following provisions are adopted in an essentially identical manner to maintain consistency with other jurisdictions because medical use of radioactive material occurs in every state. Many physicians, physicists, and others in the healthcare industry continuously cross state and federal jurisdictional boundaries. Maintaining uniformity between the several states reduces unnecessary burden on health care.
    - 35.24(c);
    - 35.433(c);
    - 35.2024;
    - 35.2310; and
    - 35.2655(a).

- The following provisions are designated by the NRC as compatibility category H&S, requiring agreement states to adopt equivalent provisions that meet the NRC's essential objective. This proposal adopts the provisions in an essentially identical manner to maintain consistency with other jurisdictions because medical use of radioactive material occurs in every state. Many physicians, physicists, and others in the healthcare industry continuously cross state and federal jurisdictional boundaries. Maintaining uniformity between the several states reduces unnecessary burden on health care.
    - 35.24(b);
    - 35.40 & 35.41;
    - 35.204(b) & (e);
    - 35.433(b); (b)(1); & (b)(2);
    - 35.610(d)(1); (d)(2); & (g); and
    - 35.655(a).
- The following provisions are designated by the NRC as compatibility category C, requiring agreement states to adopt equivalent provisions that meet the essential objective. This proposal adopts the provisions in an essentially identical manner to maintain consistency with other jurisdictions because medical use of radioactive material occurs in every state. Many physicians, physicists, and others in the healthcare industry continuously cross state and federal jurisdictional boundaries. Maintaining uniformity between the several states reduces unnecessary burden on health care.
    - 35.400(a) & (b);
    - 35.500(a); (b); & (c);
    - 35.600(a) & (b);
    - 35.3045(a)(1); (a)(2); & (g)(1)(ii);
    - 35.3047(f)(1)(ii); and
    - 35.3204(a) & (b).
- Except for 35.57(a)(3) as discussed regarding subsection (a)(14), these provisions are designated as compatibility category B, requiring agreement states to adopt equivalent provisions in an essentially identical manner. This proposal adopts the provisions is such a manner, as required.
    - 35.50; 35.51; 35.55; & 35.57;
    - 35.190;
    - 35.290;
    - 35.390; 35.392; 35.394; & 35.396;
    - 35.433(a);
        - The NRC changed the compatibility category of this provision from H&S to B.
    - 35.490; & 35.491;
    - 35.590; and
    - 35.690.

Subsections (a)(2); (a)(3); (a)(5)-(a)(8); and (a)(13) are amended to remove unnecessary verbiage, resulting in no regulatory effect.

Subsection (a)(14) is amended to maintain compatibility with the NRC's amendment of 10 CFR 35.57 under 83 FR 33046 (July 16, 2018), designated by the NRC as compatibility category B, except that 10 CFR 35.57(a)(4) is designated as compatibility category D. Existing subsection (a) incorporates by reference 10 CFR 35.57(a)(3), redesignated to section 35.57(a)(4), without change. This proposal retains that provision, as redesignated, even though it need not be adopted, since that provision is currently adopted. The provision was initially adopted for consistency because medical use of radioactive material occurs in every state. Many physicians, physicists, and others in the healthcare industry continuously cross state and federal jurisdictional boundaries. Maintaining uniformity between the several states reduces unnecessary burden on health care.

Discussions with the NRC indicated that the August 8, 2009 and November 30, 2007 dates found in section 35.57(a)(4), as redesignated, and (b)(3) must remain the same as the NRC's for consistency with the NRC's waiver authority limitation, as specified in the Energy Policy (EP) Act of 2005 [Pub.L. 109-58], section 651(d)(5)(B)(i)(III). The EP Act expanded NRC's authority over certain radioactive materials formerly only regulated by the several states. The EP Act required a transition plan that included waivers to states so states could comply with the new changes. However, Congress specified limitations on those waivers to ensure that all states met the changes by a certain date. The NRC amended its regulation in 10 CFR section 35.57 to address the EP Act, and based the August 8, 2009 and November 30, 2007 dates on the amount of time (four years from EP Act effective date) specified in that Act. Therefore, no change to those dates for purposes of this proposal is made.

Amend Section 30195.2, Special Requirements for Issuance of Specific Licenses - Emergency Plans. Subsection (b) is amended to update the date of incorporation from January 1, 2013 to January 1, 2021, and to make nonsubstantial changes. The NRC has made no changes to 10 CFR 30.32(i) and 30.72, incorporated by reference in this section. Though no changes have occurred, the incorporation date is changed so that all incorporated 10 CFR provisions in sections 30195, 30196, 30220, 30253, and 30373 are the same publication date allowing easy usage by staff and licensees, since the incorporated provisions can be easily obtained in one bound volume, electronically saved as one file, or linked via the Internet.

Subsections (b)(1) and (b)(2) are amended to remove unnecessary verbiage and to clarify where the term "Department" is defined, resulting in no regulatory effect.

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

Subsections (a) and (a)(6) are amended to update the date of incorporation from January 1, 2013 to January 1, 2021 so as to maintain compatibility with the NRC's change to 10 CFR 32.72, and to make nonsubstantial changes. The NRC has designated the changes to 10 CFR 32.72 as compatibility category B (83 FR 33095 (July 16, 2018)), requiring Agreement States to adopt an essentially identical provision. By changing the date of incorporation, the provision is adopted in such a manner.

To maintain consistency and clarity, the date of incorporation in subsection (a)(6) is also revised. The NRC amended 10 CFR 35.65 under 83 FR 33046 (July 16, 2018). The incorporation date is changed so that all incorporated 10 CFR provisions in this section and sections 30195, 30195.2, 30220, 30253, and 30373 are the same publication date allowing easy usage by staff and licensees, since the incorporated provisions can be easily obtained in one bound volume, electronically saved as one file, or linked via the Internet.

Subsection (a)(6) is further amended for clarity, due to NRC's amendment (83 FR 33046 (July 16, 2018)) of 10 CFR 35.65 (subdivisions (b) & (c)) that speak to the limits or exceptions placed on the medical use licensee's use of the material identified in 10 CFR 35.65(a). A specific license issued pursuant to 10 CFR 32, and this section, allows the licensee to commercially manufacture and distribute certain sources throughout the United States. A specific license issued pursuant to 10 CFR 35, and section 30195(a), does not authorize the licensee to manufacture or distribute sources for commercial distribution. A licensee under section 30195(a) may only use radioactive material for medical use as authorized in the license, at the specific use locations identified in the license. As it relates to the labeling requirement in 10 CFR 32.74(a)(3), the manufacturer/distributor must affix a label, as prescribed, to the source or material, and the medical use licensee may only use the source or device as stated on the label. The proposal maintains clarity by directly citing to the labeling requirement provision (32.74(a)(3)) and to the provision listing the identified sources or material, which are now listed in 10 CFR 35.65(a).

Subsections (a)(2), (a)(3), (a)(4), and (a)(6) are amended to remove unnecessary verbiage and to clarify where the term "Department" is defined, resulting in no regulatory effect.

Amend Section 30220, Special Requirements for Issuance of Specific Licenses—Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material. Subsection (a) is amended to update the date of incorporation from January 1, 2016 to January 1, 2021 so as to maintain compatibility with the NRC's changes to 10 CFR 37 made under the following Federal Registers, and to make nonsubstantial changes.

- 83 FR 30285 (June 28, 2018)
- 84 FR 63565 (November 18, 2019)

- 84 FR 65639 (November 29, 2019)

The January 1, 2021 edition of 10 CFR 37 is incorporated by reference. The following table identifies each subsection of section 30220 and its corresponding federal regulation, if applicable, in 10 CFR 37 as amended by the NRC. The table also identifies the required level of compatibility with the NRC, describes any difference between the NRC and state regulation, and explains the reasons for the difference.

Section 30220 (subsection)	**10 CFR 37** (section)	**Compatibility Category**	**Description & Rationale** EI = Essentially Identical, NA = Not Adopted, NE = No Equivalent.
(a)			EI. Subsection (a) is amended to change the date of incorporation by reference from January 1, 2016 to January 1, 2021. California, as an Agreement State, has regulatory authority over the radioactive material within the state. This incorporation is necessary to maintain California's continued compatibility with federal regulations.
(a) & (a)(4)	37.23(b)(2)	B	EI. This provision, amended by the NRC under 83 FR 30285 (June 28, 2018) and 84 FR 63565 (Nov. 18, 2019), is proposed to be adopted to maintain consistency.
(a)	37.27(c)(1) & (c)(2)	B	EI. These provisions are proposed to be adopted to maintain consistency with the NRC's provisions as amended under: • 83 FR 30285 (June 28, 2018) • 83 FR 57231 (November 21, 2018) • 84 FR 63565 (November 18, 2019) Regarding those provisions that are designated Compatibility Category C, although the Department can adopt a regulation that is stricter or accomplishes the essential objective in some other way, the Department is adopting those provisions in an essentially identical manner, in order to maintain consistency with the NRC requirements. This allows those licensees holding a Department and an NRC license to more easily comply with

Section 30220 (subsection)	**10 CFR 37** (section)	**Compatibility Category**	**Description & Rationale** EI = Essentially Identical, NA = Not Adopted, NE = No Equivalent.
			both federal and state jurisdictions, and this also maintains consistency with legislative policy (HSC § 114965).
(a)	37.43(d)(2), (d)(3) introductory text, (d)(3)(i), (d)(5) through (7), and (d)(8)(ii)	C	See_Description_Above
(a)	37.45(b)	B	See_Description_Above
(a)	37.77(a)-(d)	B	See_Description_Above
(a)	37.77(e) & (f)	C	See_Description_Above

Subsection (a)(5) is amended to remove unnecessary verbiage, resulting in no regulatory effect.

Amend Section 30253, Standards for Protection Against Radiation. Subsection (a) is amended to update the date of incorporation of 10 CFR 20 from January 1, 2013 to January 1, 2021, and to make nonsubstantial changes. The NRC has made no changes to 10 CFR 20, incorporated by reference in this section. Though no regulatory effect occurs due to only the publication date change, a regulatory effect occurs because section 30255(b)(2) requires all radiation users to conspicuously post a current copy of the regulations found in Subchapter 4, Chapter 5, Division 1 of Title 17 of the CCR (i.e., “this regulation” as defined in § 30100(y)). Thus, to comply with section 30255(b)(2), users must post the 2021 edition instead of the 2013 edition. This same incorporation date change is made in sections 30195, 30195.2, 30196, 30220, and 30373 to allow easy access to, and use of, one published 10 CFR edition, in lieu of multiple editions.

Subsections (a)(2), (a)(3), (a)(4), (a)(6), and (b) are amended to remove unnecessary and confusing verbiage, resulting in no regulatory effect. Currently, this section uses the term “this regulation” defined in section 30100(y), and means Title 17, California Code of Regulations, Division 1, chapter 5, subchapter 4.0. Confusion occurs because the regulated community continuously interprets “this regulation” to refer to the specific section being reviewed, without knowing the term is defined. Since the term is defined to refer to all provisions found within Subchapter 4.0, and that the phrase “this subchapter” is equivalent, confusion is reduced by using the phrase “this subchapter”

since it removes the need to remember the term is defined, what it means, or where it is found. Reference to the California Department of Public Health found in subsection (a)(2) is revised to direct the reader to the defined term of "Department," resulting in no regulatory effect. This maintains consistency with other provisions when referring to the Department and reduces regulatory volume.

Amend Section 30333.2, Personnel Monitoring Control. This section is amended to achieve compatibility with the NRC's changes to 10 CFR 34.47, under 85 FR 15347 (June 16, 2020), and the recordkeeping requirements in 10 CFR 34.83. The NRC has designated these provisions as compatibility category C, requiring agreement states to adopt equivalent regulations meeting the essential objective. This proposal adopts the provisions in an essentially identical manner to maintain consistency with other jurisdictions because industrial radiography operations often cross state and federal jurisdictional boundaries. Maintaining uniformity between the several states reduces unnecessary burden on these operations. This section's provisions correspond to NRC's provisions as follows, and are amended to maintain compatibility and consistency with the indicated NRC provision:

- Subsections (a) and (b) addresses 10 CFR 34.47(a), (a)(2), and (a)(3).
- No changes to subsections (c) and (d) are proposed.
    - Subsection (c) addresses 10 CFR 34.47(a)(1).
    - Subsection (d) addresses 10 CFR 34.47(b) and 34.83(a).
- Subsection (e) addresses 10 CFR 34.47(c) and is amended to specify how long the operability checks must be retained, consistent with 10 CFR 34.83(a), and to ensure the radiation response data can be matched to the specific dosimeter being checked.
- Subsection (f) addresses 10 CFR 34.47(d) and 34.83(d).
- Subsection (g) addresses 10 CFR 34.47(f) and 34.83(c).
- No changes to subsections (h) and (i) are proposed.
    - Subsection (h) addresses 10 CFR 34.47(g).
    - Subsection (i) addresses 10 CFR 34.83(b).
- Subsection (j) addresses 10 CFR 34.47(e) and 34.83(d).

Amend Section 30336, Requirements for Shielded-Room Radiography. This section is amended to allow shielded-room radiography users to use electronic personnel dosimeters that do not require processing to determine the radiation dose.

Pursuant to the RCL, as it pertains to use of X-ray machines in Shield-room Radiography (17 CCR § 30330(b)(25)) and Field Radiography (17 CCR 30330(b)(9)), users register (17 CCR § 30108) with the Department as possessing a reportable source of radiation (17 CCR § 30100(n) & (s)) and are subject to inspection (HSC § 115085).

Because such use, and its associated hazards, is similar to use of RAM in permanent radiographic installations (17 CCR § 30332.2), industrial radiography (17 CCR § 30330(b)(13) in general, and outside of such installations (i.e., field radiography (17 CCR §30330(b)(9)), the Department, based on NRC's provisions in 10 CFR Part 34, required these users (17 CCR § 30336(c) & 30336.1(*l*)) to supply personnel dosimeters that required processing to determine an occupationally exposed workers' radiation exposure. (Register 2008, No. 15.)

Based on the NRC's rationale, under 85 FR 15347 (March 18, 2020), for amending its Part 34 provisions to address technological advances in personnel dosimeters, this section is amended so that shielded-room radiography operations can use these newer dosimeters.

For those same reasons specific to field radiography operations, section 30336.1(*l*) is not amended but use of these newer dosimeters is allowed, due to the amendment of section 30333.2, since section 30336.1(*l*) invokes all provisions of that section.

Amend Section 30348.3, Personnel Monitoring. This section is amended to achieve compatibility with the NRC's changes made to 10 CFR 39.65 under 85 FR 15347 (June 16, 2020). The NRC has designated this provision as compatibility category C, requiring agreement states to adopt equivalent regulations meeting the essential objective. This proposal adopts the provisions in an essentially identical manner to maintain consistency with other jurisdictions because well logging operations often cross state and federal jurisdictional boundaries. Maintaining uniformity between the several states reduces unnecessary burden on these operations.

Subsection (a) is amended to allow use of newer personnel dosimeters that do not require processing to determine the radiation dose. The licensee may continue to use dosimeters that do require processing, but their dosimetry processor must meet 10 CFR 20.1501(d) incorporated by reference in section 30253.

Amend Section 30373, Transportation Regulations. This section is amended to maintain compatibility with NRC's provisions in 10 CFR 71, the federal DOT regulations in 49 CFR cited in 10 CFR 71.5, and to make nonsubstantial changes.

Subsection (a) is amended to update the date of incorporation of 10 CFR 20 and 49 CFR provisions cited in 10 CFR 71.5 from January 1, 2016 to January 1, 2021 to maintain compatibility as an agreement state, and to make nonsubstantial changes. The NRC's changes to 10 CFR 71 made under the following Federal Registers only address the NRC's reorganization. The specific provision addressed, and its compatibility category is indicated.

- 83 FR 30285 (June 28, 2018)
    - 10 CFR 71.97(c)(3); compatibility category B.

- 84 FR 65639 (November 29, 2019)
  - 10 CFR 71.1; compatibility category D.
  - 10 CFR 71.17(c)(3); compatibility category B.
  - 10 CFR 71.95; compatibility category D.
  - 10 CFR 71.101; compatibility category C.
- 84 FR 66561 (December 5, 2019)
  - This FR changed the effective date from December 30, 2020, specified in 84 FR 65639 (Nov. 29, 2019), to December 30, 2019. The NRC made no regulatory revisions under this FR.

Subsection (a)(1) lists those 10 CFR 71 provisions that are not currently adopted by reference. The NRC's changes to provisions indicated above that are found in subsection (a)(1) remain listed as not incorporated by reference. No changes to subsection (a)(1) are proposed.

No changes to subsections (a)(2)-(a)(4) and (a)(6)-(a)(8) are proposed.

Subsection (a)(5) incorporates by reference the Federal Department of Transportation (DOT) regulations cited in 10 CFR 71.5, as the DOT's regulations read on January 1, 2016. This proposal changes that date to January 1, 2021 to maintain consistency with the date of incorporation of the NRC's regulations. The U.S. Government Printing Office annually publishes each title of federal regulation but staggers those publications such that title 10 is published in January of each year and title 49 is published in October of each year. Thus, the January 1, 2021 date in this proposal fixes the date of effectiveness for the incorporation of DOT's regulations so that the dates of incorporation for NRC's and DOT's regulations are the same: namely, January 1, 2021. This is necessary for consistency and clarity.

Subsection (b) is amended to clarify that the exemption is from the requirements found in section 30373, not from all provisions found in Title 17, CCR, Division 1, Chapter 5, Subchapter 4, as defined by the term "this regulation" in section 30100. A review of the regulatory history of section 30373, as follows, clearly indicates that a person was exempt from California's transportation requirements, specified within section 30373, when the transporting was subject to the exclusive jurisdiction of the federal government.

- 1962 (Register 62, No. 1)
  - At this time, subchapter 4 contained five groups, and only three of the groups defined, for purposes of that group, "this regulation" to mean those provisions found within the group:
    - Group 1 - § 30105(k)
    - Group 2 - § 30175(s)
    - Group 3 - § 30258(m)
    - Group 4 – Contains §§ 30365-30380. Group is titled "Transportation of Radioactive Material."

- "This regulation" is not defined in § 30370 but is used in § 30366 (Scope) stating, "This regulation establishes requirement for *intrastate* transportation of radioactive materials." (Italics added.)
- § 30373 is specific to intrastate transportation of radioactive materials (RAM).

▪ Group 5 – Contains §§ 30385-30397. Group is titled "Participation by Local Health Departments."

- "This regulation" is not defined in § 30390 but is used in § 30386 (Effective Date).
  - § 30386 repealed in 1986 (Register 86, No. 2) and the phrase is no longer found in Group 5 provisions.

- 1967 (Register 67, No. 46)
  - § 30366 (Scope) is amended to state that "this regulation" applies to the extent that the transportation (of RAM) is not subject to specified federal agencies having jurisdiction over the *interstate* transportation of RAM.
- 1985 (Register 85, No. 23)
  - Group 4 is entirely revised by repealing §§ 30365, 30366, and 30368; repealing § 30370; renumbering and amending former Article 3 (§ 30373) to Article 1 (§ 30373), and repealing §§ 30378 and 30380).
  - § 30373(b) adopted and carries over the scope of "this regulation" from former § 30366 without regulatory effect.
- There have been no subsequent revisions to § 30373(b).
- 1987 (Register 87, No. 28)
  - Though § 30373 was not amended at this time, subchapter 4's structure was revised such that the term "this regulation," separately defined in three of the 5 Groups, was placed in § 30100 and broadened to encompass all provisions found in Subchapter 4. However, that restructuring failed to comprehensively account for all uses of the phrase within the subchapter, as evidenced in § 30373(b).

Amend Section 30393, Participation in Control Program. This section is amended to update the section's authority and reference citations, resulting in no regulatory effect pursuant to 1 CCR section 100, to 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.)

No change to the text is proposed.

Amend Section 30394, Application for Participation. The section is amended to update reference to California's agreement with the NRC as specified in the Health and Safety Code, the NRC's guidelines for reviewing Agreement State radiation control programs, and to update the authority and reference citations found in the section's note. A nonsubstantial acronym is added to reduce sentence length.

Subsection (d) is amended to correctly identify the citation, due to the 1995 recodification of the Health and Safety Code (Stats. 1995, ch. 415), resulting in no regulatory effect.

Subsection (d) is also amended to update the reference to the applicable NRC guidelines. The NRC has revised the 1981 "Guidelines for NRC Review of Agreement State Radiation Control Programs" (Guidelines) cited in this section. Its policy statement was updated and published in 2017, and its review of Agreement State radiation control programs is now embodied in MD 5.6 (Reference 2). The following Federal Registers provide the historical revision of the policy statement and guidelines:

- 46 FR 59431 (Dec. 4, 1981) – Published guidelines.
- 51 FR 41172 (Nov. 13, 1986) – Proposed revision to guidelines.
- 52 FR 21132 (June 4, 1987) - Finalized guidelines
- 55 FR 10851 (March 23, 1990) – Proposed revision to guidelines.
- 57 FR 22495 (May 28, 1992) – Finalized guidelines.
- 59 FR 40058 (Aug. 5, 1994) – Draft policy statement.
- 60 FR 54734 (Oct. 25, 1995) – Interim implementation of MD 5.6 (Reference 2).
- 62 FR 46517 (Sept. 3, 1997) – Final policy statements.
- 82 FR 46840 (Oct. 6, 2017) – Revision to policy statement.
- 82 FR 48535 (Oct. 18, 2017) – Published correction to policy statement.

The section's authority and reference citations are amended, resulting in no regulatory effect pursuant to 1 CCR § 100, to reflect the:

- Numbering system implemented by the 1995 recodification of the Health and Safety Code (Stats. 1995, ch. 415), 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.)

Amend Section 30395, Contract Authorizing Participation. This section is amended to update the section's authority and reference citations, resulting in no regulatory effect pursuant to 1 CCR § 100, to 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.)

No change to the text is proposed.

STATEMENTS OF DETERMINATIONS

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

Though there is an impact, there is no significant adverse economic impact because the proposal addresses compatibility with the NRC through restructuring, clarifying and updating existing regulations, and making a number of nonsubstantial changes.

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 submit a report and that the report is 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 United States Nuclear Regulatory Commission (HSC § 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..." (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 is unlikely to impact the creation or elimination of jobs because it 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 is unlikely to impact the creation or elimination of businesses because it 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 is unlikely to impact the expansion of businesses because it 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:
  - 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 and deletes unnecessary 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://scp.nrc.gov/procedures/md0509.pdf accessed on May 26, 2020.

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 May 26, 2020.

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 May 26, 2020.

Reference 3a.
NRC Procedure SA-201, *Review of State Regulatory Requirements – SA – 201.* https://scp.nrc.gov/procedures/sa201.pdf accessed on May 26, 2020.

Reference 4.
Regulatory Analysis for Final Rule: Amendments to Medical Use of Byproduct Material Regulations (10 CFR Parts 30, 32, and 35) (83 FR 33046 (July 16, 2018)) https://www.nrc.gov/docs/ML1612/ML16124B034.pdf accessed July 29, 2020.