

Initial Statement of Reasons

Summary of the Proposed Regulations

This proposal addresses the medical use of radioactive material (RAM). It seeks to incorporate by reference applicable sections of Title 10, Code of Federal Regulations Part 35 (Part 35 or 10 CFR 35), "Medical Use of Byproduct Material," to maintain California's continuing compatibility with federal regulations.

Program Background

RAM is widely used in the healing arts for diagnostic and therapeutic purposes, nationally and internationally. For example, nuclear medicine procedures involve the injection of RAM as a radiopharmaceutical and use imaging equipment that allows a physician to diagnose illnesses, conditions, or diseases based on image results. RAM is also used in radiation therapy to treat cancer. Because radiation and radioactive material can not only both help but also harm people and the environment, great effort is made to control RAM use and to ensure protection of the public, the environment, patients, and workers from excessive or unnecessary radiation exposure, by regulating and controlling RAM use.

Authority

The Radiation Control Law (Health & Saf. Code, §§ 114960 – 115273) requires the California Department of Public Health (CDPH) to develop programs for licensing and regulating radioactive materials. (Health & Saf. Code, § 115000, subd. (b).) The CDPH is the successor of the California Department of Health Services (CDHS) and has the authority to license and regulate radioactive material under the California Public Health Act of 2006 (Stats. 2006, ch. 241 (Senate Bill (SB) 162, Ortiz)).

In 1962, the State of California ratified and approved an agreement with the United States Atomic Energy Commission, the predecessor of the United States Nuclear Regulatory Commission (NRC), by which the federal agency discontinued its regulatory authority over certain radioactive materials. (Health & Saf. Code, § 115230.) By such action California became an "Agreement State."

California, as an Agreement State, has regulatory authority over the possession and use of RAM in medicine. All internal administrations of radioactive material or external radiation from radioactive sources given to human patients or human research subjects must be done in accordance with a medical use license issued by CDPH.

A provision of the agreement between California and the NRC specifies that the State "will use its best efforts to maintain continuing compatibility between its program and the program of the [United States Atomic Energy] Commission for the regulation of like materials." (Health & Saf. Code, § 115235, art. V.) NRC's stated policy is "to evaluate Agreement State programs established pursuant to Section 274 of the Atomic Energy

Act (AEA) of 1954, as amended, to ensure they are adequate to protect public health and safety and compatible with NRC's regulatory program." ¹

To determine a state's compatibility, the NRC uses Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs, Handbook 5.9*. ² This handbook describes the specific criteria and process that are used to determine which NRC program elements should be adopted and implemented by an Agreement State for purposes of compatibility, and which NRC program elements have a particular health and safety significance. The NRC rates the elements on the degree of compatibility required. Thus, the NRC requires that some elements be adopted by the states in a form identical to the NRC's, while adoption of others need not be identical, but are still required to meet the essential objective of the program element. The overall determination of adequacy and compatibility for an Agreement State is made pursuant to Management Directive 5.6, *The Integrated Materials Performance Evaluation Program (IMPEP)*. ³ The NRC evaluates Agreement States every four years to determine if a state's radiation safety program meets the adequacy and compatibility criteria. If California fails to meet those criteria the NRC may revoke California's status as an Agreement State.

Rationale

The NRC examined issues surrounding its medical use regulatory program in detail during a 1993 internal senior management review, a 1996 independent external review by the National Academy of Sciences, Institute of Medicine, and the NRC's Strategic Assessment and Rebaselining Initiative. In September 1997, NRC stated that its goal in regulating nuclear materials safety was to "prevent radiation-related deaths or illnesses due to civilian use of source, byproduct, and special nuclear materials." (67 Fed.Reg. 20251 (April 24, 2002).) The NRC Commissioners supported a continuation of the NRC's ongoing medical use regulatory program with improvements, a decreased oversight of low-risk activities, and a continued emphasis on high-risk activities. The Commissioners specifically directed the restructuring of Part 35 into a risk-informed, more performance-based regulation. In addition, the Commissioners expressed their support for the use of the NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI), as well as certain professional medical organizations and societies in the revision of Part 35.

During development of the rule, the NRC considered the following issues (63 Fed.Reg. 43517 (August 13, 1998)):

- Focusing Part 35 on those procedures that pose the highest risk;

¹ "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 Programs website: <http://www.nrc-stp.ornl.gov/procedures.htm> (Reference 1.)

² Ibid.

³ "Integrated Materials Performance Evaluation Program (IMPEP)," Management Directive 5.6. The document is available at the Nuclear Regulatory Commission, Office of State Programs website: <http://www.nrc-stp.ornl.gov/procedures.htm> (Reference 2.)

- Using regulatory oversight alternatives for diagnostic procedures that are consistent with the lower overall risk of these procedures;
- Determining the best way to capture not only relevant safety-significant events, but also precursor events;
- Changing the nomenclature from “misadministration” to “medical event”;
- Redesigning Part 35 so that regulatory requirements for new treatment modalities can be incorporated in a timely manner;
- Revising the requirement for a quality management program (10 CFR 35.32) to focus on those requirements that are essential for patient safety;
- Testing the viability of using or referencing available industry guidance and standards, within Part 35 and related guidance, to the extent that they meet NRC's needs.

This risk-informed and performance-based approach is intended to be less prescriptive and to allow for its implementation by licensees in a manner that may be specific to their needs, while still meeting the regulatory requirements. A risk-informed regulation incorporates an assessment of relative risk, so that the regulatory burden is commensurate with the importance of that regulation or process in protecting public health and safety. It reduces the amount of information submitted by an applicant seeking to possess and use certain quantities of RAM for medical use. In a number of instances, the regulations found in 10 CFR Part 35 do not require the submission of detailed procedures. Instead, applicants are requested to confirm that they have developed and will implement and maintain procedures required by Part 35, but they are not required to submit those procedures as part of their license application.

A performance-based approach uses an ongoing process of establishing strategic performance objectives; measuring performance; collecting, analyzing, reviewing, and reporting performance data; and using that data to drive performance improvement. The risk-informed, performance-based approach to the regulation of licensed materials is also being emphasized in the inspection and enforcement arena.

In 2002, NRC sought to significantly reduce the regulatory burden associated with diagnostic nuclear medicine by revising Part 35. The NRC believes that the regulatory burden of the revised rule is commensurate with the relatively low risk of adverse impact on health and safety from medical diagnostic procedures, while also recognizing that any further reduction of regulatory burden has the potential to increase the risk to public health and safety. The underlying premise of NRC regulations is that authorized user physicians will understand radiation safety principles and practices and will make decisions that are in the best interests of their patients. Licensees, by definition, have obtained permission to use RAM for medical use. Attached to this permission is the required commitment to follow radiation protection policies and implementing procedures.

As discussed previously, California as an Agreement State is legally obligated to use its best efforts to maintain continuing compatibility between its program and federal program for the regulation of RAM. To do this for the medical use of RAM, the

Department proposes to incorporate by reference all parts of Part 35 that the NRC has designated as compatibility categories A, B, C, or H&S, as well as some parts that the NRC has designated as compatibility category D, e.g., record keeping requirements. (The categories are explained below.)

The NRC implemented the changes to Part 35 in 2002 (67 Fed.Reg. 20249 (April 24, 2002)). All 14 Non-Agreement States, i.e., those that are directly regulated by the NRC, began following the revised Part 35 in 2002. Of the 36 Agreement States, California is one of 8 states that still has yet to adopt Part 35. Thus, 42 of the 50 states have implemented Part 35. Therefore, it is incumbent on California to adopt the revised Part 35 so as to reduce national inconsistencies with NRC's regulatory program. Failure to adopt those revisions would create gaps and conflicts nationally, and for California licensees.

NRC Compatibility Categories⁴ (underlined words are defined below)

Category A: Basic radiation protection standard, or related definitions, signs, labels or terms that are necessary for a common understanding of radiation protection principles. The State program element should be essentially identical to that of NRC.

Category B: Program element with significant direct trans-boundary implications. The State program element should be essentially identical to that of NRC.

Category C: Program element, the essential objectives of which should be adopted by the State to avoid conflicts, duplications or gaps. The manner in which the essential objectives are addressed need not be the same as NRC provided the essential objectives are met.

Category D: Not required for purposes of compatibility.

Category NRC: Not required for purposes of compatibility. These are NRC program elements that address areas of regulation that cannot be relinquished to Agreement States pursuant to the AEA or provisions of Title 10 of the Code of Federal Regulations. The State should not adopt these program elements.

Category Health & Safety (H&S): Program elements identified as H&S are not required for purposes of compatibility; however, they do have particular health and safety significance. The State should adopt the essential objectives of such program elements in order to maintain an adequate program.

⁴ Volume 5, Governmental Relations and Public Affairs, Adequacy and Compatibility of Agreement State Programs, February 27, 1998, Handbook 5.9, Part II, pp. 4-7, available at: <http://www.nrc-stp.ornl.gov/procedures.htm> (Handbook 5.9 is included within Reference 1.)

[] = 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

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

Essential objective of a regulation or program element means the action that is to be achieved, modified or prevented by implementing and following the regulation or program element. In some instances, the essential objective may be a numerical value (e.g., restriction of exposures to a maximum value) or it may be a more general goal (e.g., access control to a restricted area).

Gaps means that the essential objectives of NRC regulations or program elements are absent from the Agreement State program, and an undesirable consequence is likely to result in another jurisdiction or in the regulation of agreement materials on a nationwide basis.

Adoption of sections designated as Category C and H&S is consistent with legislative policy, which is to institute and maintain a regulatory program for sources of ionizing radiation so as to provide for: (a) compatibility with the standards and regulatory programs of the federal government, (b) an integrated effective system of regulation within the State, and (c) a system consistent insofar as possible with those of other states. (Health & Saf. Code § 114965.)

The regulations that implement, interpret and make specific the provisions of the Radiation Control Law are in title 17, California Code of Regulations, sections 30100 through 30395.

To ensure compliance with the NRC agreement and compatibility of State regulations, this proposal incorporates by reference the January 1, 2008 version of title 10, Code of Federal Regulations, Part 35 (10 CFR 35), which encompasses the changes made by NRC as specified in the following federal registers:

67 Fed.Reg. 20249 (Apr. 24, 2002)	68 Fed.Reg. 19321 (Apr. 21, 2003)
68 Fed.Reg. 75388 (Dec. 31, 2003)	69 Fed.Reg. 55736 (Sept. 16, 2004)
70 Fed.Reg. 16335 (Mar. 30, 2005)	70 Fed.Reg. 16336 (Mar. 30, 2005)
71 Fed.Reg. 1926 (Jan. 12, 2006)	71 Fed.Reg. 15005 (Mar. 27, 2006)
72 Fed.Reg. 45147 (Aug. 13, 2007)	72 Fed.Reg. 45181 (Aug. 13, 2007)
72 Fed.Reg. 55864 (Oct. 1, 2007)	

The authority and reference citations of sections being amended, resulting in nonsubstantial changes pursuant to 1 CCR 100, reflect the:

⁵ Ibid, pg. 17.

- 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 California Department of Public Health, pursuant to SB 162. (Stats. 2006, ch. 241.)

The proposed changes are explained as follows:

Section 30100. Subsection (f) is proposed to be amended to make nonsubstantial punctuation corrections. Subsection (j) “Misadministration” is repealed and replaced by the term “medical event” proposed to be incorporated by reference in §30195(a). This change is necessary to maintain consistency with the national standard for reporting an event in which an error in the administration of radioactive material occurs. This error may involve one or more factors such as the wrong dose above a certain error percentage, the wrong patient, the wrong radioactive material or the wrong route of administration. The criteria for the medical event are detailed in Part 35, section 35.3045 which is referenced in the definition of medical event in section 35.2.

Due to deletion of the definition of the term “misadministration,” existing subsections are recodified to maintain a coherent structure.

Subsection (l) (recodified to subsection (k)) is amended to include the phrase “limited liability company” for consistency with the definition of “person” specified in Health and Safety Code section 114985(c), which is a nonsubstantial change.

Subsection (t)(2) (recodified to subsection (s)(2)) is amended to correct an inconsistency by referencing section 30192.6, which, as indicated in existing section 30192.6(b)(1), requires a person possessing devices meeting section 30192.6(a) to register as possessing the devices. Subsection (t)(2) (recodified to subsection (s)(2)) is inconsistent with section 30192.6 because such devices meet the intent of the term “reportable sources of radiation” but the term’s definition fails to include a reference to section 30192.6. Therefore, subsection (t)(2) (recodified to subsection (s)(2)) is amended to include the reference to section 30192.6 for consistency with existing section 30192.6.

Also, subsection (t)(2) (recodified to subsection (s)(2)) is amended by deleting the phrase “designed and manufactured for the purpose of detecting, measuring, gauging, controlling thickness, density, level, interface location, radiation, leakage or qualitative or quantitative chemical composition, for producing light or an ionized atmosphere.” That phrase is duplicative of the verbiage found in section 30192.1(a) and is unnecessary. By deleting this unnecessary phrase, subsection (t)(2) (recodified to subsection (s)(2)) is made clearer in that it removes duplicative language.

Subsection (z) (recodified to subsection (y)) is amended to clarify the placement of the Department’s radiation control regulations (RCR) within Title 17, California Code of

Regulations (CCR) because current language fails to specify that the RCR is in Division 1. Currently, there are five Divisions in Title 17, CCR. Thus, the phrase “Division 1” is inserted after the phrase “Title 17” for clarity. The lack of the “Division 1” designation in the current regulation text makes the citation incomplete and difficult to identify if a person referenced the regulations through the cited Title and Chapter. The Department desires to ensure that the regulated public has minimal difficulty in identifying the regulations that impact on their use of radioactive materials and radiation machines.

Subsection (ab) (recodified to subsection (aa)) is amended to replace excessive verbiage with a shorter defined term. This increases clarity by reducing confusing citations and shortening sentences.

Section 30195.

The following table identifies each section’s subsection and: its corresponding federal regulation, if applicable, as found in 10 CFR 35; the required level of compatibility with the NRC; and describes and explains any difference between the two, the reasons for the difference, and the purpose of the proposed regulation.

Section 30195 (subsection)	10 CFR 35 (section)	Compatibility Category	Description & Rationale EI = Essentially Identical, NA = Not Adopted, NE = No equivalent.
(a) & (b)			<p>NE. Subsections (a) and (b) are deleted to accommodate the proposed incorporation of the NRC’s regulations. Subsection (b) is deleted because the adoption of 10 CFR 35.24 in subsection (a) address the authority and responsibilities for a radiation protection program, including the Radiation Safety Committee and Radiation Safety Officer. Existing subsections are recodified to maintain a coherent structure. Subsection (a) is adopted to incorporate by reference the NRC’s regulations governing the medical use of radioactive material in 10 CFR 35, January 1, 2008, with exceptions. California, as an Agreement State, has regulatory authority over the possession and use of radioactive material in medicine. This incorporation is necessary to maintain California’s continued compatibility with federal regulations.</p> <p>Additionally, subsection (a) informs the applicant that, if a license is issued, the applicant must also maintain compliance with the adopted regulations. This is needed to ensure that the applicants clearly understand that they not only must be capable of</p>

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			<p>initially complying with the adopted regulations, but that they must also maintain compliance with the adopted regulations after issuance of the license.</p> <p>NRC provisions not being incorporated as listed in proposed subsection (a)(1) are indicated in this table in the column titled "Section 30195 (subsection)" as well as the column titled "Description & Rationale."</p>
(a)(1)	35.1	D	NA. This section is not adopted as identified in subsection (a)(1).
(a)	35.2		Each term is addressed below.
(a)	Address of use	D	EI. Though this provision is not required for adoption, it is proposed to be 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.
(a)	Agreement State	[B]	See discussion regarding proposed subsection (a)(7).
(a)	Area of use	D	<p>EI. These provisions, some of which are not required for purposes of compatibility or adequacy, are proposed to be 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.</p> <p>For the following terms referring to medical professionals, see discussion of identified subsection:</p> <ul style="list-style-type: none"> • Dentist: subsection (a)(9);
(a)	Authorized medical physicist	B	
(a)	Authorized nuclear pharmacist	B	
(a)	Authorized user	B	
(a)	Brachytherapy	D	
(a)	Brachytherapy source	D	
(a)	Client's address	D	
(a)	Cyclotron	D	

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(a)	Dedicated check source	D	<ul style="list-style-type: none"> • Pharmacist: subsection (a)(10); • Podiatrist: subsection (a)(11); and • Physician: subsection (a)(12).
(a)	Dentist	D	
(a)	High dose-rate remote afterloader	D	
(a)	Low dose-rate remote afterloader	D	
(a)	Management	D	
(a)	Manual Brachytherapy	D	
(a)	Medical event	D	
(a)	Medical institution	D	
(a)	Medical use	C	
(a)	Medium dose- rate remote afterloader	D	
(a)	Mobile medical service	D	
(a)	Output	D	
(a)	Patient intervention	D	
(a)	Pharmacist	D	
(a)	Physician	D	
(a)	Podiatrist	D	
(a)	Positron Emission Tomography	H&S	
(a)	Preceptor	D	
(a)	Prescribed dosage	C	
(a)	Prescribed dose	C	
(a)	Pulsed dose- rate remote afterloader	D	
(a)	Radiation safety officer	B	
(a)	Sealed source	[B]	See discussion regarding proposed subsection

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			(a)(8).
(a)	Sealed source and device registry	D	EI. These provisions, some of which are not required for purposes of compatibility or adequacy, are proposed to be 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.
(a)	Stereotactic radiosurgery	D	
(a)	Structured educational program	D	
(a)	Teletherapy	D	
(a)	Temporary jobsite	D	
(a)	Therapeutic dosage	D	
(a)	Therapeutic dose	D	
(a)	Treatment site	C	
(a)	Type of use	D	
(a)	Unit dosage	D	
(a)	Written directive	D	
(a)(1)	35.5	D	
(a)	35.6	C	EI. Though this provision need only meet the essential objective for purposes of compatibility or adequacy, it is proposed to be 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.
(a)(1)	35.7	D	NA. These sections are not adopted as identified in subsection (a)(1).
(a)(1)	35.8	D	
(a)(1)	35.10	D	
(a)	35.11 (a) & (b)	[C]	EI. The bracket “[]” around a compatibility category designation means that the section may have been

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			<p>adopted elsewhere in a state rule and it is not necessary to adopt it again. Though this provision need only meet the essential objective for purposes of compatibility or adequacy, it is proposed to be 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.</p> <p>10 CFR 35.11(a) is mostly duplicative of Health and Safety Code section 115165 but proposed to be adopted to provide clarity, as it is specific to medical use of radioactive material. Further, clarity is maintained as it relates to the adoption of 10 CFR 35.27, in that that the latter section cross references 35.11(a).</p>
(a)(1)	35.11 (c)(1)	NRC	NA. 10 CFR 35.11(c) is proposed to not be adopted as it applies to the NRC and its
(a)(1)	35.11 (c)(2)	D	implementation of the federal Energy Policy Act of 2005 [Pub. L. 109-58].
(a)(1)	35.12	D	NA. These sections are not adopted as identified in subsection (a)(1).
(a)(1)	35.13 (a)(1)	NRC	
(a)(1)	35.13 (a)(2), (b), (c), (d), (e), (f), & (g)	D	
(a)(1)	35.14	D	
(a)(1)	35.15	D	
(a)(1)	35.18	D	
(a)(1)	35.19	D	EI. These provisions, some of which are not required for purposes of compatibility or adequacy, are proposed to be adopted for consistency because medical use of radioactive material occurs
(a)	35.24 (a), (c), (d), (e), (f), & (h)	D	
(a)	35.24	H&S	

Section 30195 (subsection)	10 CFR 35 (section)	Compatibility Category	Description & Rationale EI = Essentially Identical, NA = Not Adopted, NE = No equivalent.
	(b) & (g)		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.
(a)(1)	35.26	D	NA. This section is not adopted as identified in subsection (a)(1).
(a)	35.27	H&S	EI. These provisions, some of which are not required for purposes of compatibility or adequacy, are proposed to be 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.
(a)	35.40 (a) & (b)	H&S	
(a)	35.40 (c) & (d)	D	
(a)	35.41 (a)	H&S	
(a)	35.41 (b) & (c)	D	
(a)	35.49	[C]	
(a)	35.50	B	
(a)	35.51	B	
(a)	35.55	B	
(a)	35.57 (a)(1), (a)(2), (b)(1), & (b)(2)	B	
(a)	35.57 (a)(3) & (b)(3)	D	
(a)	35.59	B	
(a)	35.60 (a) & (b)	H&S	
(a)	35.60 (c)	D	
(a)	35.61 (a)(1), (a)(2), & (b)	H&S	
(a)	35.61 (a)(3) & (c)	D	
(a)	35.63 (a), (b), (c), & (d)	H&S	
(a)	35.63	D	

Section 30195 (subsection)	10 CFR 35 (section)	Compatibility Category	Description & Rationale EI = Essentially Identical, NA = Not Adopted, NE = No equivalent.
	(e)		
(a)(1)	35.65	D	NA. This section is not adopted as identified in subsection (a)(1).
(a)	35.67 (a), (b), (c), (e), & (g)	H&S	EI. These provisions, some of which are not required for purposes of compatibility or adequacy, are proposed to be 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.
(a)	35.67 (d) & (f)	D	
(a)	35.69	H&S	
(a)	35.70 (a)	H&S	
(a)	35.70 (b) & (c)	D	
(a)	35.75 (a) & (b)	C	
(a)	35.75 (c) & (d)	D	
(a)	35.80 (a)(2), (a)(3), (a)(4), & (b)	H&S- paragraphs for those States which authorize this activity D for States not authorizing this activity	
(a)	35.80 (a)(1) & (c)	D	
(a)	35.92	H&S - for those States that authorize this activity D for States not authorizing this activity	
(a)	35.100	H&S	

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(a)	35.190	B	
(a)	35.200	H&S	
(a)	35.204 (a) & (b)	H&S	
(a)	35.204 (c) & (d)	D	
(a)	35.290	B	
(a)	35.300	H&S	
(a)	35.310 (a)	H&S	
(a)	35.310 (b)	D	
(a)	35.315	H&S	
(a)	35.390	B	
(a)	35.392	B	
(a)	35.394	B	
(a)	35.396	B	
(a)	35.400	[C]	
(a)	35.404 (a) & (b)	H&S	
(a)	35.404 (c)	D	
(a)	35.406 (a) & (b)	H&S	
(a)	35.406 (c)	D	
(a)	35.410 (a)	H&S	
(a)	35.410 (b)	D	
(a)	35.415	H&S	
(a)	35.432 (a), (b), & (c)	H&S	
(a)	35.432 (d)	D	
(a)	35.433 (a)	H&S	
(a)	35.433 (b)	D	
(a)	35.457	H&S	
(a)	35.490	B	

Section 30195 (subsection)	10 CFR 35 (section)	Compatibility Category	Description & Rationale EI = Essentially Identical, NA = Not Adopted, NE = No equivalent.
(a)	35.491	B	
(a)	35.500	[C]	
(a)	35.590	B	
(a)	35.600	[C]	
(a)	35.604 (a)	H&S	
(a)	35.604 (b)	D	
(a)	35.605 (a), (b), & (c)	H&S	
(a)	35.605 (d)	D	
(a)	35.610 (a), (b), (c), (d), & (e)	H&S	
(a)	35.610 (f) & (g)	D	
(a)	35.615	H&S	
(a)	35.630 (a) & (b)	H&S	
(a)	35.630 (c)	D	
(a)	35.632 (a), (b), (c), (d), (e), & (f)	H&S	
(a)	35.632 (g)	D	
(a)	35.633 (a), (b), (c), (d), (e), (f), (g), & (h)	H&S	
(a)	35.633 (i)	D	
(a)	35.635 a), (b), (c), (d), (e), & (f)	H&S	
(a)	35.635 (g)	D	
(a)	35.642 (a), (b), (c), (d), & (e)	H&S	

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(a)	35.642 (f)	D		
(a)	35.643 (a), (b), (c), (d), & (e)	H&S		
(a)	35.643 (f)	D		
(a)	35.645 (a), (b), (c), (d), (e), & (f)	H&S		
(a)	35.645 (g)	D		
(a)	35.647 (a), (b), (c), & (d)	H&S-for those States which authorize this activity, D - for States not authorizing this activity		
(a)	35.647 (e)	D		
(a)	35.652 (a) & (b)	H&S		
(a)	35.652 (c)	D		
(a)	35.655 (a) & (b)	H&S		
(a)	35.655 (c)	D		
(a)	35.657	H&S		
(a)	35.690	B		
(a)	35.1000 through 35.2655 (consecutive)	D		
(a)	35.3045	C		
(a)	35.3047	C		
(a)	35.3067	C		
(a)(1)	35.4001	D		NA. This section is not adopted as identified in subsection (a)(1).

Section 30195 (subsection)	10 CFR 35 (section)	Compatibility Category	Description & Rationale EI = Essentially Identical, NA = Not Adopted, NE = No equivalent.
(a)(1)	35.4002	D	NA. This section is not adopted as identified in subsection (a)(1).
(a)(2)			NE: Subsection (a)(2) is needed to clarify that the California Department of Public Health, not the NRC, is the organization responsible for radiological health in California. As an Agreement State, California has regulatory authority over the possession and use of radioactive material in medicine.
(a)(3)			NE: Subsection (a)(3) is needed to clarify that record requirements for the receipt, transfer and disposal of radioactive material are already addressed in Title 17 section 30293, and that any reference to 10 CFR 35.5, Maintenance of Records, is to be a reference to section 30293. This reduces unnecessary duplication of regulations.
(a)(4)			NE: Subsection (a)(4) is needed to clarify that any reference to a "Person" is already defined in California law in section 114985(c) of the Health and Safety Code, which supersedes any reference to "Person" found in 10 CFR 35. The NRC's definition of person found in Part 20 is broad and applies nationally. The State's definition applies to California and the clarification is needed since this proposal applies only to matters within this State's jurisdiction.
(a)(5)			NE: Subsection (a)(5) is needed to clarify that any reference to a "Licensee" is a reference to "User" as defined in section 30100. A "user" is any person who is licensed to possess radioactive material, or who has registered as possessing a reportable source of radiation, or who otherwise possesses a source of radiation which is subject to licensure or registration. This clarification is necessary because the State's definition is broader than the NRC's in that it applies to persons with or without a license.

Section 30195 (subsection)	10 CFR 35 (section)	Compatibility Category	Description & Rationale EI = Essentially Identical, NA = Not Adopted, NE = No equivalent.
(a)(6)			NE: Subsection (a)(6) is needed to clarify that any reference to a “byproduct material” is a reference to “radioactive material” because, within the State, CDPH has regulatory authority over types of material not subject to federal law. By directing the reference for “byproduct material” to “radioactive material”, accelerator produced isotopes used in positron emission tomography (PET) are included – and CPDH already has jurisdiction over their use.
(a)(7)			NE: Subsection (a)(7) is needed to clarify that any reference to “Agreement State” is a reference to the term “Agreement State,” as defined in section 30100, not in Part 35. The NRC’s definition is written from NRC’s perspective and applies nationally. The State’s definition is written from California’s perspective, and the clarification is needed since this proposal applies only to this State’s jurisdiction. Further, it prevents duplicating of the term’s definition.
(a)(8)			NE: Subsection (a)(8) is needed to clarify that any reference to “Sealed source” is a reference to the term “Sealed source,” as defined in section 30100, not in Part 35. This is needed to prevent duplicating of the term’s definition.
(a)(9)			NE: Subsection (a)(9) is needed to clarify that any reference to “Dentist” is a reference to an individual possessing a current and valid license to practice as a dentist in California pursuant to the California Dental Practice Act (Business and Professions Code section 1600 et seq.)
(a)(10)			NE: Subsection (a)(10) is needed to clarify that any reference to “Pharmacist” is a reference to an individual possessing a current and valid license to practice as a pharmacist in California pursuant to the California Pharmacy Law (Business and Professions Code section 4000 et seq.).
(a)(11)			NE: Subsection (a)(11) is needed to clarify that any

Section 30195 (subsection)	10 CFR 35 (section)	Compatibility Category	Description & Rationale EI = Essentially Identical, NA = Not Adopted, NE = No equivalent.
			reference to "Podiatrist" is a reference to an individual possessing a current and valid license to practice as a podiatrist in California pursuant to the California Business and Professions Code sections 2460 et seq.
(a)(12)			NE: Subsection (a)(12) is needed to clarify that any reference to a "Physician" is a reference to an individual possessing a current and valid license to practice as a physician and surgeon or as an osteopathic physician and surgeon in California pursuant to the California Medical Practice Act (Business and Professions Code section 2000 et seq.)
(a)(13)			NE: Subsection (a)(13) is needed to clarify that any reference to 10 CFR 19.12, "Instructions to Workers" shall be deemed a reference to section 30255, "Notices, Instructions and Reports to Personnel." This clarification is needed because it is the Department, not the NRC, that within California oversees and establishes requirements for notices, instructions and reports by users engaged in work with radioactive material.
(a)(14)			<p>NE: Subsection (a)(14) is needed to clarify the NRC's grandfathering provision as it relates to California. Discussions with the NRC indicated that the dates found in section 35.57(a)(1), (a)(2), (b)(1), and (b)(2) should be the date on which this proposal would take effect under State law. Therefore, the dates found in those provisions are proposed to coincide with the effective date of this proposal. However, because the effective date cannot be determined, the Department proposes to authorize the Office of Administrative Law (OAL) to insert the date for clarity.</p> <p>Further discussions with the NRC indicated that the August 8, 2009 and November 30, 2007 dates found in section 35.57(a)(3) 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</p>

Section 30195 (subsection)	10 CFR 35 (section)	Compatibility Category	Description & Rationale EI = Essentially Identical, NA = Not Adopted, NE = No equivalent.
			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 (4 years from EP Act effective date) specified in that Act. Therefore, no change to those dates for purposes of this proposal is made.
(a)(15)			NE: Subsection (a)(15) is needed to clarify that the Department will rely on the NRC to approve specialty boards, because the administrative structure and financial resources are not in place to approve such boards. The Department is not sufficiently staffed to evaluate the adequacy of medical specialty boards or specialty boards specified in the training requirements of 10 CFR 35. Thus, nothing in the incorporation of 10 CFR 35 shall be construed to indicate this.

Section 30321. Repeal this section because it is duplicative of provisions within this proposal. The proposal includes adoption of 10 CFR 35.404, "Surveys after source implant and removal" and 35.406, "Brachytherapy sources and accountability." These two sections address the source accountability of radioactive sources and provide consistency with the national requirements for surveys, accountability and records.

Section 30321.1. Repeal this section because it is duplicative of provisions within this proposal. The proposal includes adoption of 10 CFR 35.404, "Surveys after source implant and removal" and 35.406, "Brachytherapy sources and accountability." These two sections address the source accountability of radioactive sources and provide consistency with the national requirements for surveys, accountability and records.

Section 30322. Repeal this section because the record and reporting requirements for a "medical event" is addressed in the incorporated material. Maintaining this section would create duplicative and conflicting reporting requirements with 10 CFR 35.3045.

Consideration of Reasonable Alternatives

Alternatives have been considered in those areas not subject to or specifically limited by the adequacy and compatibility criteria applicable under the State of California agreement with the United States Atomic Energy Commission, the predecessor to the United States Nuclear Regulatory Commission (Health & Saf. Code, § 115230). 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..." (Health & Saf. Code, § 115235, art. V).

STATEMENTS OF DETERMINATIONS

The Department has determined that the proposed regulatory action would have no significant adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states. Thus, there will be no significant adverse economic impact on California businesses.

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.

The Department has determined that the regulation would not significantly affect the following:

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

The Department has determined that 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.

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