



State of California—Health and Human Services Agency  
California Department of Public Health



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Director

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**ACTION:** Notice of Proposed Rulemaking  
Title 17, California Code of Regulations

**SUBJECT:** Medical Use of Radioactive Material, DPH-05-018

**PUBLIC PROCEEDINGS:** Notice is hereby given that the California Department of Public Health (CDPH) proposes to amend and repeal certain sections of Title 17, California Code of Regulations (17 CCR), relating to the medical use of radioactive material after considering comments from the public. CDPH will conduct a written comment period, during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in this notice.

**INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW:**

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 (10 CFR 35), "Medical Use of Byproduct Material," to maintain California's continuing compatibility with federal regulations.

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 both help and harm people and the environment, great effort is made to ensure protection of the public, the environment, the patient, and workers from radiation exposure and to control its use.

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 (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 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*.<sup>2</sup> This handbook describes the specific criteria and process that are used to clarify the NRC program elements that should be adopted and implemented by an Agreement State for purposes of compatibility, and those NRC program elements that have a particular health and safety significance. The NRC rates the elements on the degree of compatibility required. Thus, the NRC requires that some be adopted by the states in a form identical to the NRC's, while adoption of others need not be identical but are 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)*.<sup>3</sup> 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.

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).)

<sup>1</sup> "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>.

<sup>2</sup> Ibid.

<sup>3</sup> "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>.

NRC Commissioners supported continuation of NRC's ongoing medical use regulatory program with improvements, decreased oversight of low-risk activities, and 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 NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI) and professional medical organizations and societies in the revision of Part 35.

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

- Focusing Part 35 on those procedures that pose the highest risk;
- 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 the implementation by licensees that may be specific to their needs while meeting the regulatory requirements. A risk-informed regulation incorporates an assessment of relative risk so that the regulatory burden imposed is commensurate with the importance of that regulation or process to protect public health and safety and the environment. It reduces the amount of information required to be 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 low risk of adverse impact on

health and safety from these diagnostic procedures and that 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 shall use its best efforts to maintain continuing compatibility between its program and the 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 required by NRC to be adopted in an essentially identical manner or so that it meets the essential objective. The proposal also adopts some provisions not required for compatibility or adequacy, such as record keeping requirements, for consistency with NRC and other states because the use of RAM in medicine crosses state lines in terms of training and education requirements for physicists and physicians, radiation safety standards, and medical practice.

The NRC implemented the changes to Part 35 in 2002 ((67 Fed.Reg. 20249 (April 24, 2002)). All 12 Non-Agreement States, those that are directly regulated by the NRC, began following the revised Part 35 in 2002. Of the 38 Agreement States, California is one of 7 states that still has yet to adopt Part 35. Thus, 43 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.

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:

- 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 Department proposes to:

Amend **Section 30100** to correct punctuation in subsection (f); to repeal and replace subsection (j) "Misadministration" with the term "medical event," proposed to be incorporated by reference in §30195(a); to correct inconsistencies; and to provide clarity regarding the terms "person," "reportable sources of radiation," "this regulation," and "worker." Existing subsections are recodified to maintain a coherent structure.

Amend **Section 30195** to maintain consistency with NRC's regulations governing the medical use of radioactive material in 10 CFR 35. Title 10, Code of Federal Regulations, Part 35 as of January 1, 2008 is incorporated by reference with exceptions. Existing subsections are recodified to maintain a coherent structure.

Repeal **Section 30321** as it is duplicative of provisions within this proposal.

Repeal **Section 30321.1** as it is duplicative of provisions within this proposal.

Repeal **Section 30322** as it is duplicative of provisions within this proposal.

#### Consideration of Reasonable Alternatives

Alternatives have been considered in those areas not subject to or specifically limited by the adequacy and compatibility criteria 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).

AUTHORITY: Sections 114975, 115000 and 131200, Health and Safety Code.

REFERENCE: Sections 114965, 114970, 115060, 115165, 115235, 131050, 131051 and 131052, Health and Safety Code.

COMMENTS: Any written comments pertaining to these regulations, regardless of the method of transmittal, must be received by the Office of Regulations and Hearings by 5 p.m. on May 20, 2010, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely. Persons wishing to use the California Relay Service may do so at no cost. The telephone numbers for accessing this service are: 1-800-735-2929, if you have a TDD; or 1-800-735-2922, if you do not have a TDD. Written comments may be submitted as follows:

1. By mail or hand-delivered to the Office of Regulations and Hearings, California Department of Public Health, MS 0507, 1501 Capitol Avenue, P.O. Box 997377, Sacramento, CA 95899-7377. It is requested but not required that written comments sent by mail or hand-delivered be submitted in triplicate; or

2. By fax transmission: (916) 440-5747; or

3. By email to [regulations@cdph.ca.gov](mailto:regulations@cdph.ca.gov) (it is requested that email transmissions of comments, particularly those with attachments, contain the regulation package identifier "DPH -05-018" in the subject line to facilitate timely identification and review of the comment).

All comments, including email or fax transmissions, should include the author's name and U.S. Postal Service mailing address in order for the Department to provide copies of any notices for proposed changes to the regulation text on which additional comments may be solicited.

**INQUIRIES:** Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Phillip L. Scott of the Radiologic Health Branch at (916) 440-7978.

All other inquiries concerning the action described in this notice may be directed to Linda M. Cortez of the Office of Regulations and Hearings at (916) 440-7683, or to the designated backup contact person, Marylyn Willis, at (916) 440-7807.

**CONTACTS:** In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-05-018.

**AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF REGULATIONS:** The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations and Hearings, at the address noted above, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file). In addition, a copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations and Hearings.

Materials regarding the action described in this notice (including this public notice, the regulation text, and the initial statement of reasons) that are available via the Internet may be accessed at [www.cdph.ca.gov](http://www.cdph.ca.gov) by clicking on these links, in the following order: Decisions Pending and Opportunity for Public Participation, Regulations, Proposed.

In order to request a copy of this public notice, the regulation text, and the initial statement of reasons be mailed to you, please call (916) 440-7695 (or California Relay at 711/1-800-735-2929), or email [regulations@cdph.ca.gov](mailto:regulations@cdph.ca.gov), or write to the Office of Regulations and Hearings at the address noted above. Upon specific request, these

documents will be made available in Braille, large print, and audiocassette or computer disk.

**AVAILABILITY OF CHANGED OR MODIFIED TEXT:** The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations and Hearings at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

**FISCAL IMPACT ESTIMATE:**

- A. Fiscal Effect on Local Government: None.
- B. Fiscal Effect on State Government: None.
- C. Fiscal Effect on Federal Funding of State Programs: None.
- D. All cost impacts, known to the Department at the time the notice of proposed action was submitted to the Office of Administrative Law, that a representative private person or business would necessarily incur in reasonable compliance with the proposed action: The agency is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.
- E. Other Nondiscretionary Cost or Savings Imposed on Local Agencies: None.

**DETERMINATIONS:** The Department has determined that the regulations 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 made an initial determination that the regulations would not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

The Department has determined that the regulations 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 the regulations would have an affect 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.

The Department has determined that the regulations will have no impact on housing costs.

**ADDITIONAL STATEMENTS AND COMMENTS:** In accordance with Government Code Section 11346.5(a)(13) the Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action.

No hearing has been scheduled; however any interested person or his or her duly authorized representative may request in writing, no later than 15 days prior to the close of the written comment period, a public hearing pursuant to Government Code Section 11346.8.

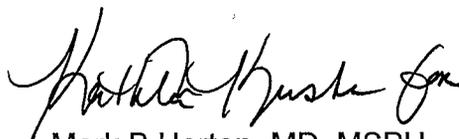
Other regulation changes may be scheduled for hearing at the same time appointed for public hearing on the action described in this notice. An agenda for the public hearing will be posted at the time and place of hearing designated above.

For individuals with disabilities, the Department will provide assistive services such as sign-language interpretation, real-time captioning, note takers, reading or writing assistance, and conversion of public hearing materials into Braille, large print, audiocassette, or computer disk. To request such services or copies in an alternate format, please call or write: Linda M. Cortez, Office of Regulations and Hearings, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377, voice (916) 440-7683 and/or California Relay 711/1-800-735-2929. Note: The range of assistive services available may be limited if requests are received less than ten business days prior to a public hearing.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

DPH-05-018

Date: February 10, 2010



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