



MARK B HORTON, MD, MSPH  
Director

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



ARNOLD SCHWARZENEGGER  
Governor

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

**SUBJECT: Transportation of Radioactive Material, DPH-07-008**

**PUBLIC PROCEEDINGS:** Notice is hereby given that the California Department of Public Health will conduct written public proceedings, 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:** The Radiation Control Law (Health & Saf. Code, §§ 114960 – 115273), requires the California Department of Public Health (Department), the successor to the California Department of Health Services pursuant to the California Public Health Act (CPHA) of 2006 (Stats. 2006, c. 241 (Ortiz, SB 162)) as of July 1, 2007, to develop programs for licensing and regulating radioactive materials. (Health & Saf. Code, § 115000, subd. (b).) In 1962, the State of California ratified and approved the State entering into an agreement with the United States Atomic Energy Commission (AEC), 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."

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." To determine a state's compatibility, the NRC uses Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs, Handbook 5.9*. 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 elements be adopted by the states in a form identical to the NRC's while adoption of other elements need not be identical but are required to meet the essential objective of the NRC program element. (For NRC compatibility definitions,

see Attachment 1.) 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)*. The NRC evaluates Agreement States every three to 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.

Two federal agencies, the Department of Transportation (DOT) and the NRC have established strict requirements for packaging and shipping radioactive material. These requirements are based on the volume, nature and radioactivity of the material. DOT regulates package labeling, shipping papers, personnel training, handling and storage as well as transportation routing and vehicle requirements. The NRC regulates package safety to protect workers and the public. It also establishes regulations for radiation protection and regulates the use of radioactive materials, including the licensing and regulation of shippers and carriers.

Each year, there are approximately 400 million packages of hazardous material shipped in the United States. Radioactive materials account for less than one percent of these shipments. Of these three million packages containing radioactive material, the vast majority are shipments of radiopharmaceuticals and radioisotopes used in medical applications. Transported radioactive materials also include smoke detectors, luminous dials, sources used in non-destructive testing, and waste from industrial and medical facilities contaminated with small amounts of radioactive material.

The proposed changes to the California Code of Regulations are in response to changes made by the NRC regarding the packaging and transportation of radioactive materials found in title 10, Code of Federal Regulations (CFR), Part 71 (10 CFR 71). The NRC amended its regulations on packaging and transporting radioactive materials effective October 1, 2004. This rulemaking made the NRC regulations compatible with the latest version of the International Atomic Energy Agency (IAEA) standards. As international standards are updated, national and state regulations must be amended to maintain consistency and compatibility on all levels including the packaging and transportation of radioactive material across state and national borders.

The IAEA reviews its transportation regulations at intervals of about 10 years recognizing that its international regulations for the safe transportation of radioactive material should be revised periodically to reflect scientific and technical advances and experiences.

The NRC also periodically revises its regulations for the safe transportation of radioactive material to make them compatible with those of the IAEA. On August 5, 1983, the NRC published a revision of 10 CFR 71. That revision, in combination with a parallel revision of the hazardous materials transportation regulations of the Department of Transportation (DOT), brought U.S. domestic transport regulations into general accord with the 1973 edition of the IAEA transport regulations. Another revision to 10 CFR 71 was published on September 28, 1995 (60 FR 50248) to make part 71

compatible with the 1985 IAEA Safety Series No. 6. The DOT published its corresponding revision to title 49, CFR (49 CFR) on the same date (60 FR 50291).

The last revision to the IAEA Safety Series 6, Safety Standards Series ST-1 was published in December 1996, and revised with minor changes on June 2000, and redesignated as TS-R-1. NRC Staff compared changes made in TS-R-1 and identified affected sections of 10 CFR 71. Based on this comparison, NRC amended 10 CFR 71 (69 FR 3968, January 26, 2004) and implemented those changes effective October 1, 2004.

Historically, the NRC has coordinated its part 71 revisions with the DOT because the DOT is the responsible national authority for transportation of hazardous materials. "Radioactive Materials" is a subset of "Hazardous Materials" in 49 CFR under DOT authority. Currently, DOT and NRC co-regulate transport of nuclear material in the United States.

To ensure compliance with the NRC agreement and compatibility of State regulations including consistency with DOT requirements, this proposal amends existing regulations relating to transportation of radioactive material and addresses those changes made by the NRC as noted in the following Federal Registers regarding transportation:

60 FR 50248 (Sep. 28, 1995)  
69 FR 3697 (Jan. 26, 2004)

61 FR 28724 (Jun. 6, 1996)

The statutory authority and reference citation numbers of sections being amended are changed to reflect the numbering system implemented by the 1995 re-codification of the Health and Safety Code and the authority granted the Department under the California Public Health Act of 2006, resulting in non-substantial changes pursuant to title 1, California Code of Regulations, §100.

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

The Department has determined that, because the radiation control program must maintain compatibility with the regulations of the United States Atomic Energy Commission, the predecessor to the United States Nuclear Regulatory Commission (Health & Saf. Code, § 115230), no alternative considered by the Department would be more effective in carrying out the purpose for which the regulation is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

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). 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..." (Health & Saf. Code, § 115235, art. V).

The Department proposes to:

Amend **Section 30100, General Definitions**, for consistency with the California Public Health Act (CPHA) of 2006 (Stats. 2006, c. 241 (Ortiz, SB 162)) as it relates to the definition of “Department” found in section 30100(d) and the corresponding sections in the California Vehicle Code and Health and Safety Code as it relates to the definition of “Hazardous radioactive material” found in section 30100(f).

Amend **Section 30346.1, Labels, Security and Transportation**, for consistency with Section 30373.

Amend **Section 30373, Transportation Regulations**, for consistency with NRC’s regulations in title 10 Code of Federal Regulations (10 CFR), Part 71 published January 1, 2007. Title 10, CFR, Part 71 published on January 1, 2007 is incorporated by reference. Title 49, CFR, parts 107, 171 through 180, and 390 through 397 referenced in 10 CFR 71 effective on or as of January 1, 2007 are incorporated by reference.

**AUTHORITY:** Sections 114765, 114820, 115000 and 131200, Health and Safety Code.

**REFERENCE:** Sections 114740, 114765, 114965, 114970, 114985, 115060, 115230, 115235 and 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 August 29, 2008, 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) 440-7714; 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-07-008**” 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, or to the designated backup contact person, Jennifer Granger at (916) 440-7443.

All other inquiries concerning the action described in this notice may be directed to Barbara Gallaway of the Office of Regulations and Hearings at (916) 440-7689, or to the designated backup contact person, Miyoko Sawamura at (916) 440-7690.

**CONTACTS: In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-07-008.**

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) 440-7689 (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 proposed 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 proposed 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. Businesses in being compliant with federal requirements for transporting radioactive material already meet the proposed regulations. Thus, there will be no significant adverse economic impact on California businesses.

The Department has determined that the proposed 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 proposed regulations would affect small business.

The Department has determined that the proposed 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.

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: Barbara Gallaway, Office of Regulations and Hearings, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377, voice (916) 440-7689 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-07-008

Date: May 22, 2008

“Signature On File”  
Mark Horton, M.D., M.S.P.H.  
Director