



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: General License Requirements, DPH-07-002.

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 California Department of Health Services was legislatively reorganized as of July 1, 2007 (SB 162, ch. 241, Stats. 2006) into two separate departments, the Department of Health Care Services and the Department of Public Health (Department). The Department received authority for certain duties and responsibilities formerly carried out by the Department of Health Services pursuant to Health and Safety Code (HSC) sections 131051 and 131200.

The Radiation Control Law (HSC sections 114960 et seq.) requires the Department to develop programs for licensing and regulating radioactive materials (HSC section 115000(b)). In 1962, the California Legislature granted approval for the State to enter into an agreement with the United States Atomic Energy Commission (AEC), the predecessor of the current NRC. By such action the AEC discontinued its regulatory authority over certain radioactive materials within the State (HSC section 115230), and 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." (HSC section 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."¹ To determine a state's compatibility, the NRC uses Management Directive 5.9, *Adequacy and Compatibility of*

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://nrc-stp.ornl.gov/procedures.html>. (Reference 1.)

*Agreement State Programs, Handbook 5.9.*² This handbook describes the specific criteria and process that are used to clarify both the NRC program elements that should be adopted and implemented by an Agreement State for purposes of compatibility, and also 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 is required to meet the essential objective of the 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)*.³ 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.

The NRC amends its regulations on a frequent basis. NRC amendments can affect the compatibility of State regulations with those of the NRC, and may potentially impact California's status as an Agreement State. To ensure California's compliance with the NRC agreement and the compatibility of its regulations, this proposal addresses changes made to title 10, Code of Federal Regulations, Part 31 (10 CFR 31) specified in the December 18, 2000 issue (65 Fed. Reg. 79161) and the October 16, 2007 issue (72 Fed. Reg. 58473) of the Federal Register. Due to those changes, related sections were reviewed for compatibility with NRC-equivalent regulations. Needed changes were identified. Therefore, this proposal amends, adopts or repeals State regulations pertaining to the General License provisions found in 10 CFR 31 and 40 and the reciprocity provisions found in 10 CFR 150.

Nonsubstantial changes are made in each section to correct grammar, spelling, or capitalization, to include the use of acronyms in order to reduce the physical size of the regulations, or to maintain consistency with proposed changes.

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

- The numbering system implemented by the 1995 recodification of the Health and Safety Code.
- The reorganization of the Department of Health Services into the California Department of Health Care Services and the California Department of Public Health, pursuant to SB 162 (Stats. 2006, ch. 241).

² "Adequacy and Compatibility of Agreement State Programs," Management Directive 5.9, Handbook 5.9. The document is available at the Nuclear Regulatory Commission, Office of State Programs website: <http://nrc-stp.ornl.gov/procedures.html>. (Handbook 5.9 is included within Reference 1.)

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://nrc-stp.ornl.gov/procedures.html>. (Reference 2.)

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 (HSC section 115230), and 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 section 115235, art. V), no alternative considered by the Department would be more effective in carrying out the purpose for which the regulation is proposed. No alternative considered by the Department would be as effective as, and less burdensome to, affected private persons than the proposed regulation.

The Department proposes to:

Amend **Section 30108** to reference all provisions applicable to registration.

Add **Section 30108.1** to specify how to register as possessing devices described in sections 30192.1 and 30192.6 and for consistency with 10 CFR 31.5.

Amend **Section 30115** to exempt persons possessing devices pursuant to sections 30192.1 or 30192.6 from the report of change requirements in this section.

Amend **Section 30125** to specify that a person possessing devices pursuant to section 30192.6 is not excluded from registration requirements.

Amend **Section 30145** to specify the fees for registering devices described in section 30192.1 and to clarify other provisions in the section due to the proposed addition of specified fees.

Amend **Section 30190** to address other related regulations regarding general and specific licensing and registration of devices. Further, grammatical changes are made, which are nonsubstantial changes.

Amend **Section 30191** to maintain consistency with 10 CFR 40.22 regarding general licenses for possession of source material.

Amend **Section 30192** to maintain consistency with 10 CFR 31.3 regarding general licenses for possession of radioactive material contained in static elimination or ion generation devices.

Amend **Section 30192.1** to maintain consistency with 10 CFR 31.5 regarding general licenses for possession of radioactive material contained in gauging and controlling devices.

Amend **Section 30192.2** to maintain consistency with 10 CFR 31.7 regarding general licenses for possession of radioactive material contained in aircraft safety devices.

Amend **Section 30192.3** to maintain consistency with 10 CFR 31.8 regarding general licenses for possession of radioactive calibration or reference sources.

Amend **Section 30192.4** to maintain consistency with 10 CFR 31.10 regarding general licenses for possession of radioactive material contained in ice detection devices.

Amend **Section 30192.5** to maintain consistency with 10 CFR 31.11 regarding general licenses for possession of radioactive material for diagnostic in vitro test kits, and to make nonsubstantial changes.

Amend **Section 30192.6** to maintain consistency with 10 CFR 40.25 regarding general licenses for possession of depleted uranium in industrial products used to provide a concentrated mass of the product.

Amend **Section 30225** to maintain consistency with 10 CFR 150.20 by clarifying that reciprocal recognition of licenses issued by specified entities does not authorize the conduct of activities in areas that are under exclusive federal jurisdiction within this State.

Add **Section 30226** to specify that a person generally licensed by the NRC or an Agreement State other than this State need not register unless they use the device in this State for a period exceeding 180 calendar days, for consistency with 10 CFR 31.5.

Repeal **Section 30236** and recodify it under section 30192.5.

Amend **Section 30257** to maintain consistency with 10 CFR 30.34(h) regarding bankruptcy notification by persons possessing devices under a general license pursuant to sections 30192.1 or 30192.6.

AUTHORITY: Sections 114970, 114975, 115000, 115060, 115065, 115080, 115085, 131051, 131052, 131055 and 131200, Health and Safety Code.

REFERENCE: Sections 114965, 114970, 114980, 114985, 114990, 115000, 115060, 115065, 115080, 115085, 115090, 115093, 115105, 115110, 115120, 115165, 115175, 115205, 115230 and 115235, 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 September 15, 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 by dialing 711.

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 (it is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier "DPH-07-002" 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 Scott, Radiologic Health Branch, at (916) 440-7978.

All other inquiries concerning the action described in this notice may be directed to Marylyn Willis, Office of Regulations and Hearings, at (916) 440-7807, or to the designated backup contact person, Coleen Keelan, at (916) 440-7439.

CONTACTS: In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-07-002.

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 by clicking on these links, in the following order: Decisions Pending and Opportunity for Public Participation, Regulations, Proposed.

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you,

please call (916) 440-7807 (or California Relay Service at 711), send an email to 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: There will be an impact as described in item B.1 below.

B. Fiscal Effect on State Government:

1. State agencies using radiation sources are subject to the proposal. Health & Safety Code section 115065 requires agencies to pay fees. Based on Department data, there are approximately 4,500 devices that must be registered. If all 4,500 devices were possessed by government entities and not exempt from the proposed \$70 registration fee, the maximum annual cost is \$315,000 per year, but because current database configuration does not identify whether a radiation user is state government or meets the exemption criteria, an accurate estimate of total cost cannot be made. Therefore, actual costs to agencies cannot be estimated, but are expected to be less than \$315,000.

2. Based on Department data, there are approximately 4,500 devices that must be registered. This proposal would charge a registration fee of \$70 per device but would exempt specific licensees possessing devices from paying registration fees. Thus, assuming all licensees subject to registration of devices and not exempt paid fees, the Radiation Control Fund (RCF) would increase by \$315,000. There are licensees who would meet the exemption proposal, but current data does not identify these licensees. Therefore, actual increases to the RCF cannot be estimated, but are expected to be less than \$315,000.

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: There will be a fiscal impact on private persons or businesses possessing devices that must be registered. This proposal would charge a registration fee of \$70 per device, but would exempt specific licensees possessing devices from paying registration fees. Current data indicates that approximately

2,500 licensees would have to register 4,500 devices resulting in an average of 1.8 devices per licensee ($4,500 \div 2,500 = 1.8$ [1.8 rounded]) or \$140 per licensee per year. However, there are licensees who would meet the exemption proposal but current data does not identify these licensees.

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 affect small business.

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.

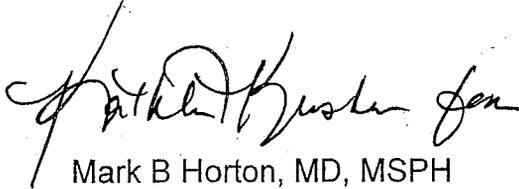
No hearing has been scheduled; however, any interested person or his or her duly authorized representative may request in writing, no later than 15 days prior to the close of the written comment period, a public hearing pursuant to Government Code section 11346.8. For individuals with disabilities, should a public hearing be scheduled, the Department will provide assistive services such as sign-language interpretation, real-time captioning, note takers, reading or writing assistance, and conversion of written public hearing materials into Braille, large print, audiocassette, or computer disk. Note: The range of assistive services available may be limited if requests are received less than ten business days prior to a public hearing. To request such services or copies of

materials in an alternate format, please write to Marylyn Willis, Office of Regulations and Hearings, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377, or call (916) 440-7807, or use the California Relay Service by dialing 711.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

DPH-07-002

Date: 2/1/10



Mark B Horton, MD, MSPH
Director