



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: STANDARDS FOR PROTECTION AGAINST RADIATION, DPH-08-008

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: This proposal amends Title 17, California Code of Regulations relating to standards for protection against radiation and makes nonsubstantial changes.

Authority

The California Department of Health Services was legislatively reorganized as of July 1, 2007 (S.B. 162, ch. 241, Stats 2006) into two separate departments, the Department of Health Care Services and the Department of Public Health (the 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 sections 131051 and 131200.

The Radiation Control Law (HSC section 114960 et seq.) requires the Department to develop programs for licensing and regulating radioactive materials (HSC 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 United States Nuclear Regulatory Commission (NRC). By such action the Commission discontinued its regulatory authority over certain radioactive materials (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, § 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 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 the 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 continuously. NRC's amendments can affect this State's status as an Agreement State, by raising issues as to the compatibility of State regulations with those of the NRC. To ensure compliance with the NRC agreement and compatibility of State regulations, this proposal addresses changes made by the NRC to title 10, Code of Federal Regulations, Parts 19 and 20, specified in the following federal registers:

71 Fed.Reg. 15005 (Mar. 27, 2006)
72 Fed.Reg. 55864 (Oct. 1, 2007)
72 Fed.Reg. 68043 (Dec. 4, 2007)

71 Fed.Reg. 65685 (Nov. 8, 2006)
72 Fed.Reg. 59162 (Oct. 19, 2007)

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 CPDH under the California Public Health Act of 2006 (CPHA), resulting in non-substantial change pursuant to title 1, California Code of Regulations, §100.

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#directives>. (Reference 1.)

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#directives>. (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#directives>. (Reference 2.)

The Department proposes to:

Amend **Section 30253, Standards for Protection Against Radiation**, to achieve compatibility with NRC radiation protection standards. The January 1, 2008 publication of Title 10, Code of Federal Regulations, Part 20 is incorporated by reference with exceptions. Nonsubstantial changes are made for clarity.

Amend **Section 30255** for consistency with NRC requirements found in 10 CFR 19.13 and the CPHA.

Amend **Section 30256** to remove and replace a gender-specific pronoun and to make nonsubstantial changes to referenced form RHB 314 (12/95).

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

Reference: Sections 114960, 114965, 114970, 114985, 114990, 115000, 115060, 115105, 115110, 115120, 115165, 115230, 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, it is requested that email transmissions of comments, particularly those with attachments, contain the regulation package identifier "DPH -08-008" 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 Scott of the Radiologic Health Branch at (916) 440-7978.

All other inquiries concerning the action described in this notice may be directed to Coleen Keelan of the Office of Regulations and Hearings at (916) 440-7439, 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-08-008.

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 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, 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: Local governmental agencies using radioactive materials are subject to the proposal, however they already comply with the regulations; thus, no additional cost is incurred.

- B. Fiscal Effect on State Government: State governmental agencies using radioactive materials are subject to the proposal, however they already comply with the regulations; thus, no additional cost is incurred.
- C. Fiscal Effect on Federal Funding of State Programs: No fiscal impact exists because this regulation does not affect any federally funded state agency or program.
- 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 affect small business.

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

The proposed regulations require regulated entities to report radiation exposure annually to monitored individuals. Additionally, the proposed regulations require reports of transactions and inventories required in 10 CFR 20, section 20.2207 to be submitted

to the National Source Tracking System. These are necessary for the health, safety, or welfare of the people of the state that the regulations apply to businesses.

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: Coleen Keelan, Office of Regulations and Hearings, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377, voice (916) 440-7439 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-08-008

Date:

16 Feb 2010


Mark B Horton, MD, MSPH
Director

INITIAL STATEMENT OF REASONS

Summary of the Proposed Regulations

This proposal amends Title 17, California Code of Regulations relating to standards for protection against radiation and makes nonsubstantial changes.

Authority

The California Department of Health Services was legislatively reorganized as of July 1, 2007 (S.B. 162, ch. 241, Stats 2006) into two separate departments, the Department of Health Care Services and the Department of Public Health (the 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 sections 131051 and 131200.

The Radiation Control Law (HSC section 114960 et seq.) requires the Department to develop programs for licensing and regulating radioactive materials (HSC 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 United States Nuclear Regulatory Commission (NRC). By such action the Commission discontinued its regulatory authority over certain radioactive materials (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 § 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 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 the 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

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#directives>. (Reference 1.)

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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 continuously. 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 compliance with the NRC agreement and to ensure the compatibility of State regulations, this proposal addresses changes made by the NRC to title 10, Code of Federal Regulations, Parts 19 and 20, specified in the following federal registers:

71 Fed.Reg. 15005 (Mar. 27, 2006)
72 Fed.Reg. 55864 (Oct. 1, 2007)
72 Fed.Reg. 68043 (Dec. 4, 2007)

71 Fed.Reg. 65686 (Nov. 8, 2006)
72 Fed.Reg. 59162 (Oct. 19, 2007)

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 CPDH under the California Public Health Act of 2006, resulting in non-substantial change pursuant to title 1, California Code of Regulations, §100.

Rationale

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. The changes to existing state regulations are explained as follows:

Section 30253, Standards for Protection Against Radiation, is proposed to be amended to achieve compatibility with the updated NRC radiation protection standards.

Subsection (a) is amended to incorporate by reference those changes that were made to 10 CFR 20 from January 1, 2005 to January 1, 2008. By changing the date, the incorporated material will include the changes made by the NRC in the Federal Register Notices identified in the following discussion, which are available at "<http://www.gpoaccess.gov/fr/index.html>". The following changes, identified by compatibility category, were made to 10 CFR 20 between January 1, 2005 and January 1, 2008. Some nonsubstantial changes are made to existing language for clarity.

- **10 CFR 20.1003:** Six definitions, identified by compatibility category, are added, and one amended:
 - Added:

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#directives>. (Reference 2.)

- Accelerator produced radioactive material: H&S
- Discrete Source: H&S
- Nationally tracked source: B
- Particle Accelerator: H&S
- Total Effective Dose Equivalent (TEDE): A
- Waste: B
- Amended:
 - Byproduct material: [H&S]

NRC amended its regulations to include discrete sources of radium-226, accelerator-produced radioactive materials, and discrete sources of naturally occurring radioactive material, as required by the Energy Policy Act of 2005 (EPAAct) (Pub.Law, 109-58), signed into law on August 8, 2005.

Accelerator produced radioactive material, Discrete Source, and Particle Accelerator terms and definitions are added for consistency with NRC as a result of the EPAAct. Even though the Department is not required to adopt these definitions exactly as written, the NRC requires an agreement state to adopt a regulation that meets the essential objective of the requirement. The Department agrees that consistent definitions are necessary for the administration of the radioactive materials program and proposes to adopt the NRC's definitions for these three terms.

The term and definition of TEDE means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). The revised definition of TEDE will allow licensees to substitute "effective dose equivalent (EDE)" for "deep-dose equivalent (DDE)" with regard to external exposures. The term and definition are identical to provide uniform interpretation between this regulation and the NRC requirements. (72 Fed.Reg. 68043 (Dec. 4, 2007).)

The term and definition of *Waste* is added to clarify that, as mandated by the EPAAct, byproduct material as defined in Sections 11e.(3) and 11e.(4) of the AEA is not low-level radioactive waste as defined in the Low Level Radioactive Waste Policy Amendments Act (LLRWPA) of 1985.

The EPAAct expanded the Atomic Energy Act of 1954 definition of byproduct material to include any discrete source of radium-226, any material made radioactive by use of a particle accelerator, and any discrete source of naturally occurring radioactive material, other than source material, that the Commission, in consultation with other Federal officials named in the EPAAct, determines would pose a similar threat to the public health and safety or the common defense and security as a discrete source of radium-226, that are extracted or converted after extraction for use for a commercial, medical, or research activity. (72 Fed.Reg. 55864 (Oct. 1, 2007).)

For the definition of byproduct material, [H&S], see the discussion regarding subsection (a)(3). A bracket around a category, [H&S], means that the section may have been adopted elsewhere and it is not necessary to adopt it again.

- **10 CFR 20.1201(c):** Compatibility category A

10 CFR 20.1201(c) is revised to add the requirement that when the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent (DDE) must be used in place of the effective dose equivalent (EDE), unless the EDE is determined by a dosimetry method approved by the NRC. (72 Fed.Reg. 68043 (Dec. 4, 2007).)

The requirement is identical for all agreement states in order to provide uniform application of NRC requirements for determining external exposure. The State program element should be essentially identical to that of the NRC.

In many external exposure monitoring situations, determining EDE from external exposures may not be practicable. The added administrative burden associated with determining EDE may not be warranted, or an applicable dosimetry method for determining EDE may not exist. The revised wording to 10 CFR 20.1201(c) clarifies that licensees can still use DDE in place of EDE for the external exposure in demonstrating compliance with the TEDE dose limit, consistent with the existing regulatory framework. However, the DDE must be measured by the licensee for the part of the whole body receiving the highest exposure.

This change will not affect the level of protection for either the health and safety of workers and the public or for the environment because the revised definition of TEDE does not decrease the ability to determine dose.

- **10 CFR 20.1905(g):** This subsection is an exception and thus not incorporated. See discussion regarding subsection (a)(1).

- **10 CFR 20.2001(a)(4):** Compatibility category C

This provision concerning general requirements for disposal of licensed material adds a reference to section 20.2008, in order to maintain consistency with updated regulations. (72 Fed.Reg. 68043 (Dec. 4, 2007).)

The essential objectives of this program element should be adopted by the State to avoid conflicts, duplications or gaps.

- **10 CFR 20.2006(e):** Compatibility category B

Paragraph (e) requires the use of uniform manifests for disposal of byproduct material, as defined in Sections 11e(3) and 11e(4) of the AEA, if such material is intended for ultimate disposal at a land disposal facility licensed under 10 CFR Part 61. (72 Fed.Reg. 55864 (Oct. 1, 2007).) Because this is a program element with significant direct transboundary implications, NRC requires State programs to adopt regulations that are essentially identical to NRC's provision.

- **10 CFR 20.2008:** Compatibility category B

This section is added to part 20 to address disposal requirements for byproduct material as defined in the AEA. (72 Fed.Reg. 55864 (Oct. 1, 2007).) Because this is a program element with significant direct transboundary implications for states, NRC requires State programs to adopt regulations that are essentially identical to NRC's provision.

- **10 CFR 20.2104(a):** Compatibility category D

Removes the provision in 10 CFR 20.2104(a)(2) that requires licensees to attempt to obtain the records of cumulative occupational radiation dose for each worker requiring monitoring under 10 CFR 20.1502, "Conditions Requiring Individual Monitoring of External and Internal Occupational Dose." In 1991, the NRC revised 10 CFR 20 by removing the need to capture cumulative lifetime dose, except for cases involving planned special exposures. That revision made it unnecessary for licensees to attempt to obtain lifetime exposures for workers who are not participating in a planned special exposure program. (71 Fed.Reg. 55382 (Sept. 22, 2006).)

The proposed amendment to 10 CFR 20.2104(a)(2) would result in a significant reduction in administrative and information collection burdens on licensees and would not affect the level of protection to either the health and safety of workers and the public, or the environment, since the determination of an individual's dose during the current year or cumulative dose prior to permitting a planned special exposure, would still be required and is not be amended. (72 Fed.Reg. 68043 (Dec. 4, 2007).)

Even though not required for purposes of compatibility, the Department agrees with the NRC that reducing administrative burdens while still maintaining the same level of protection is beneficial.

- **10 CFR 20.2205:** Compatibility category C

Section 20.2205 is revised to remove the reference to 10 CFR 20.2206, in order to consolidate the requirement to report annual dose to the individual into a single requirement in 10 CFR 19.13(d). (72 Fed.Reg. 68043 (Dec. 4, 2007).)

Under the existing regulatory framework, the requirement to inform individuals of their routine annual doses, when determined through the results of individual monitoring, appears multiple times in the regulations. This requirement appears in 10 CFR 19.13(d) and 20.2205 through the reference to 10 CFR 20.2206. To improve regulatory efficiency, the change to 20.2205 removes the reference to 10 CFR 20.2206 and consolidates the requirement to report annual dose to the individual into a single requirement in 10 CFR 19.13(b), resulting in the need to amend section 30255. Please see the discussion regarding section 30255.

- **10 CFR 20.2207: Compatibility Category B**

This section (71 Fed.Reg. 65685 (Nov. 8, 2006)) specifies the information that must be submitted regarding nationally tracked sources as defined in the incorporated material. The EPAAct required the NRC to issue regulations establishing a mandatory tracking system for radiation sources in the United States. This tracking system is called the National Source Tracking System (NSTS) and is an on-line system managed by the NRC. Because of the transboundary nature of this tracking system, the NRC has designated its compatibility as Category B, requiring Agreement States to adopt an essentially identical regulation. However, because the system is to capture information on sources throughout the United States, both NRC and Agreement State licensees must report, when required, to the NSTS and not to the individual states.

As originally adopted (71 Fed.Reg. 65685 (Nov. 8, 2006)), implementation of the NSTS was expected to start, depending on the source's category of 1 or 2, November 15, 2007 and November 30, 2007. The NRC changed those compliance dates (72 Fed.Reg. 59162 (Oct. 19, 2007)) to allow finalization of the NSTS and implementation by Agreement States. The compliance date of January 31, 2009 in 10 CFR 20, section 20.2207(h) is maintained because the NRC designated the rule as an immediate mandatory matter of compatibility and directed all Agreement States to ensure its licensees complied with that date. The Department specifically directed those licensees possessing applicable sources to provide this information; the requirement is not being applied generally throughout the state. See also the discussion regarding subsection (a)(10).

Pursuant to Government Code section 11346.3(c), the Department finds that the reports required by incorporation of 10 CFR 20, section 20.2207 are necessary for the health, safety, and welfare of the people of this state. This finding is based on NRC's adoption of the rule under its statutory authority for protection of the public health and safety (71 Fed.Reg. 65705 (Nov. 8, 2006)).

- **10 CFR 20 Appendix B: Compatibility category A**

The List of Elements table is revised to include the elements nitrogen and oxygen that are now considered byproduct material pursuant to the EPAct. Tables 1, 2, and 3 are revised to specifically include nitrogen-13 and oxygen-15 and their associated values. (72 Fed.Reg. 55864 (Oct. 1, 2007).) Further, "Thalium" was replaced with "Thulium" for the element Tm with Atomic Number 69. A typographical error was corrected. (71 Fed.Reg. 15005 (Mar. 27, 2006).)

- **10 CFR 20 Appendix E: "Nationally Tracked Source Thresholds,"** Compatibility Category B

The NRC supports federal efforts to establish international guidance for the safety and security of radioactive materials of concern that resulted in a major revision of the International Atomic Energy Association's (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct). The revised Code of Conduct was approved by the IAEA Board of Governors in September 2003, and is available on the IAEA Web site (www.iaea.org). In particular, the Code of Conduct recommends that each IAEA Member State develop a national source registry of radioactive sources that includes at a minimum Category 1 and Category 2 radioactive sources as described in Annex 1 of the Code of Conduct. The source registry recommendation addressed 16 radionuclides.

Under the EP Act, radiation source means a Category 1 source or a Category 2 source, as defined in the Code of Conduct, and any other material that poses a threat, as determined by the Commission, by regulation, other than spent nuclear fuel and special nuclear material. Appendix E provides the thresholds for nationally tracked sources at the Category 1 and Category 2 levels. Radium-226 has been added to the Appendix and Plutonium-236, Plutonium-239, and Plutonium-240 have been deleted from the Appendix.

Subsection (a)(1) is proposed to be amended to clarify that 10 CFR 20.1905(g) is not incorporated by reference; 10 CFR 20.1905(g) pertains to exemptions from labeling at power reactors and is not adopted because it is an NRC program element that addresses a regulation that cannot be relinquished to Agreement States. Program elements designated compatibility category NRC should not be adopted by Agreement States. (72 Fed.Reg. 68043 (Dec. 4, 2007).)

Subsection (a)(2) is proposed to be amended for consistency with the California Public Health Act of 2006 (CPHA), which reorganized the California Department of Health Services (DHS) into two departments; namely, California Department of Public Health (CDPH) and Department of Health Care Services (DHCS).

Subsection (a)(3) is proposed to be amended 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.

Subsection (a)(5) is proposed to be amended to make grammatical changes by placing parentheses around the phrase “including source material, special nuclear material, or byproduct material.” This is a nonsubstantial change.

Subsection (a)(10) is proposed to be adopted to clarify to whom and how reports required in 10 CFR 20, section 20.2207 must be sent. As discussed in subsection (a) regarding this provision, specific reports must be submitted to the NSTS that is maintained by the NRC. (71 Fed.Reg. 65705 (Nov. 8, 2005); 72 Fed.Reg. 59163 (Oct. 19, 2007).) Also, 10 CFR 20, section 20.2207(f) specifies methods of submittal, but is not specific regarding accessing of the internet website for NSTS, facsimile numbers, mailing address and telephone numbers. That provision does reference NRC Form 748, which provides specific information; thus, this proposal directs the licensee to where the information can be found, and is needed for clarity.

Subsection (b)(1) is proposed to be amended for structural consistency with subsection (b)(2), and to remove a duplicative definition of “Act,” which is also defined in section 30100. Having and citing to only one definition prevents the confusion of having multiple definitions in other regulatory sections. This is a nonsubstantial change.

Subsection (b)(2) is proposed to be amended for the same reason stated regarding subsection (a)(2).

Section 30255 is proposed to be amended for consistency with NRC requirements (10 CFR 19.13(b) & (d)), the CPHA, and to replace a gender-specific pronoun with a gender-neutral pronoun. Subsection (b)(6) is amended to remove a gender-specific pronoun and replace it with a gender-neutral pronoun and to change the reference to the former Department of Health Services to the Department of Public Health for consistency with CPHA. These are nonsubstantial changes.

Subsection (b)(6)(A) is amended for consistency with 19 CFR 19.13(b) and (d). The compatibility category for 10 CFR 19.13 is C, requiring Agreement States to adopt regulations that meet the essential objective of the provision. Previously, users were required to annually provide a report to monitored individuals upon request, regardless of the dose received. The NRC, based on recent occupational radiation exposure data, found that about 80 percent of the individuals monitored annually received a TEDE that did not exceed 1 mSv (100 mrem), the public dose limit specified in 10 CFR 20.1301. Based upon this information, the NRC amended that provision to provide flexibility that will significantly reduce administrative and reporting burdens on licensees, while still ensuring that the monitored individual can obtain the report upon request. The Department agrees that this change is beneficial and would not reduce the level of

protection for workers. Therefore, the proposal is essentially identical to the NRC's provision.

Subsection (b)(6)(C) is amended for consistency with the proposed adoption of 10 CFR 20.2104(a), as discussed regarding section 30253(a), and those changes made by the NRC to 10 CFR 19.13(d). (72 Fed.Reg. 68043 (Dec. 4, 2007).) Punctuation corrections are made that are nonsubstantial.

Section 30256 is proposed to be amended to remove a gender-specific pronoun and replace it with a gender-neutral noun found in subsection (b), correct punctuation, and to make nonsubstantial changes to form RHB 314 (12/95) as follows:

- The Department's name at the top of the form and the form number at the bottom of the form are being changed for consistency with the California Public Health Act of 2006, which reorganized the California Department of Health Services (DHS) into two departments; namely, California Department of Public Health (CDPH) and Department of Health Care Services (CDHCS).
 - The form number is changed from RHB 314 (12/95) to RH 5314 (06/09).
- The Branch responsible for the form and disposition of materials is named for clarity.
- Form instructions are amended to correctly identify the mailing address as the address has changed since 1995. The Branch's internet page is also identified for clarity.
- The sentence found in section "A. Materials Data" that is underlined is reformatted to be in bold and italic font. Its content remains as in the original December 1995 published form. The sentence is not being added to the form but is bolded and italicized to heighten the licensee's awareness of the need to attach the required list.

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 (NRC) (HSC, § 115230). NRC categories A and B require that the State be "essentially identical" to the NRC; category C requires that the "essential objectives" are met; category D is not required for purposes of compatibility; and category H&S is not required for purposes of compatibility, but does have health and safety significance and requires adoption of regulations meeting the essential objectives for an adequate program. According to the agreement, the state is to use its "best efforts to maintain continuing compatibility between its program and the program of the [United States Atomic Energy] Commission for the regulation of like materials..." (HSC, § 115235, art. V).

STATEMENTS OF DETERMINATIONS

The Department of Public Health ("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.

**TITLE 17, CALIFORNIA CODE OF REGULATIONS
DIVISION 1, CHAPTER 5, SUBCHAPTER 4.0
Group 3. Standards for Protection Against Radiation**

(1) Amend Section 30253 to read:

§ 30253. Standards for Protection Against Radiation.

(a) The regulations governing standards for protection against radiation in title 10, Code of Federal Regulations, part 20, (10 CFR 20) sections 20.1001 through 20.2402 and Appendices A through G, (January 1, ~~2005~~2008) are hereby incorporated by reference with the following exceptions:

(1) Title 10, Code of Federal Regulations, sections 20.1001, 20.1002, 20.1006, 20.1007, 20.1008, 20.1009, 20.1401, 20.1402, 20.1403, 20.1404, 20.1405, 20.1406, 20.1905(g), 20.2106(d), 20.2302, 20.2401, and 20.2402, and Appendix D are not incorporated by reference.

(2) Any references to the United States Nuclear Regulatory Commission (NRC) or any component thereof shall be deemed to be a reference to ~~State~~the California Department of Public Health~~Services~~.

(3) The definition of the term "Byproduct material" in 10 CFR 20, section 20.1003 is replaced by the definition of the term "radioactive material" as defined in section 30100 of this regulation~~modified to mean any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to, the process of producing or utilizing special nuclear material.~~

(4) The definition of the term "License" in 10 CFR 20, section 20.1003 is replaced by the definition of the term "License" as defined in section 30100 of this regulation.

(5) The definition of the term "Licensed material" in 10 CFR 20, section 20.1003 is modified to mean any radioactive material (including source material, special nuclear material, or byproduct material) received, possessed, used, transferred or disposed of under a general or specific license issued by the NRC, or by any other Agreement State or by any state that has been either provisionally or finally designated as a Licensing State by the Conference of Radiation Control Program Directors, Inc. With respect to dose limits and reporting requirements, the term "Licensed material" is to be construed broadly in context to include any source of ionizing radiation subject to the requirements of this regulation.

(6) The definition of the term "Licensee" as defined in 10 CFR 20, section 20.1003 is replaced by the definition of the term "User" as set forth in section 30100 of this regulation.

(7) The definition of the term "Person" as defined in 10 CFR 20, section 20.1003 is replaced by the definition of the term "Person" as set forth in section 114985(c) of the Health and Safety Code.

(8) The definition of the term "Radiation (ionizing radiation)" as defined in 10 CFR 20, section 20.1003 is replaced by the definition of the term "Ionizing radiation" as set forth in section 114985(b) of the Health and Safety Code.

(9) The definition of the term "Special nuclear materials" as defined in 10 CFR 20, section 20.1003 is replaced by the definition of the term "Special nuclear material" as set forth in section 114985(f) of the Health and Safety Code.

(10) Reports of transactions and inventories required in 10 CFR 20, section 20.2207 shall be submitted to the National Source Tracking System maintained by NRC as specified in section 20.2207. Methods of reporting specified in section 20.2207(f) are identified on NRC's form, referenced in section 20.2207(f)(4).

(b) The terms defined in 10 CFR 20, section 20.1003, as incorporated by reference, shall apply to this regulation, except that:

(1) The term "Act" as defined in 10 CFR 20, section 20.1003 is limited to the textual material incorporated by reference in subsection (a) above. The meaning of the term "Act" elsewhere in this regulation, is as defined in section 30100 of this regulation~~means the "Radiation Control Law," Health and Safety Code, Division 104, Part 9, chapter 8, sections 114960 et seq.~~

(2) The term "Department" as defined in 10 CFR 20, section 20.1003 is limited to the provisions incorporated by reference in subsection (a). The meaning of the term "Department" elsewhere in this regulation, is as defined in section 30100 of this regulation~~114985(j) of the Health and Safety Code.~~

Note: Authority cited: Sections 400275-114975, and 115000 and 131200, Health and Safety Code. Reference: Sections 114960, 114965, 114970, 114985, 114990, 115060, 115105, 115110, 115120, 115165, 115230, and 115235, 131050, 131051 and 131052, Health and Safety Code.

(2) Amend Section 30255 to read as follows:

§ 30255. Notices, Instructions, and Reports to Personnel.

(a) *No change to text*

(b) Each user shall:

(b)(1) through (b)(5) No change to text

(6) Provide reports to any individual of ~~his~~their radiation exposure data and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of that individual as specified in this section. The information reported shall include data and results obtained pursuant to Department regulations, orders, or license conditions, as shown in records maintained by the user pursuant to Department regulations. Each notification and report shall: be in writing; include appropriate identifying data such as the name of the user, the name of the individual, the individual's Social Security number; include the individual's exposure information; and contain the following statement:

"This report is furnished to you under the provisions of the California State Department of ~~Public Health Services~~ Regulations: Standards for Protection Against Radiation. You should preserve this report for future reference."

These reports shall be provided as follows:

(A) ~~At the request of any individual, each user shall advise such individual annually of his exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to United States, title 10, Code of Federal Regulations, part 20, subpart M as incorporated by reference in section 30253, including the results of any calculations and analyses of radioactive material deposited in the body of the individual. If required to monitor an individual's exposure pursuant to that part of title 10, Code of Federal Regulations, part 20 (10 CFR 20), section 20.2106 that has been incorporated by reference in section 30253, the user shall provide an annual report to each monitored individual of the dose received in that monitoring year if:~~

1. The individual's occupational dose exceeds 100 mrem total effective dose equivalent or 100 mrem to any individual organ or tissue; or
2. The individual requests his or her annual dose report.

(B) *No change to text.*

(C) ~~When a user is required pursuant to United States, title 10, Code of Federal Regulations, part 20, subpart M 10 CFR 20, sections 20.2202, 20.2203, or 20.2204, as incorporated by reference in section 30253, to report to the Department any exposure of~~

an individual to radiation or radioactive material, the user shall also provide the individual a report on his exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Department.

(D) *No change to text.*

Note: Authority cited: Sections ~~208 and 25811~~114975, 115000 and 131200, Health and Safety Code. Reference: Sections ~~25801, 25802, 25811, 25815, 25826, 25875 and 25876~~, 114965, 114970, 115000, 115060, 115110, 115230, 115235, 131050, 131051 and 131052, Health and Safety Code.

(3) Amend Section 30256 to read as follows:

§ 30256. Vacating Installations: Records and Notice.

(a) *No change to text.*

(b) Each person granted a specific license pursuant to Group 2 of this Subchapter shall, no less than 30 days before vacating any installation which may have been contaminated with radioactive material as a result of ~~his~~the licensee's activities, notify the department in writing of intent to vacate. This notice shall be submitted on form ~~RHB 314 (12/95)~~RH 5314 (06/09), entitled "Certificate of Disposition of Materials," which is incorporated by reference herein, and shall address all requirements specified in Subsection (c).

(c) If a licensee does not submit an application for license renewal under section 30194, the licensee shall on or before the expiration date specified in the license:

(1) through (3) *No change to text.*

(4) Submit a completed form ~~RHB 314 (12/95)~~RH 5314 (06/09), which certifies information concerning the disposition of materials; and

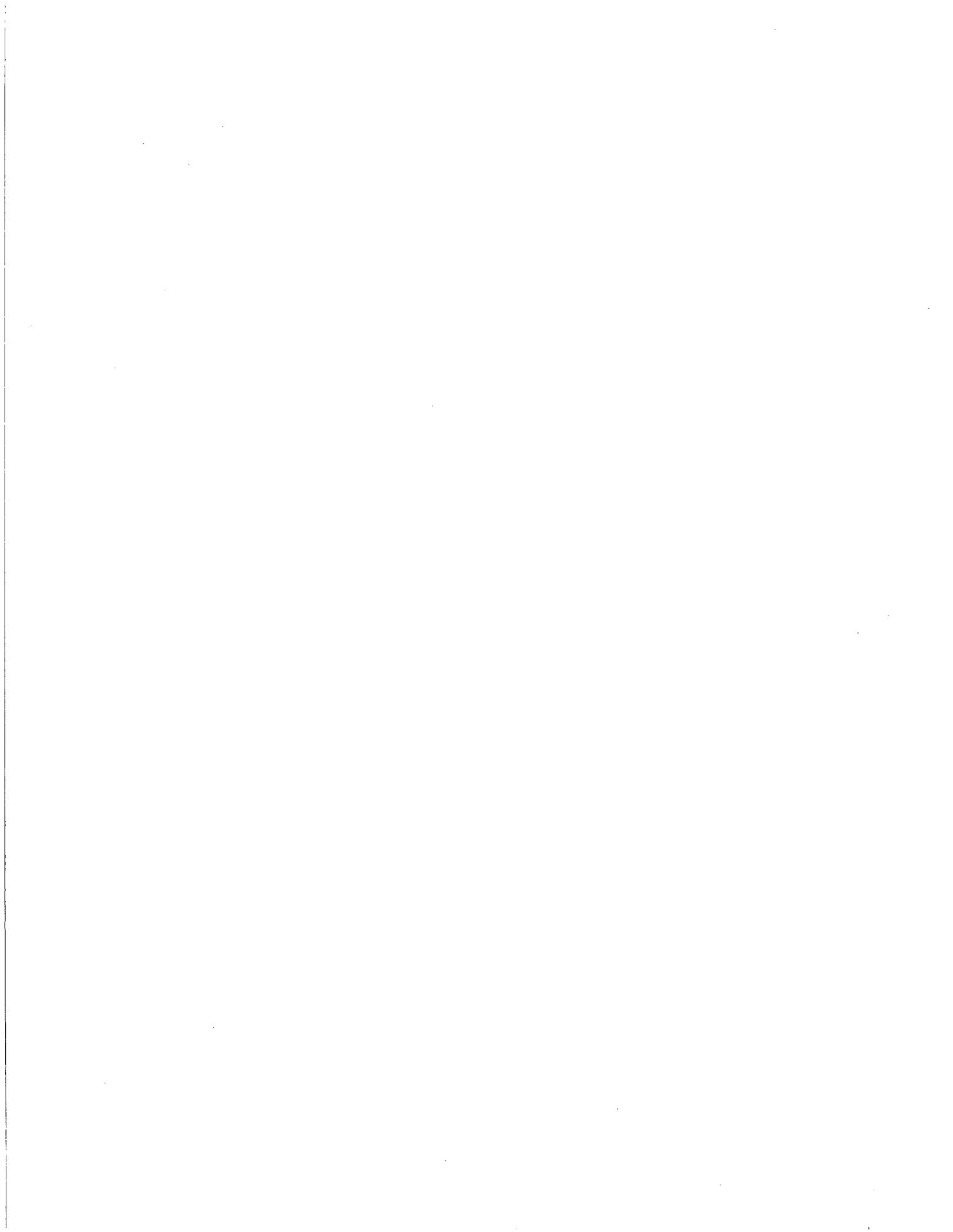
(5) *No change to text.*

(d) through (g) *No change to text.*

(h) Upon approval of the decommissioning plan by the Department, the licensee shall complete decommissioning in accordance with the approved plan. As a final step in decommissioning, the licensee shall again submit the information required in Subsection (c)(5) and shall certify the disposition of accumulated wastes from decommissioning by completing form ~~RHB 314 (12/95)~~RH 5314 (06/09).

(i) through (k) *No change to text.*

Note: Authority cited: Sections ~~400275-114975~~, 115000, and 131200, Health and Safety Code. Reference: Sections 114965, 114970, 115060, 115230, and 115235, 131050, 131051 and 131052, Health and Safety Code.



CERTIFICATE OF DISPOSITION OF MATERIALS

INSTRUCTIONS: ~~All items must be completed — print or type — send the completed certificate to the Department of Health Services, Radiologic Health Branch, P.O. Box 942732, MS 178, Sacramento, CA 95234-7320. Mail completed and signed form to California Department of Public Health, Radiologic Health Branch (RHB), Licensing Section, MS 7610, P.O. Box 997414, Sacramento, CA 95899-7414. For more information, phone (916) 327-5106 or go to <http://www.cdph.ca.gov/programs/Pages/RadiologicHealthBranch.aspx>.~~

LICENSEE NAME AND ADDRESS:	LICENSE NUMBER:
	LICENSE EXPIRATION DATE:

A. MATERIALS DATA (Check one and complete as necessary.)

THE LICENSEE OR ANY INDIVIDUAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE LICENSEE CERTIFIES THAT: (Check and/or complete the appropriate item(s) below.)

- 1. NO MATERIALS HAVE EVER BEEN PROCURED OR POSSESSED BY THE LICENSEE UNDER THIS LICENSE, OR
- 2. ALL MATERIALS PROCURED AND/OR POSSESSED BY THE LICENSEE UNDER THE LICENSE NUMBER CITED ABOVE HAVE BEEN DISPOSED OF IN THE FOLLOWING MANNER. (If additional space is needed, use the reverse side or provide attachments.)

Describe specific material transfer actions and, if there were radioactive wastes generated in terminating this license, the disposal actions including the disposition of low-level radioactive waste, mixed waste, greater than Class C waste, and sealed sources, if applicable.

For transfers, specify the date of the transfer, the name of the license recipient, and the recipient's California license number or NRC or Agreement State name and the license number.

If materials were disposed of directly by the licensee rather than transferred to another licensee, licensed disposal site or waste contractor, describe the specific disposal procedures (e.g., decay in storage).

Attach a list containing the location and description of all equipment to remain onsite after license termination that was contaminated when final decommissioning was initiated.

B. OTHER DATA

- 1. OUR LICENSE HAS NOT YET EXPIRED, PLEASE TERMINATE IT.
- 2. A RADIATION SURVEY WAS CONDUCTED BY THE LICENSEE TO CONFIRM THE ABSENCE OF LICENSED RADIOACTIVE MATERIALS AND TO DETERMINE WHETHER ANY CONTAMINATION REMAINS ON THE PREMISES COVERED BY THE LICENSE. (Check one)
 - NO (attach explanation)
 - YES, THE RESULTS (check one)
 - ARE ATTACHED, or
 - WERE FORWARDED TO RHB ON (date): _____

3. PERSON TO BE CONTACTED	NAME:	TELEPHONE NUMBER (include area code):
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4. MAIL ALL FUTURE CORRESPONDENCE REGARDING THIS LICENSE TO:

CERTIFYING OFFICIAL

I CERTIFY THAT THE FOREGOING IS TRUE AND CORRECT

PRINT NAME AND TITLE	SIGNATURE	DATE
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