



RON CHAPMAN, MD, MPH
Director

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



EDMOND G. BROWN JR.
Governor

June 15, 2011

Mr. Terrence Reis, Deputy Director
Division Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs (FSME)
U.S. Nuclear Regulatory Commission
11545 Rockville Pike, MS T8E24
Rockville, MD 20852

Dear Mr. Reis:

Enclosed for your review is a copy of the final adopted revision to the California Radiation Control Regulations addressing changes to 10 CFR 31, 40, and 150. Though the below cited NRC provisions do not specifically address 10 CFR 40, the California State Department of Public Health is amending regulations to ensure they are compatible with NRC's requirements. The date by which the comments are needed is September 15, 2010.

The final regulations addressed NRC's comments dated September 28, 2010 and are discussed in the document title Final Statement of Reasons. The final adopted text is identified by line-in/line-out text and correspond with the following equivalent amendments to NRC's regulations pertaining to 10 CFR 31, 40, and 150:

Rats ID	Title	State Section
1997-2	Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State 10 CFR 150	30225, 30226
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material 10 CFR 30, 31, 32	30108.1, 30115, 30145, 30190, 30191, 30192, 30192.1
2007-2	Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements 10 CFR Parts 30, 31, 32, and 150	30192.2, 30192.3, 30192.4, 30192.5, 30225, 30226, 30257

Mr. Terrence Reis
Page 2
June 15, 2011

Differences between the proposed regulation and the NRC equivalent regulation are addressed in the document titled Initial Statement of Reasons. Existing regulations referenced in the proposal are attached.

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the FSME Procedure SA-200. Differences between the proposed regulation and the NRC equivalent regulation are addressed in the document titled Initial Statement of Reasons.

If you have any questions, please feel free to contact me at (916) 440-7942 or Phillip Scott of my staff at (916) 440-7978 or phillip.scott@cdph.ca.gov.

Sincerely,

Gary W. Butner, Chief
Radiologic Health Branch

Enclosure

cc: Kathleen Schneider
Monica Orendi

ATTACHMENTS

Excerpts from Title 17, California Code of Regulations

(Existing regulations, except fee regulations, referenced in proposal DPH-07-002)

§ 30194.2. Amendment Requests.

To amend an existing license, a licensee shall submit a written request to the Department containing:

- (a) The licensee's name and license number as shown on the specific license.
- (b) The nature and scope of the request.
- (c) The reasons for the request and supporting justifications including any documents relied upon.
- (d) If the request proposes to increase the maximum possession limit specified on the license, the request shall include the fee specified in section 30231(c).

§ 30210. Authorization for Transfer.

(a) A licensee may transfer radioactive material only to persons listed below and only following acceptance of such transfer:

- (1) the Department;
- (2) any person who is exempt from this regulation to the extent permitted under such exemption; or
- (3) any person licensed or authorized to receive the material by the United States Nuclear Regulatory Commission, the Department, or any other Agreement State.

(b) This section does not authorize the commercial distribution of radioactive material other than those items listed in section 30192 through 30192.6, except when such distribution is authorized by a specific license.

§ 30210.1. Verification Required.

(a) Before transferring radioactive material to a licensee, the licensee transferring the material shall verify license authorization for the receipt of the type, form and quantity of radioactive material to be transferred.

(b) The transferor shall utilize methods of verification and maintain records of verification required by subsection (a) as specified in 10CFR30.41 (38FR33968).

§ 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, 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), 20.2203(c), 20.2206, 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 the California Department of Public Health.

(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.

(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.

(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.

§ 30254. Inspection.

(a) Each user shall afford to the Department or other official agency specifically designated by the Department, at all reasonable times, opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these regulations.

(b) During an inspection, inspectors may consult privately with workers as specified below. The user may accompany inspectors during other phases of an inspection.

(1) Inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Department regulations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(2) During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violation of the Radiation Control Law, these regulations, or license condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material or a registered radiation machine under the user's control. Any such notice in writing shall comply with the requirements of subsection (h) hereof.

(3) The provision of paragraph (b)(2) of this section shall not be interpreted as authorization to disregard instructions pursuant to section 30255(b)(1).

(c) If, at the time of inspection, an individual has been authorized by the workers to represent them during inspections, the user shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(d) Each worker's representative shall be routinely engaged in work under control of the user and shall have received instructions as specified in section 30280(b)(1).

(e) Different representatives of users and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(f) With the approval of the user and the workers' representative, an individual who is not routinely engaged in work under control of the user, for example, a consultant to the user or to the workers' representative, shall be afforded the opportunity to accompany inspectors during the inspection of physical working conditions.

(g) Notwithstanding the other provisions of this section, inspectors are authorized to refuse to permit accompaniment by an individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the user to enter that area.

(h) Any worker or representative of workers who believes that a violation of the Radiation Control Law, these regulations or license conditions exists, or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Department or other official agency specifically designated by the Department. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the user by the Department no later than at the time of inspection except that, upon the request of the worker giving such notice, his name and the name of individuals referred to therein shall not

appear in such copy or on any record published, released, or made available by the Department except for good cause shown.

(i) If, upon receipt of such notice, the Chief, Radiologic Health Branch, of the Department, determines that the complaint meets the requirements set forth in subsection (h) hereof, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he shall cause an inspection to be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this section need not be limited to matters referred to in the complaint.

(j) No user shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these regulations or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by this section.

(k) If the Chief, Radiologic Health Branch, of the Department, determines with respect to a complaint under subsection (h) hereof that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the complainant shall be notified in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position to the Director of the Department, who will provide the user with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The user may submit an opposing written statement of position with the Director of the Department who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the Director of the Department, or his designee, may hold an informal conference in which the complainant and the user may orally present their views. An informal conference may also be held at the request of the user, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written or oral views presented, the Director of the Department shall affirm, modify, or reverse the determination of the Chief, Radiologic Health Branch, of the Department, and furnish the complainant and the user a written notification of his decision and the reason thereof.

(l) If the Department determines that an inspection is not warranted because the requirements of subsection (h) hereof have not been met, it shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of subsection (h) hereof.

§ 30293. Records.

(a) Each user shall keep records showing the receipt, transfer, and disposal of each source of radiation which is subject to licensure or registration pursuant to groups 1.5 and 2 of this subchapter as follows:

(1) The user shall retain each record of receipt of a source of radiation as long as the source of radiation is possessed and for three years following transfer or disposal of the source of radiation.

(2) The user who transferred the source of radiation shall retain each record of transfer for three years after each transfer unless a specific requirement in another part of the regulations in this subchapter dictates otherwise.

- (3) The user who disposed of the radioactive material shall retain each record of disposal of the radioactive material until the Department terminates each license that authorizes disposal of the radioactive material.
- (b) The user shall retain each record that is required by the regulations in this subchapter or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record shall be retained until the Department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.
- (c) Records which shall be maintained pursuant to this subchapter may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by department regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, shall include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.
- (d) If there is a conflict between the Department's regulations in this subchapter, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this subchapter for such records shall apply unless the Department, pursuant to 30104, has granted a specific exemption from the record retention requirements specified in the regulations in this subchapter.
- (e) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall, if requested by the Department, forward the following records to the Department:
- (1) Records of disposal of licensed material made under Title 10, Code of Federal Regulations, sections 20.2002, 20.2003, 20.2004, 20.2005, incorporated by reference in section 30253; and
 - (2) Records required by Title 10, Code of Federal Regulations section 20.2103(b)(4), incorporated by reference in section 30253.
- (f) If licensed activities are transferred or assigned in accordance with section 30194(c), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:
- (1) Records of disposal of licensed material made under Title 10, Code of Federal Regulations, sections 20.2002, 20.2003, 20.2004, 20.2005, incorporated by reference in section 30253; and
 - (2) Records required by Title 10, Code of Federal Regulations, section 20.2103(b)(4), incorporated by reference in section 30243.
- (g) Prior to license termination, each licensee shall, if requested by the Department, forward the records required by section 30256(a) to the Department.

§ 30295. Notification of Incidents.

(a) Each user shall notify the Department as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits.

(b) Each user shall notify the Department within 24 hours after the discovery of any of the following events involving radiation or radioactive materials:

(1) An unplanned contamination event involving licensed radioactive material that:

(A) Requires access to the contaminated area by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(B) Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of Title 10, Code of Federal Regulations, part 20, incorporated by reference in section 30253 for the material; and

(C) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(2) An event in which equipment is disabled or fails to function as designed when:

(A) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(B) The equipment is required to be available and operable when it is disabled or fails to function; and

(C) No redundant equipment is available and operable to perform the required safety function.

(3) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(4) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(A) The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of Title 10, Code of Federal Regulations, part 20, incorporated by reference in section 30253 for the material; and

(B) The damage affects the integrity of the licensed material or its container.

(c) Reports made by users in response to the requirements of this section shall be made as follows:

Each user shall make reports required by subsections (a) and (b) by telephone to the Department. To the extent that the information is available at the time of notification, the information provided in these reports shall include:

(1) The caller's name and call back telephone number;

(2) A description of the event, including date and time;

(3) The exact location of the event;

(4) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(5) Any personnel radiation exposure data available.

(d) Each user who makes a report required by this section shall submit a written follow-up report within 30 days of the initial report. These written reports shall be sent to the Department and include:

- (1) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;
- (2) The exact location of the event;
- (3) The isotopes, quantities, and chemical and physical form of the licensed material involved;
- (4) Date and time of the event;
- (5) Corrective actions taken or planned and the results of any evaluation or assessment; and
- (6) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

FINAL STATEMENT OF REASONS

The information contained in the Initial Statement of Reasons (ISR) at the time of Public Notice remains unchanged with the exception of the following modifications.

Section 30192: Due to comments received from the U.S. Nuclear Regulatory Commission (NRC), subsection (a) is amended for consistency with title 10, Code of Federal Regulations (10 CFR), section 31.3.

Section 30192.1(d)(1): Due to public comments, an additional review of title 10, Code of Federal Regulations (10 CFR), section 31.5(c)(13)(i) shows that radium-226 is included as a registration-triggering isotope and quantity. However, as proposed, subsection (d)(1) did not include the radioisotope. Therefore, to address the comment and to ensure consistency with NRC's provision, the phrase "0.1 mCi of radium-226" is added.

Section 30192.1(d)(10)(B): A commenter indicated that in the proposed amendment the transfer of a device to a specific licensee whose license authorizes possession of a device, such as the manufacturer who will repair the device, requires prior written Department approval, and that this is a significant departure from 10 CFR 31.5(c)(8)(i). Existing section 30192.1(b)(2), 10 CFR 31.5(c)(8)(i), and the proposal were reviewed and it was determined that the proposal was inconsistent with the federal provision and inadvertently created a burdensome approval process. The comment is accepted and the Department proposes to insert language for consistency with the federal requirement so as to not require written prior approval when transferring a device to a specific licensee authorized to possess the device.

Section 30192.2: Due to comments received from NRC, the following changes are made:

- Subsection (a) is amended for consistency with 10 CFR 31.7.
- Language is amended and added in subsection (b) for consistency with 10 CFR 31.7.

Section 30192.3: An additional review of proposed changes in this section indicates that the proposal was inconsistent with NRC's 10 CFR 31.8. Therefore, the following changes are made:

- Subsection (a): a nonsubstantial capitalization change is made regarding the label statement. The word "or" found between "plutonium" and "radium-226" is changed to "OR".
- Subsection (a): A commenter indicated that this section was inconsistent with the U.S. Nuclear Regulatory Commission's (NRC) provision in 10 CFR 31.8 in that the Department limited to whom the general license could be issued. Existing section 30192.3 limits issuance of the specified general license to both Department specific licensees authorized to possess any radioactive material and to NRC specific licensees authorized to possess special nuclear material. However, NRC's provision in 10 CFR 31.8 provides that the general license may be issued to NRC specific licensees authorized to possess byproduct material, source material, or special nuclear material (10 CFR 31.8(a)(1)). Thus, NRC's provision grants the general license to a broader category of users.

The Department accepts the recommendation and proposes to change subsection (a) by deleting the words “special nuclear” and inserting “radioactive” so as to be more consistent with NRC. Though NRC’s provision uses the terms “byproduct material,” “source material,” and “special nuclear material” and the Department’s proposal refers to “radioactive material” as defined in section 30100(r), consistency is maintained because the Department’s term includes the same materials included in NRC’s terminology. Also, the State of Texas issues the same type of general license based on 10 CFR 31.8 (25 TAC 289.251(f)(4)(D)) and uses the term “radioactive material” (25 TAC 289.251(f)(4)(D)(i)(II)) as it relates to NRC licensees. Both Texas regulations (25 TAC 289.201(b)(82) and Department regulations (17 CCR 30100(r)) define the term “radioactive material” as any material that emits radiation spontaneously.

- In addition, the Department corrected a formatting error regarding two commas in subsection (a).
- Subsection (c): Corrections are made for consistency with 10 CFR 31.8(c) to identify those sections to which the general licensee is subject. NRC’s provision identifies other provisions the general licensee must comply with. The corresponding California regulation is listed after the federal provision referenced in 10 CFR 31.8(c) and further discussed:
 - 10 CFR 30.14(d); see below discussion of subsection (d).
 - 10 CFR 30.34(a) to (e); Sections 30210, 30210.1 and, in general, Health and Safety Code section 115165. 10 CFR 30.34(a), (b), & (c) are compatibility category B and 10 CFR 30.34(d) & (e) are compatibility category NRC. Amendment of the proposed regulation is not necessary because the general license is already required to meet the law and sections 30210 and 30210.1 as indicated in section 30190(d). The phrase “this regulation” as found in section 30190(d) is defined in section 30100(z) to mean California Code of Regulations, title 17, Division 1, chapter 5, subchapter 4.0. Thus, the general licensee is already subject to sections 30210 and 30210.1.
 - 10 CFR 30.50; section 30295. 10 CFR 30.50(a), (b), and (c) through (c)(2) are compatibility category C and subdivision (c)(3) is category D. Thus, section 30295 is added for consistency with 10 CFR 31.8(c).
 - 10 CFR 30.51; section 30293. The proposal includes section 30293(a), however, it fails to encompass all NRC provisions in 10 CFR 30.51. Therefore, to maintain consistency, section “30293(a)” is amended to “30293” to ensure all provisions apply.
 - 10 CFR 30.53; section 30275(a) & (b). Though 10 CFR 30.53 is a compatibility category D, it is proposed it be included to maintain consistency with NRC’s provision. Section 30275(a) and (b) only are being added as the other provisions of section 30275 do not apply to the types of devices for which the general license is issued.
 - 10 CFR 30.55; no equivalent. 10 CFR 30.55 is a compatibility category NRC meaning that an agreement state may not adopt it. Therefore, it is not included in this proposal.
 - 10 CFR 30.61; section 30205. 10 CFR 30.61 is a compatibility category D. Though the provision is not required to meet compatibility with NRC, existing

section 30192.3 is nearly identical to the NRC's provision. The proposed changes were to ensure section 30192.3 was essentially identical to 10 CFR 31.8. However, as proposed, section 30192.3 is not amended to address 10 CFR 30.61 because the general license is already required to meet section 30205 as specified in section 30190. The phrase "this regulation" as found in section 30190(d) is defined in section 30100(z) to mean California Code of Regulations, title 17, Division 1, chapter 5, subchapter 4.0. Thus, the general license is already subject to section 30205.

- 10 CFR 30.62 & 30.63; generally, Health and Safety Code sections 115095, 115150, 115160, 115165, 115170, and 115175. Further, the compatibility category for both provisions is D. Therefore, because the law already applies to the general license and the compatibility category is D, the proposal is not amended.
- 10 CFR Parts 19, 20, and 21; section 30253, 30254, and 30255. The proposal is amended to include the equivalent sections to maintain consistency with NRC's provisions. Section 30253 incorporates by reference 10 CFR Part 20. Sections 30254 and 30255 contain provisions equivalent to 10 CFR Part 19. 10 CFR Part 21 is compatibility category NRC and is solely reserved to NRC and agreement states are not authorized to adopt it.
- Subsection (d): a phrase is added to clarify that the issued general license does not authorize the introduction of the specified radioactive material into a product or material so as to be consistent with 10 CFR 30.14(d) referenced in 10 CFR 31.8(c). 10 CFR 30.14(d) is compatibility category B and the equivalent Agreement State provision is required to be essentially identical to the NRC's provision.

Section 30192.4: Due to comments received from NRC and further evaluation of the proposal, the section is amended to maintain consistency with NRC's provision in 10 CFR 31.10. Nonsubstantial changes, including creating the "10 CFR 20" acronym in subsection (b)(2) instead of subsection (c), are made for consistency.

Section 30192.6: Due to comments received from NRC, the section is amended for consistency with 10 CFR 40.25.

Section 30257: Due to comments received from NRC, subsection (a)(2) is amended for consistency with 10 CFR 30.34(h)(1)(ii).

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE:

- INITIAL NOTICE PERIOD OF JULY 29, 2010 THROUGH SEPTEMBER 15, 2010;
and
- FIRST 15-DAY NOTICE PERIOD OF DECEMBER 1, 2010 THROUGH
DECEMBER 17, 2010.
- SECOND 15-DAY NOTICE PERIOD OF FEBRUARY 15, 2011 THROUGH
MARCH 7, 2011.

This regulation (DPH-07-002) was made available to the public from July 29, 2010 through at 5:00 p.m. on September 15, 2010. A 15-day written public comment period was conducted that ended at 5:00 p.m. on December 17, 2010. An untimely comment was received after the 15-day comment period and before the second 15-day comment period. A second 15-day public comment period was conducted that ended at 5:00 p.m. on March 2, 2011; however, the comment period was extended to March 7, 2011 due to a copying oversight after the Notice of Availability was mailed. A request for a public hearing was not received and, thus, no public hearing was held. The written proceeding produced comments from those noted below.

List of Commenters during Initial 45-day Proceeding

(Written testimony)

1. Greg Yuhas, Radiation Safety Officer, UC Berkeley, CA
2. Terrence Reis, Deputy Director, Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission (NRC)

List of Commenters during first 15-day Proceeding

(Written testimony)

3. Greg Yuhas, Radiation Safety Officer, UC Berkeley, CA

List of Commenters – Untimely Comment

4. Mike Lewandowski, Certified Health Physicist, Manager, Ionizing Radiation, Corporate Health Physics, 3M, St. Paul, MN.

List of Commenters during second 15-day Proceeding

(Written testimony)

No comments were received during the second 15-day proceeding.

Summary of comments and responses

Note: The first digit of the number designation identifies the Commenter as listed above. The digit(s) after the decimal point indicate the identified comment from that commenter.

- 1.1 Proposed §30115 requires the registrant shall report in writing to the Department, within 30 days any ...”discontinuance of use of use of any reportable source.” This seems to be an onerous burden for sources of such limited safety significance that they are generally licensed and exempt from most radiation safety requirements. It infers additional training and recording**

keeping requirements will be necessary to ensure compliance without a proportional reduction in radiological risk.

Response: Section 30115 is an existing section being amended to exclude persons who possess devices subject to sections 30192.1(d)(1) or 30192.6(b)(1). These persons would only be subject to the reporting requirement in proposed section 30108.1(c), which does include discontinuance of use. However, the commenter does not clarify how such notification is onerous or creates the need for additional training. Proposed section 30192.1 contains other reporting and testing provisions to ensure the radioactive material is controlled and accounted for. Discontinuance of use can, and has in many instances, result in loss of material such that it makes its way to consumer products increasing radiological risk. Thus, informing CDPH that the device is no longer used allows staff, and the licensee, to ensure it is properly accounted for and disposed, as applicable. Therefore, no change is made.

- 1.2 Proposed §30108.1 (a) would seem to require a broad scope licensee to register sources meeting the criteria presented in §30192.1(d) (1) or §301292.6(b)(1) despite the fact the sources may be listed on their specific license. This seems redundant.**

Response: Current regulatory structure requires a specific licensee to register, if applicable, as possessing a device held under a general license (GL). If the generally licensed device is listed on the specific license (SL), it is inadvertent and the specific licensee should contact CDPH staff.

- 1.3 Proposed §30192.1(d)(1) does not include the 0.1 mCi of Ra-226 presented in 10 CFR 31.5 (c)13 (i). Was this deliberate?**

Response: Exclusion of Radium-226 was inadvertent. The isotope has now been added for consistency with 10 CFR 31.5(c)(13)(i).

- 1.4 Proposed §30192.1(d)(16) requires in part: “Devices kept in standby for future use are excluded from the two year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.” This could be confusing for a specific licensee holding generally licensed sources. For example, a specific licensee is required to inventory sealed sources semi-annually. Quarterly inventories of generally licensed sources seems unnecessarily restrictive given they may be considerably less hazardous than category I or II increased control sources.**

Response: As indicated in the response to comment 1.2, current regulatory structure, as well as this proposal, requires a specific licensee who also becomes a general

licensee to control the generally licensed device (GLD) in accordance with the GL. If the specific licensee wants to control the GLD under the SL, the GLD must be returned to the manufacturer for re-labeling and revision of the device registration documents and the SL, to take possession of the re-labeled device, must be authorized to possess the particular radioactive material. However, as proposed in section 30192.1(d)(10)(C), and as adopted by NRC, there is flexibility in this transfer by allowing the SL to modify, in a limited manner, the labeling of the device and compliance with other provisions.

It is also noted that NRC has proposed (Federal Register, Vol. 74, No. 147 (August 3, 2009)) an amendment to 10 CFR 31.5 that will accomplish what the comment alludes to; namely, allowing the specific licensee who holds a GLD to be held to the terms and conditions of the specific license in lieu of the provisions of the general license. Until NRC adopts that change as a final rule, CDPH can make no change to the proposal as such a change would result in a different standard than is allowed by NRC under compatibility category B. Therefore, no change in the proposal is made.

1.5 Generally, a specific comment in the regulations indicating that any generally licensed material held by broad scope licensees, must be controlled in accordance with the broad scope license and the broad scope licensee is exempt from the registration requirements might be considered helpful. However, many broad scope licensees might have to amend their quantity limits address tritium exit signs, etc.

Response: Tritium exit signs are proposed to not be subject to the registration requirements. See the response to comment 1.4.

2.1 – 2.24. For summary of the comments, please see the chart attached to NRC’s letter dated September 28, 2010; however, responses to those comments are presented below in the order the comments are given in NRC’s chart.

Comment #	Response
2.1	The comment is accepted and the proposal amended.
2.2 – 2.20	These comments are outside the scope of this proposal.
2.21	The comment is accepted and the proposal amended. Note: comparing the NRC’s comment to the applicable NRC provision indicates an error occurred during drafting of the comment that was not corrected. NRC’s comment regarding the quoted phrase to be inserted into section 30192(a) uses the conjunction “or” between “using and “owning whereas the correct conjunction should be “and.”

	Further, NRC's comment cites to 10 CFR 30.31 and the table column titled "NRC SECTION" cites 31.3. Contact with NRC verified that the quoted phrase should reflect the NRC's provision in 10 CFR 31.3 and that the cited 10 CFR 30.31 should be to 10 CFR 31.3.
2.22	The comments are accepted and the proposal amended to be consistent with NRC's provision.
2.23	The comments are accepted and the proposal amended to be consistent with NRC's provision.
2.24	The comments are accepted and the proposal amended to be consistent with NRC's provision.

3 Comments from commenter #3 are summarized or verbatim. Responses are provided in full.

3.1 The proposed changes in 30192.1(d)(3)(B) regarding testing are inconsistent with other regulations as indicated.

Response: The commenter believes the proposal is inconsistent with Title 10, code of Federal Regulations, sections 20.1101(d) and 35.67(f)(5) (10 CFR 20.1101(d) and 10 CFR 35.67(f)(5)). However, as indicated in the proposal (sections 30192.1(d)(13)) and as found in NRC regulations (10 CFR 31.5(c)(10)), 10 CFR 20.1101 does not apply to a person possessing radioactive material under the issued general license; thus, it is not inconsistent as it does not apply. Further, 10 CFR 35.67 also does not apply and thus, is not inconsistent because that section applies to a specific licensee who has obtained one of the indicated radioactive sources from a manufacturer (another specific licensee) authorized to manufacture sources that may only be possessed by a specific licensee authorized to use such sources for medical use. Thus, the comments are combining the regulatory structure of specific licenses (SL) and general licenses (GL), which creates the inconsistency. For a person to possess a radioactive source under a GL they must obtain it and comply with the specific regulation and the source itself must be labeled as a source that may be possessed under a GL. The sources referred to in 10 CFR 35.67 are labeled to indicate they may be possessed only under a SL. Control of the radioactive source between the SL and GL is addressed by section 30192.1(d)(10). Therefore, the comment is rejected because the cited regulations do not apply to the proposal.

3.2 Section 30192.1(d)(6) lacks specificity due to the definition of "sealed source" in section 30100(v). Recommended changes are given.

Response: As indicated in the response to comment 3.1, the commenter is combining the regulatory structure of specific licenses and general licenses creating confusion. Further, the commenter misstates the proposal. Section 30192.1 applies to a person who possesses radioactive material under a general license. This person is commonly called the general licensee. Section 30190 clarifies that a general license is effective without the filing of an application with the department or the issuance of licensing documents to particular persons. Section 30192.1(d)(6) applies to a general licensee who must stop using the particular device because the radioactive material's shielding has been compromised or protection from that material or emitted radiation is in question. The regulation then tells the general licensee that they may not operate the device until it has been repaired by the manufacturer (who has a specific license authorizing manufacturing and repair of the device) or some other specific licensee authorized to repair the device. Lastly, the comment as to what the "broad scope" licensee (a specific licensee) may do in relation to the proposal is unclear as the commenter misstates the proposal and the comment is based on that misunderstanding.

The recommended changes address the manufacturing process whereas the proposal addresses the end user of the manufactured source or device; thus, the comment is outside the scope of this proposal and is rejected.

3.3 Questions the necessity of the reporting requirement in section 30192.1(d)(10)(C) if they are already licensed to possess the source.

Response: Again, the commenter is combining two separate regulatory structures creating confusion as to how they work. Further, the comment misstates the actual requirement. Section 30192.1(d)(10)(C) applies to a general licensee, not a specific licensee. The regulatory structure of general and specific licenses was established by and currently controlled at the federal level by the NRC. The commenter is proposing that California regulations should be amended to combine the regulatory structure of general and specific licenses. However, California does not have that authority as the NRC has designated the compatibility and adequacy requirements of this proposal as category B. Category B requires the Agreement State (California) to be essentially identical to NRC requirements. NRC has proposed (Reference 14) to do what the commenter suggests but has not yet adopted a final rule. That proposal would provide that for devices meeting the criteria of this general license (10 CFR 31.5), but instead held under the authority of a specific license, all of the terms and conditions of the specific license apply in lieu of the provisions in this general license. Until NRC adopts that provision as a final rule, California cannot accept the comment. Therefore, the comment is rejected.

3.4 §30192.1 (d) (16) requires that sealed sources and devices, "not in use," cannot be held for more than two years. This is an unreasonable requirement for those individuals holding sources or devices where the working, or service life, stated in the SS&DR is more than two years.

Response: Because NRC has categorized the proposal as a Category B compatibility requirement, the comment is rejected.

- 3.5 §30192.3 is inconsistent with 10 CFR31.8 and deprives the public from use of small americium-241 or radium-226 calibration and reference sources because, as general licensees, CDPH included plutonium and the requirement for a specific license that permits possession of special nuclear material. Since americium and radium are not special nuclear material they should be available to general licensees as permitted by 10 CFR 31.8.**

Response: Existing section 30192.3 limits issuance of the specified general license to both Department specific licenses authorized to possess any radioactive material and to NRC specific licensees authorized to possess special nuclear material. However, NRC's provision in 10 CFR 31.8 provides that the general license may be issued to NRC specific licensees authorized to possess byproduct material, source material, or special nuclear material (10 CFR 31.8(a)(1)). Thus, NRC's provision grants the general license to a broader category of users of the identified sources.

The recommendation is accepted and the provision changed to be more consistent with NRC. A review of other Agreement States' regulations indicate that the States of Washington, Oregon, Colorado, and Louisiana continue to limit issuance of this type of general license in the same manner as the Department's existing regulations whereas the State of Texas consistently follows the NRC's provision.

- 3.6 §30192.6 long established general license restrictions on the use of depleted uranium made for the purpose of providing a concentrated mass. While §30100 does not define "concentrated mass," the term might now be used to describe depleted uranium penetrators, possibly used by special police. The radiological controls described in §30192.6 seem reasonable and appropriate if, in fact, these bullets are held by civilian police forces. However, if D-38 penetrators are intended to be regulated by §30192.6, more work and public involvement is suggested.**

Response: The comment is rejected because the proposed changes do not apply to bullets or other penetrators. The existing requirement and the proposed changes apply only to possession and use of depleted uranium contained in industrial products or devices for the purpose specified.

- 4.1 Proposed revision to 30192.1(d)(10) requires prior written approval by the Department to specific licensees authorized to possess the device. This is a significant departure from the current requirements in 10 CFR 31.5(c)(8)(i).**

Response: Existing section 30192.1(b)(2), 10 CFR 31.5(c)(8)(i), and the proposal were reviewed and it was determined that the proposal was inconsistent with the federal provision and inadvertently created a burdensome approval process. The comment was accepted. An additional 15-day comment period was conducted to insert language for consistency with the federal requirement so as to not require written prior approval when transferring a device to a specific licensee authorized to possess the device.

ALTERNATIVES DETERMINATION

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

IMPOSITION OF LOCAL MANDATE

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, nor are there any other nondiscretionary costs imposed.

IMPACT ON BUSINESS

The Department has made a 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.

California Code of Regulations
TITLE 17. Public Health
Division 1. Department of Health Services
Chapter 5. Sanitation
Subchapter 4.0. Radiation
Group 1.5. Registration of Sources of Radiation
Article 1. Registration Procedure

(1) Amend Section 30108 to read as follows:

§ 30108. Registration Requirement.

Every person possessing a reportable source of radiation shall register with the Department in accordance with the provisions of ~~Sections 30110 through 30146~~this Group.

Note: Authority cited: Sections ~~208 and 25814~~ 114975, 115000 and 131200, Health and Safety Code. Reference: Sections ~~25845~~ 115060, 131050, 131051 and 131052, Health and Safety Code.

(2) Adopt Section 30108.1 to read as follows:

§ 30108.1. Registration and General Provisions for Persons Possessing Devices Under Sections 30192.1 and 30192.6.

(a) A person required to register pursuant to sections 30192.1(d)(1) or 30192.6(b)(1) shall, within 30 calendar days of taking possession of a device or product, submit to the Department the following:

(1) Legal name, mailing address, and telephone number of the registering person. If renewing registration, the registration number previously issued to the registrant shall also be included;

(2) For each device subject to section 30192.1:

(A) The manufacturer's name, serial number, model number, the radioisotope, and the radioisotope's activity (as indicated on the device's label). For devices used in a fixed location, the physical address of each location where a device is used and the total number of devices at each location shall be submitted. For portable devices, the physical address of each primary place of storage and the total number of devices stored at each location shall be submitted. If renewing registration and there has been no change in the previously indicated devices, indicate that no change has occurred;

(B) Name, title, and telephone number, if different than the number specified in subsection (a)(1), of the individual appointed pursuant to section 30192.1(d)(15);

(C) Name and license number of the distributor from whom the device was obtained;
and

(D) Signature and date of signature of the individual identified in subsection (a)(2)(B), attesting to the following statement:

"I [insert name as it appears in response to subsection (a)(2)(B)] attest that I am aware of the requirements of the general license specified in section 30192.1 of title 17, California Code of Regulations, and that the information provided concerning the device or product has been verified through a physical inventory and checking of label information."

(3) For persons possessing devices subject to section 30192.6:

(A) A statement that the registrant has, pursuant to section 30192.6(b)(3), developed, implemented, and will continue to maintain procedures designed to establish physical control over the depleted uranium described in section 30192.6(a), and designed also

so as to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(B) Name, title, and telephone number, if different than the number specified in subsection (a)(1), of the individual appointed pursuant to section 30192.6(b)(4);

(4) Except for persons possessing devices pursuant to section 30192.6, the registration fee specified in section 30145.

(b) Each person shall renew registration annually on or before the current registration's expiration date, by submitting to the Department all required items in subsection (a).

(c) In lieu of the requirements in section 30115, within 30 calendar days of the occurrence of the event, each person registered pursuant to this section shall notify the Department of any change in the information submitted in response to subsection (a), including discontinuance of use of a device or product.

Note: Authority cited: Sections 114975, 115000 and 131200, Health and Safety Code.
Reference: Sections 115000, 115060, 115065, 115230, 115235, 131050, 131051 and 131052, Health and Safety Code.

(3) Amend Section 30115 to read as follows:

§ 30115. Report of Change.

Except for persons subject to section 30108.1, tThe registrant shall report in writing to the Department, within 30 days, any change in: registrant's name, registrant's address, location of the installation, or receipt, sale, transfer, disposal, or discontinuance of use of any reportable source of radiation.

Note: Authority cited: Sections ~~208 and 25814~~ 114975, 115000 and 131200, Health and Safety Code. Reference: Sections ~~25815~~ 115060, 131050, 131051 and 131052, Health and Safety Code.

Article 2. Exclusions from Registration

(4) Amend Section 30125 to read as follows:

§ 30125. Excluded Material and Devices.

The following devices and materials do not require registration:

(a) *No change to text.*

(b) All radioactive materials except as specified in ~~Section~~sections 30192.1 and 30192.6.

Note: Authority Cited: Sections ~~208 and 25811(c)~~ 114975, 115000 and 131200, Health and Safety Code. Reference: Sections ~~25845~~ 115060(c), 131050, 131051 and 131052, Health and Safety Code.

Article 4. Fees

(5) Amend Section 30145 to read as follows:

§ 30145. Registration Fees.

(a) *No change to text.*

(b) *No change to text.*

(c) For registration or renewal of registration as a general licensee pursuant to section 30192.1, the fee shall be \$70.00 for each device in possession, except that persons possessing such devices under a specific license shall be exempt from this fee.

(de) Except as provided in subsection (de), initial registration shall be valid for a period of one year.

(de) The initial registration period for a reportable source of radiation being registered by a person who has a reportable source of radiation already registered with the Department shall be coterminous with the existing registration.

(ef) Any fees collected for a radiation machine or a device for any registration period shall be transferred to any replacement radiation machine or device for the remainder of the registration period.

(fg) For initial registration or renewal of registration, the fees shall be \$214.00 annually for each high priority radiation machine, \$172.00 annually for each medium priority radiation machine and, except as provided in section 30145.1, \$475.00 annually for each special priority radiation machine. Where the initial registration period is less than one year pursuant to subsection (de), the initial registration fee shall be prorated, based on the priority classification and number of full months in the initial registration period in accordance with the following formula:

$$\text{Initial registration Fee} = A \times [B / (12 \text{ months})]$$

Where:

A = Annual fee as specified above, dollars per year

B = Number of full months remaining in coterminous period

(gh) *No change to text.*

(hi) *No change to text.*

(ij) *No change to text.*

Note: Authority cited: Sections ~~100275~~ 114975, 115000, 115060, 115065, 115080, and 115085 and 131200, Health and Safety Code. Reference: Sections 114980, 115065, 115080, 115085, and 115165, 131050, 131051 and 131052, Health and Safety Code

Group 2. Licensing of Radioactive Materials
Article 4. Licenses

(6) Amend Section 30190 to read as follows:

§ 30190. Types of Licenses.

(a) Department licenses for radioactive material are of two types: general and specific.

(b) General licenses provided in this regulation are effective without the filing of an application with the Department or the issuance of licensing documents to particular persons, except that any person to whom a general license is issued pursuant to sections 30192.1 and 30192.6 shall be subject to the registration requirements specified in section 30108.1.

(c) Specific licenses are issued to named persons upon approval of an application filed pursuant to this regulation. A specific license issued by the Department is required by any person to possess any radioactive material in this state, except as otherwise provided in Sections 30180, ~~30181, 30182,~~ 30191, 30192, 30192.1, 30192.2, 30192.3, 30192.4, 30192.5, 30192.6, ~~or~~ 30225, or 30226.

(d) Every specific and general license is subject to all applicable provisions of this regulation and, except as otherwise specified, to the provisions of Group 3 of this subchapter (Standards for Protection Against Radiation).

Note: Authority cited: Sections 114970, 114975, 115000 and 131200, Health and Safety Code. Reference: Sections 114970, 115060, 115165, 115235, 131050, 131051 and 131052, Health and Safety Code.

(7) Amend Section 30191 to read as follows:

§ 30191. General Licenses-Source Material.

(a) A general license is hereby issued to commercial firms, educational institutions, and medical institutions and government agencies, authorizing the possession, ~~and use, and transfer~~ of not more than 15 pounds of source material at any one time, for research, development, educational, commercial or operational purposes. Persons authorized to possess, ~~and use, or transfer~~ source material, pursuant to this general license, may not receive more than a total of 150 pounds of source material in any one calendar year. ~~Any person shall, w~~With respect to such source material, any person shall be exempt from the provisions of Group 3 of this subchapter, except for ~~sections~~ Sections 30253, 30254 and 30293(a), unless such person also possesses source material under a specific license.

(b) A general license described in ~~Section 30191~~ subsection (a) shall not authorize human use; ~~or the use in any device or article which is intended to be placed on or in the human body;~~ or the use of any instrument or apparatus (including component parts and accessories thereto) intended for human use.

Note: Authority cited: Sections ~~400275 and~~ 114975, 115000 and 131200, Health and Safety Code. Reference: Sections 114965, 114970, 114985(g), 115000, 115060, 115165, ~~and 115235, 131050, 131051 and 131052~~, Health and Safety Code.

(8) Amend Section 30192 to read as follows:

§ 30192. General Licenses—Static Elimination or Ion Generation Devices.

(a) A general license is hereby issued to any person, authorizing possession, transference, receipt, acquisition, use and ownership of radioactive material incorporated in any of the following items when manufactured, tested, and labeled pursuant to a specific license, which authorizes distribution to general licensees:

(1) Static eliminators containing sealed sources of up to 500 microcuries of ~~polonium~~ polonium-210 per device.

(2) Air ionization devices containing, as sealed sources, up to 500 microcuries of ~~polonium-210~~ polonium-210 or 50 millicuries of ~~hydrogen-3~~ tritium per device.

(b) Possession of radioactive material listed in this section is exempt from the requirements of Group 3 of this subchapter, except for sections 30254 and 30293(a) of this subchapter and sections 20.2201 and 20.2202 of title 10, Code of Federal Regulations, Part 20, incorporated by reference in section 30253 ~~Sections 30253, 30254, and 30293(a).~~

Note: Authority cited: Sections ~~400275 and~~ 114975, 115000 and 131200, Health and Safety Code. Reference: Sections 114965, 114970, 114985(g), 115060, 115165, and 115235, 131050, 131051 and 131052, Health and Safety Code.

(9) Amend Section 30192.1 to read as follows:

§ 30192.1. General Licenses—Gauging and Controlling.

~~(a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and government agencies to possess and use radioactive material when contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, qualitative or quantitative chemical composition or for producing light or an ionized atmosphere when such devices are manufactured pursuant to a specific license authorizing distribution to general licensees provided that each such device:~~

~~(1) Is labeled in accordance with the provisions of the specific license which authorizes distribution of the device;~~

~~(2) Bears a label containing the following or substantially similar statement:~~

~~"The receipt, possession, use and transfer of this device, Model _____, Serial No. _____, are subject to a general license or equivalent and the regulations of the United States Nuclear Regulatory Commission or of a state with which the United States Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. Removal of this label is prohibited.~~

~~CAUTION—RADIOACTIVE MATERIAL~~

~~_____

(Name of Supplier)"~~

~~The model, serial number and name of supplier may be omitted from this label provided they are elsewhere specified in labeling affixed to the device; and~~

~~(3) Is installed on the premises of the general licensee by a person having a specific license which authorized installation of such devices when required by the label on the device.~~

~~(b) Persons who possess a device pursuant to the general license contained in Section 30192.1(a) shall:~~

~~(1) Within 30 days of the receipt of any such device, register with the Department and within 30 days of transfer of any such device, notify the Department in accordance with the provisions of Group 1.5 of this subchapter (Registration of Radiation Sources).~~

~~(2) Not transfer, abandon or dispose of the device, except by transfer to a person holding a specific license to receive such device.~~

~~(3) Transfer the device to another general licensee only;~~

~~(A) Where the device remains in use at a particular location. In such case the transferrer shall give the transferee a copy of this section and any safety documents identified in the label of the device, or;~~

~~(B) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by the general licensee.~~

~~(4) Assure that all labels affixed to the device at the time of receipt and bearing the statement, "Removal of this label is prohibited" are maintained thereon and comply with all instructions contained in such labels.~~

~~(5) Have the device tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at the time of installation of the device or replacement of radioactive material on the premises of the general licensee and thereafter~~

~~at no longer than six month intervals or at such longer intervals as may be specified in the specific license which authorized distribution of the device to general licenses. Devices containing only krypton need not be tested for leakage. Devices containing only tritium or not more than 100 uCi of other beta and/or gama emitting material or 10 uCi of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any reason.~~

~~(6) Have the test required by Section 30192.1(b)(5) and all other services involving the radioactive material, its shielding and containment performed:~~

~~(A) In accordance with the instructions provided by the label; or~~

~~(B) By a person holding an appropriate license therefor.~~

~~(7) Maintain records of all tests performed on the devices as required under this section, including the dates and results of these tests and the names and addresses of the persons conducting the test.~~

~~(8) Upon occurrence of a failure of or damage to, or any indication of a possible failure of or damage to the shielding or containment of the radioactive material, or of the on-off mechanism or indicator, immediately suspend operation of the device until it has been repaired by or disposed of to a person holding a specific license therefor.~~

~~(9) Within 30 days after the occurrence of a failure of or damage to the shielding or containment of radioactive material or the on-off mechanism or indicator or upon the detection of 0.005 microcuries or more of removable radioactive material, furnish to the Department a complete description of the device (manufacturer, type, serial number) and a brief description of the event and the remedial action taken.~~

~~(c) Persons who possess a device pursuant to the general license contained in Section 30192.1(a) shall with respect thereto be exempt from the requirements of Group 3 of this subchapter except for Sections 30253, 30254, and 30293(a).~~

(a) A general license is hereby issued to commercial and industrial firms, research, educational and medical institutions, individuals in the conduct of their business, and government agencies, to acquire, receive, possess, use or transfer, in accordance with this section, radioactive material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(b) The general license issued pursuant to subsection (a) applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the provisions of:

(1) A specific license, which authorizes distribution of the device, issued by the Department pursuant to section 30195(d);

(2) An equivalent specific license issued by an Agreement State other than this State; or

(3) A specific license issued by the United States Nuclear Regulatory Commission (NRC) under section 32.51 of title 10, Code of Federal Regulations (10 CFR), Part 32.

(c) Devices described in subsection (a) shall have been received from one of the specific licensees described in subsection (b), or through a transfer made pursuant to subsection (d)(12).

(d) Persons who acquire, receive, possess, use or transfer a device under the general license issued pursuant to subsection (a) shall:

(1) Register and renew registration pursuant to section 30108.1 any devices containing at least 10 millicuries (mCi) of cesium-137, 0.1 mCi of strontium-90, 1 mCi of cobalt-60, 0.1 mCi of radium-226, or 1 mCi of americium-241 or any other transuranic (i.e., an element with atomic number greater than uranium (92)), based on the activity indicated on the label. The licensee shall be subject to the reporting requirement in section 30108.1(c) for such devices;

(2) Ensure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon, and comply with all instructions and precautions provided by such labels;

(3) Ensure that the device is tested for leakage of radioactive material and that the on-off mechanism and indicator, if any, operate as designed. These tests shall be performed at intervals no longer than six months or at such other intervals as are specified in the device's label. However:

(A) Devices containing only krypton need not be tested for leakage; and

(B) Devices containing only tritium, or not more than 100 microcuries (uCi) of other beta and/or gamma emitting material or 10 uCi of alpha emitting material, and devices held in storage in the original shipping container prior to initial installation, need not be tested for any purpose;

(4) Ensure that the tests required by subsection (d)(3) and any testing, installation, servicing, and removal from installation involving the radioactive material, its shielding, or containment, are performed:

(A) In accordance with the instructions provided by the device's labels; or

(B) By a person holding a specific license issued by the Department or an Agreement State other than this State, authorizing the licensee to perform those activities;

(5) Maintain records showing compliance with the requirements of subsections (d)(3) and (d)(4), to include the results of tests, the dates of performance of tests, and the names of the persons performing testing, installing, servicing, and removing from the installation radioactive material, its shielding, or containment. The licensee shall retain records of tests required by:

(A) Subsection (d)(3) for three years after the next required test for leakage and test of the on-off mechanism and indicator is performed, or until the sealed source is transferred or disposed of; and

(B) Subsection (d)(4) for three years from the date of the recorded event or other test, or until the device is transferred or disposed of;

(6) Immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 uCi or more of removable radioactive material. The device shall not be operated until it has been repaired by the manufacturer or a person holding a specific license issued by the Department, the NRC, or an Agreement State other than this State, authorizing the licensee to repair the device. The device, and any radioactive material from the device, may only be disposed of in accordance with subsection (d)(10);

(7) Within 30 calendar days of an event specified in subsection (d)(6), submit a report to the Department containing:

(A) A brief description of the event and the remedial action taken; and

(B) If removable radioactive material greater than or equal to 0.005 uCi has been detected, or failure of or damage to a sealed source is likely to result in contamination of the premises or the environs, a plan to ensure that the premises and environs are acceptable for unrestricted use;

(8) Not abandon the device;

(9) Not export the device except in accordance with an export license issued by the NRC pursuant to 10 CFR, Part 110. This provision shall not be construed to incorporate by reference 10 CFR, Part 110;

(10) Transfer or dispose of the device only:

(A) By export as provided by subsection (d)(9);

(B) By transfer to a specific licensee authorized to receive such device or another general licensee as authorized in subsection (d)(12); or

(C) After obtaining written Department approval authorizing transfer or disposal to any other specific licensee not specifically identified in subsection (d)(10)(A) or (B), except that a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if the holder:

1. Verifies that the specific license authorizes the possession and use, or pursuant to section 30194.2 applies for and obtains an amendment to the license authorizing the possession and use;

2. Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by subsection (d)(2)), so that the device is labeled in compliance with section 20.1904 of 10 CFR, Part 20, incorporated by reference in section 30253; however, the manufacturer, model number, and serial number shall be retained;

3. Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

4. Reports the transfer under subsection (d)(11);

(11) Within 30 calendar days after transfer of a device pursuant to subsection (d)(10), submit a report to the Department containing the:

(A) Identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;

(B) Name, address, and license number of the person receiving the device (license number not applicable if exported); and

(C) Date of the transfer;

(12) Transfer the device to another general licensee only if:

(A) The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of this section, sections 30108.1, 30254, 30257 and 30293(a) of this subchapter, sections 20.2201 and 20.2202 of 10 CFR, Part 20, incorporated by reference in section 30253, and any safety documents identified in the label of the device. Within 30 calendar days of the transfer, the transferor shall submit a report to the Department containing:

1. The manufacturer's (or initial transferor's) name;
2. The model number and the serial number of the device transferred;
3. The transferee's name and mailing address for the location of use; and
4. The name, title, and phone number of the responsible individual identified by the transferee pursuant to subsection (d)(15); or

(B) The device is held in storage by an intermediate person in the original shipping container at its intended location of use, prior to initial use by a general licensee;

(13) Comply with sections 20.2201 and 20.2202 of 10 CFR, Part 20, incorporated by reference in section 30253, for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from other requirements in Group 3 of this subchapter, except for sections 30257 and 30293(a);

(14) Upon Department request, provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee is unable to provide the requested information within the allotted time, a request for extending that time shall be submitted prior to the end of the allotted time, and the request for an extension of time shall include a written justification as to why the allotted time should be extended;

(15) Appoint an individual responsible for having knowledge of required actions and authority for taking required actions, so as to comply with this section and all sections cited or referenced within this section. Appointment of the responsible individual does not relieve the general licensee of any of its own responsibility for complying with the Act and this subchapter; and

(16) Not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter shall be locked in the closed position. The testing required by subsection (d)(3) need not be performed during the period of

storage. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they shall be tested for leakage before use or transfer, and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(e) The general license issued pursuant to this section does not authorize the manufacture or import of devices containing radioactive material.

Note: Authority cited: Sections ~~100275~~ and 114975, 115000 and 131200, Health and Safety Code. Reference: Sections 114965, 114970, 114985(g), 115060, 115165, 115230, and 115235, 131050, 131051 and 131052, Health and Safety Code.

(10) Amend Section 30192.2 to read as follows:

§ 30192.2. General Licenses--Aircraft Safety Devices.

(a) A general license is hereby issued to any person to possess, own, receive, acquire and use tritium or ~~promethium-147~~promethium-147 contained within luminous safety devices designed for use in aircraft, provided that each such device contains not more than 10 curies of tritium or 300 millicuries of ~~promethium-147~~promethium-147 and provided further that each such device has been manufactured, assembled, initially transferred or imported in accordance with a specific license authorizing distribution to general licensees.

(b) The general license ~~contained in Section 30192.2~~issued pursuant to subsection (a) does not authorize:

(1) The manufacture, assembly, disassembly, repair, import or disposal of such devices;

(2) The export of luminous safety devices containing tritium or promethium-147;

(23) The use of such devices other than in aircraft; and

(34) The possession, ownership, receipt, acquisition, or use of promethium 147promethium-147 contained in instrument dials.

(c) Persons who possess a device ~~pursuant to~~under the general license ~~contained in Section 30192.2~~issued pursuant to subsection (a) shall, with respect thereto, be exempt from the requirements of Group 3 of this subchapter except for sections 30254 and 30293(a) of this subchapter and sections 20.2201 and 20.2202 of title 10, Code of Federal Regulations, Part 20, incorporated by reference in section 30253~~Sections 30253, 30254, and 30293(a).~~

Note: Authority cited: Sections ~~400275 and~~ 114975, 115000 and 131200, Health and Safety Code. Reference: Sections 114965, 114970, 114985(g), 115000, 115060, 115165, and 115235, 131050, 131051 and 131052, Health and Safety Code.

(11) Amend Section 30192.3 to read as follows:

§ 30192.3. General Licenses—Calibration or Reference Sources.

(a) A general license is hereby issued to persons who hold either a specific license issued by the Department for any radioactive material, or a specific license issued by the United States Nuclear Regulatory Commission for any ~~special nuclear~~ radioactive material, to possess americium-241, ~~or plutonium,~~ or radium-226 in the form of calibration or reference sources. Calibration or reference sources shall be manufactured in accordance with the specifications contained in an appropriate specific license, which authorizes distribution under a general license. Each source possessed pursuant to the general license or its storage container shall bear a label, which includes the information required in the following statement:

"The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license or its equivalent, and are further subject to the regulations of the United States Nuclear Regulatory Commission or ~~of~~ a state with which the United States Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. Removal of this label is prohibited.

CAUTION--RADIOACTIVE MATERIAL--THIS SOURCE CONTAINS (AMERICIUM-241 ~~--241, OR PLUTONIUM, OR RADIUM--226,~~ whichever is appropriate). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

"_____
(Name of Manufacturer or Importer)

(b) Persons who possess a source pursuant to under the general license ~~contained in Section 30192.3~~ issued pursuant to subsection (a) shall:

(1) Not have, at any one time, at any one location of storage or use, more than 5 microcuries of americium-241, ~~and 5 microcuries of plutonium,~~ 5 microcuries of radium-226 contained in such sources.

(2) Not transfer, abandon or dispose of such sources, except by transfer to a person authorized by a license to receive the source.

(3) With respect to each such source when not in use, store the source in a closed container adequately designed and constructed to contain any of the radioactive material in ~~case~~ the event the source is ruptured or leaks.

(4) Not use such source for any purpose other than calibration of radiation detectors or standardization of other sources.

(c) Persons who possess a source pursuant to under the general license contained in ~~Section 30192.3~~ issued pursuant to subsection (a) shall, with respect thereto, be exempt from the requirement of Group 3 of this subchapter, except for sections 30253, 30254, 30255, 30275(a) and (b), 30293, and 30295 ~~Sections 30253, 30254, and 30293(a).~~

(d) The general license issued pursuant to ~~in paragraph~~ subsection (a) of this section does not authorize the manufacture, import, or export of calibration or reference sources containing americium-241, or plutonium, or radium-226 or the introduction of americium-241, plutonium, or radium-226 into any product or material.

Note: Authority cited: Sections ~~400275 and~~ 114975, 115000 and 131200, Health and Safety Code. Reference: Sections 114965, 114970, 114985(g), 115000, 115060, 115165, 115230, ~~and~~ 115235, 131050, 131051 and 131052, Health and Safety Code.

(12) Amend Section 30192.4 to read as follows:

§ 30192.4. General Licenses—Ice Detection Devices.

(a) A general license is hereby issued to any person to possess, own, receive, acquire, use, or transfer ~~strontium-90~~strontium-90 contained in ice detection devices, provided that each device contains not more than 50 microcuries of ~~strontium~~ 90strontium-90, and provided further that each device has been manufactured or imported in accordance with a specific license which authorizes distribution under a general license.

(b) Persons who possess, own, receive, acquire, use or transfer a device ~~pursuant to~~ under the general license contained in Section 30192.4 issued pursuant to subsection (a) shall:

(1) Assure that all labels affixed to the device at the time of receipt, and which bear a statement that prohibits removal of the labels, are maintained thereon; and

(2) Immediately ~~Upon~~ occurrence of damage, discontinue use of the device until it has been inspected, tested for leakage, and repaired by a person holding a specific license authorizing such testing or repair; or dispose of the device pursuant to section 20.2001 of title 10, Code of Federal Regulations, Part 20 (10 CFR 20), incorporated by reference in section 30253.

(c) Persons who possess, own, receive, acquire, use, or transfer a device ~~pursuant to~~ under the general license contained in Section 30192.4 issued pursuant to subsection (a) shall, with respect thereto, be exempt from the requirements of Group 3 of this subchapter, except for sections 30254 and 30293(a) of this subchapter and sections 20.2001, 20.2201 and 20.2202 of 10 CFR 20, incorporated by reference in section 30253~~Sections 30253, 30254 and 30293(a).~~

(d) This general license does not authorize the manufacture, assembly, disassembly, or repair, or import of ice detection devices containing ~~strontium-90~~strontium-90.

Note: Authority cited: Sections ~~400275 and~~ 114975, 115000 and 131200, Health and Safety Code. Reference: Sections 114965, 114970, 114985(g), 115060, 115165, 115230, ~~and 115235, 131050, 131051 and 131052~~, Health and Safety Code.

(13) Amend Section 30192.5 to read as follows:

§ 30192.5. General Licenses—In Vitro Testing.

(a) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to possess and use radioactive material in prepackaged units described in ~~Section 30236, Schedule B, Table I,~~ for in vitro clinical testing, not exceeding the following:

<u>Radionuclide</u>	<u>Maximum uCi* per unit</u>	<u>Maximum uCi total</u>
Tritium.....	50	2,000
Carbon-14.....	10	2,000
Iron-59.....	20	200
Selenium-75.....	10	200
Cobalt-57.....	10	200
Iodine-125 or Iodine-131.....	10	200
Mock Iodine-125 Reference Source		
Iodine-129	0.05	-
Americium-241.....	0.005	-

* microcurie (uCi)

(b) The general licensee shall not possess or use radioactive material ~~pursuant to~~ under the general license contained in this section issued pursuant to subsection (a):

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued by the United States Nuclear Regulatory Commission or a state with which the United States Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority; and

(2) Unless the prepackaged unit bears a label or is accompanied by a package insert containing the following or a substantially similar statement:

"This radioactive material may be received and used only by physicians, veterinarians, clinical laboratories or hospitals, and only for in vitro clinical or laboratory tests not involving internal or external administration of the material or the radiation therefrom to human beings or animals. The receipt, possession, use and transfer of this material is subject to the regulations and general license of the United States Nuclear Regulatory

Commission or ~~the~~ a state with which the Commission has entered into an agreement for the exercise of regulatory authority."

(c) Persons who possess radioactive material pursuant to under the general license contained in ~~Section 30192.5~~ issued pursuant to subsection (a), shall, with respect thereto, be exempt from the requirements of Group 3 of this subchapter, except for ~~Sections 30253, 30254, and 30293(a)~~ that persons using Mock Iodine-125 shall comply with sections 20.2001, 20.2201 and 20.2202 of title 10, Code of Federal Regulations, Part 20, incorporated by reference in section 30253.

Note: Authority cited: Sections ~~400275 and~~ 114975, 115000 and 131200, Health and Safety Code. Reference: Sections 114965, 114970, 114985(g), 115000, 115060, 115165, 115230, ~~and~~ 115235, 131050, 131051 and 131052, Health and Safety Code.

(14) Amend Section 30192.6 to read as follows:

§ 30192.6. General Licenses--Depleted Uranium.

(a) A general license is hereby issued to any person to receive, acquire, transfer, possess ~~and/or~~ use depleted uranium contained in industrial products or devices, for the purpose of providing a concentrated mass of the product or device, when such products or devices are manufactured pursuant to a specific license authorizing distribution to general licensees.

(b) Persons who receive, acquire, use, transfer or possess depleted uranium ~~pursuant to~~ under the general license contained in Section 30192.6 issued pursuant to subsection (a) shall:

(1) ~~Within 30 days of receipt of any such product or device, register with the Department and within 30 days of transfer of any such device, notify the Department in accordance with provisions of Group 1.5 of this subchapter~~ Register in accordance with section 30108.1;

(2) Not introduce such depleted uranium into any chemical, physical or metallurgical treatment or process, other than ~~except~~ a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

(3) Develop, implement and Maintain procedures designed to establish physical control over such depleted uranium in order to prevent its unauthorized use or transfer in any form, including metal scrap;

(4) Appoint an individual responsible for having knowledge of required actions and authority for taking required actions, so as to comply with this section and all sections cited or referenced within this section. Appointment of the responsible individual does not relieve the general licensee of any of its own responsibility for complying with the Act and this subchapter;

(5) Not abandon such depleted uranium;

(46) ~~Not t~~ Transfer, abandon or dispose of such depleted uranium only by transfer in accordance with sections 30210 and 30210.1 ~~except by transfer to a person holding a specific or general license to receive such material.~~

(7) Within 30 calendar days of any transfer, report in writing to the Department the transferee's name and address.

(c) Persons who possess, receive, acquire, transfer or use depleted uranium pursuant ~~to~~under the general license contained in this section ~~issued pursuant to subsection (a)~~ shall, with respect thereto, be exempt from the requirements of Group 3 of this subchapter ~~except for Section 30253, 30254, and 30293(a).~~

Note: Authority cited: Sections ~~400275 and~~ 114975, 115000 and 131200, Health and Safety Code. Reference: Sections 114965, 114970, 114985(g), 115060, 115165, 115230, ~~and 115235, 131050, 131051 and 131052~~, Health and Safety Code.

Article 7. Reciprocal Recognition of Licenses

(15) Amend Section 30225 to read as follows:

§ 30225. Persons Specifically Licensed by Other Agencies.

(a) Any person who holds a specific license issued by the United States Nuclear Regulatory Commission (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. (CRCPD), other than this State, may conduct activities of the kind therein authorized within this State for a period not in excess of 180 days in any calendar year without obtaining a specific license from the ~~department~~Department, provided that the following conditions are satisfied:

(1) The person maintains an office for directing the licensed activity, and at which radiation safety records are normally maintained, in a location under jurisdiction of the agency which issued the specific license;

(2) The license does not limit the authorized activity to specified installations or locations;

(3) The person provides written notice to the ~~department~~Department at least ~~3~~three days prior to engaging in such activity. Such notice shall indicate the location, specific time period, and type of proposed possession and use within this state, and shall be accompanied by a copy of the pertinent license. If, for a specific case, the 3-day period would impose an undue hardship on the person, the person may make application to the ~~department~~Department to proceed sooner;

(4) The person complies with all applicable regulations of the ~~department~~Department and with all the terms and conditions of the license, except such terms and conditions which as may be inconsistent with said regulations;

(5) The person supplies such other information as the ~~department~~Department may request; and

(6) The person pays a fee in accordance with section 30230(f) to the Department, prior to the engagement of activities within the state.

(b) Any person who holds a specific license issued by the ~~United States Nuclear Regulatory Commission~~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. CRCPD,~~ other than this State, authorizing the holder to manufacture, install or service a device described in section 30192.1(a), ~~shall be~~ is hereby issued a general license to install or service such device in this State, provided that ~~the following conditions are satisfied:~~

(1) The person files a report with the ~~d~~Department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State, identifying each device recipient by name and address, identifying the type of device transferred or installed, and identifying the quantity and type of radioactive material contained in each device.;

(2) The device has been manufactured and labeled and is installed and serviced in accordance with applicable provisions of the specific license.;

(3) The person assures that any labels required to be affixed to the device, under regulations of the authority which licensed manufacture of the device, are affixed and bear a statement that "Removal of this label is prohibited.;" and

(4) The person furnishes to each device recipient in this State to whom he or she transfers such a device, or on whose premises he or she installs the device, a copy of the regulations contained in Group 1.5 of this subchapter, ~~of and~~ sections 30192.1(a) and (b) of this regulation, ~~and of sections 30253, 30254, 30257, 30293(a)(2) and 30295 of Group 3 of this subchapter, and sections 20.2201 and 20.2202 of title 10, Code of Federal Regulations, Part 20, incorporated by reference in section 30253.~~

(c) The ~~department~~Department may withdraw, limit, or qualify its acceptance of any license specified in ~~sections 30225~~subsection (a) or (b) upon determining that such action is necessary to protect health or to minimize danger to life or property.

(d) Authorization granted pursuant to this section does not authorize a person to conduct activities in areas within this State that are under exclusive federal jurisdiction.

Note: Authority cited: Sections ~~400275~~ 114975, 115000, and 115060 and 131200, Health and Safety Code. Reference: Sections 114965, 114970, 114985, 114990, 115060, 115065, 115090, 115093, 115105, 115110, 115120, 115165, 115230, and 115235, 131050, 131051 and 131052, Health and Safety Code.

(16) Adopt Section 30226 to read as follows:

§ 30226. Persons Generally Licensed by Other Agencies.

(a) A person generally licensed by the United States Nuclear Regulatory Commission, or an Agreement State other than this State, is not subject to the registration requirements specified in section 30192.1(d)(1) if the device is used in areas subject to the Department's jurisdiction for a period less than 180 days in any calendar year.

(b) Authorization granted pursuant to this section shall not authorize a person to conduct activities in areas within this State that are under exclusive federal jurisdiction within this State.

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

Article 9. Schedules

(17) Repeal Section 30236 as follows:

§ 30236. Schedule B, Table 1, In Vitro Clinical Tests.

<i>Radionuclide</i>	<i>Maximum Microcuries Per Unit</i>	<i>Maximum Microcuries Total</i>
Hydrogen 3.....	50	2,000
Carbon 14.....	10	2,000
Iron 59.....	20	200
Selenium 75.....	10	200
Cobalt 57.....	10	200
Iodine 125 or Iodine 131.....	10	200
Mock Iodine 125		
Reference Source		
Iodine 129.....	0.05	-
Americium 241.....	0.005	-

Note: Authority cited: Sections 208 and 25811, Health and Safety Code. Reference: Sections 25801, 25802, 25811, 25815, 25855, 25875 and 25876, Health and Safety Code.

Group 3. Standards for Protection Against Radiation
Article 2. Notices, Instructions, and Reports to Workers; Inspections and Investigations

(18) Amend Section 30257 to read as follows:

§ 30257. Bankruptcy Notification.

(a) Each general licensee required to register pursuant to sections 30192.1(d)(1) or 30192.6(b)(1), and each specific licensee, shall notify the Department in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter ~~or~~of title 11 (Bankruptcy) of the United States Code (11 U.S.C.) by or against:

- (1) ~~Any~~The licensee;
- (2) An entity (as that term is defined in 11 U.S.C. 101 (14)) controlling the licensee or listing the license or licensee as property of the estate; or
- (3) An affiliate (as that term is defined in 11 U.S.C. 101 (2)) of the ~~licensee~~licensee.

(b) ~~This~~The notification to the Department ~~must~~ shall indicate:

- (1) The bankruptcy court in which the petition for bankruptcy was filed; and
- (2) The date of the filing of the petition.

Note: Authority cited: Sections ~~208 and 25811~~ 114975, 115000 and 131200, Health and Safety Code. Reference: Sections ~~28501, 28502, 25815, 25860, 25863, 25875 and 25876~~ 114965, 114970, 115060, 115175, 115205, 115230, 115235, 131050, 131051 and 131052, Health and Safety Code.