Initial Statement of Reasons

Summary of the Proposed Regulations

This proposal addresses the possession of radioactive material (RAM) under a general license, which is a license issued pursuant to regulation and allows a person to possess and use certain types of devices containing RAM or specific amounts of RAM isotopes. It further addresses applicable sections of title 10, Code of Federal Regulations, Parts 31, 40, and 150 to maintain California's continuing compatibility with the U.S. Nuclear Regulatory Commission's (NRC) regulations.

Authority

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

The Radiation Control Law (HSC sec. 114960 et seq.) requires the Department to develop programs for licensing and regulating radioactive materials (HSC sec. 115000(b)). In 1962, the California Legislature granted approval for the State to enter into an agreement with the United States Atomic Energy Commission (AEC), the predecessor of the current NRC. By such action the AEC discontinued its regulatory authority over certain radioactive materials within the State (HSC sec. 115230), and California became an "Agreement State."

A provision of the agreement between California and the NRC specifies that the State "will use its best efforts to maintain continuing compatibility between its program and the program of the [United States Atomic Energy] Commission for the regulation of like materials." (HSC sec. 115235, art. V.) NRC's stated policy is "to evaluate Agreement State programs established pursuant to Section 274 of the Atomic Energy Act of 1954, as amended, to ensure they are adequate to protect public health and safety and compatible with NRC's regulatory program." [1] To determine a state's compatibility, the NRC uses Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*, *Handbook 5.9.* [2] This handbook describes the specific criteria and process that are used to clarify both the NRC program elements that should be adopted and implemented by an Agreement State for purposes of compatibility, and also those NRC program elements that have a particular health and safety significance. The NRC rates the elements on the degree of compatibility required. Thus, the NRC requires that

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

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

some be adopted by the states in a form identical to the NRC's while the adoption of others need not be identical but is required to meet the essential objective of the program element. (For NRC compatibility definitions, see Attachment 1.) The overall determination of adequacy and compatibility for an Agreement State is made pursuant to Management Directive 5.6, *The Integrated Materials Performance Evaluation Program (IMPEP)*. [3] The NRC evaluates Agreement States every four years to determine if a state's radiation safety program meets the adequacy and compatibility criteria. If California fails to meet those criteria the NRC may revoke California's status as an Agreement State.

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

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

The authority and reference citations are being amended, resulting in nonsubstantial changes pursuant to title 1, California Code of Regulations, (CCR) section 100, to reflect the following:

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

Because the radiation control program must maintain compatibility with the regulations of the United States Atomic Energy Commission, the predecessor to the United States Nuclear Regulatory Commission (HSC sec. 115230), and "maintain continuing compatibility between its program and the program of the [United States Atomic Energy] Commission for the regulation of like materials..." (HSC sec. 115235, art. V), the Department has determined that no alternative considered by the Department would be

[3] "Integrated Materials Performance Evaluation Program (IMPEP)," Management Directive 5.6. The document is available at the Nuclear Regulatory Commission, Office of State Programs website: http://nrc-stp.ornl.gov/procedures.html. (Reference 2.)

more effective in carrying out the purpose for which the regulation is proposed, or would be less burdensome to affected private persons than the proposed regulation.

The following table identifies the state regulation proposed to be changed or adopted and the corresponding federal regulation, if applicable, found in 10 CFR 31, 40, and 150. The table lists existing or proposed regulations, and references the required level of compatibility that is necessary for compliance with the NRC's corresponding regulations. The table also describes and explains any differences between the state and federal regulations, states the reasons for the differences, and explains the purpose and reasons for the proposed regulation change.

Existing or Proposed Section	**10 CFR Section**	**Compatibility Category**	**Description & Rationale** NE = No Equivalent, I = Identical, EI = Essentially Identical, EO = Essential Objective[4]
30108			NE. This section is proposed to be amended to reference all sections in Group 1.5, not just those within the stated range, as they are all applicable to registration requirements. This amendment also includes the new section in this group proposed for adoption in this package.
30108.1	31.5 & 40.25	B & C, respectively.	EI. Subsection (a) is needed to specify the information that must be submitted for registration. The requirement to register within 30 calendar days of taking possession of a device or product is needed for consistency with both NRC's provision (10 CFR 31.5(c)(13)(ii)) and the Department's provision in section 30110(a). In subsection (a)(1), the applicant's legal name, mailing address and telephone number are needed so that the Department knows who is responsible for maintaining control of the device, where to mail documents, and how to contact the person by telephone. A phone

[4] The Essential Objective (EO) of the NRC regulation is stated in NRC's draft revision of Procedure SA-200 "*Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements* - SA-200" available on the Internet at: http://nrc-stp.ornl.gov/procedures.html. (Reference 3.) (Note: Regulations that are essentially identical meet the essential objective.)

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			number allows the Department to increase its ability to easily contact the licensee to verify device, personnel, and registration information. As further discussed regarding proposed section 30192.1(d)(15), NRC found through a survey that identified problems could be resolved by more frequent and timely contact with general licensees. For renewing applicants, providing the general license registration number allows staff to efficiently process applications by directly opening registration files without lengthy file searches. Subsection (a)(2)(A) is needed so that Department staff can know the device's location for inspection purposes, which includes the ability of the registrant to track each device so that it does not end up in a scrap yard, verifying that the required tests are performed, and verifying that the device is used in accordance with existing laws and regulations. The specific device information is needed to ensure that a device that is not manufactured for use under a general license is not received. If such a device is received, a greater hazard exists, in that devices manufactured for use under a specific license emit greater radiation levels and are to be used by individuals with extensive training in their use. Subsection (a)(2)(B) is needed to identify the general licensee's designated individual and to allow the Department to easily contact the designee in order to schedule inspections and obtain information, should a situation arise in which the Department must contact the licensee. Subsection (a)(2)(C) is needed to identify from whom the licensee received the device. This is consistent with NRC's implementation of 10

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			CFR 31.5(c)(13)(iii) as indicated in Section 2 of NRC's Form 664 (3-2007), used by licensees to register and identify a device distributor. (NRC Form 664 (3-2007) is available at: http://www.nrc.gov/reading-rm/doc-collections/forms/nrc664.pdf.) Requiring this information is needed to ensure the device transfer was in accordance with NRC and state requirements. Subsection (a)(2)(D) is needed to ensure the general licensee's designated individual is aware of their responsibility regarding the registered device, and to maintain consistency with NRC's provision in 10 CFR 31.5(c)(13)(iii)(E) & (F), as implemented by NRC in Section 5 of NRC Form 664 (3-2007). Subsection (a)(3) is needed for consistency with NRC's provision in 10 CFR 40.25(c)(1)(iii), which is designated as a compatibility category C. Even though the Department is not required to adopt this provision as written, the Department agrees that designation of an individual by the general licensee as being the person responsible for ensuring the security of the device is essential. Such a requirement helps to ensure that the device does not make its way into the general public, especially into a scrap metal facility, where it could be melted and used in a broad range of consumer products. Thus, this subsection is adopted essentially identical to NRC's provision. Subsection (a)(3)(A) is needed so that registrants, if registering a device as described in section 30192.6(a), provide written acknowledgement of their responsibility to maintain physical control of the radioactive source, and to prevent unauthorized transfer. This provides the

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			Department written assurance that the registrants have been informed of their responsibility. Subsection (a)(3)(B) is needed for consistency with NRC's implementation of this registration program. This also provides the Department with a contact person. Subsection (a)(4) is needed to inform the applicant that there is a specified registration fee, with an exception regarding devices possessed pursuant to section 30192.6, because these devices are almost exclusively used in commercial and military aircraft. The owners are mostly found on federal facilities, or are aerospace contractors who already possess specific licenses for possession of radioactive materials. Thus, either the licensees are not within the Department's jurisdiction, or they already pay fees for the specific license. Charging an additional fee would equate to duplicate fees; therefore, no fee is proposed for registration of devices under section 30192.6. Subsection (b) is needed to inform the registrant how often they must renew the registration, and to inform them what they must submit in order to renew. The requirement of annual renewal of registration is specified in current regulations at section 30111; however, that section does not clearly identify the information that is required for renewal. The NRC is very specific in 10 CFR 31.5 that the general licensee must annually update its registering information on all devices. Therefore, the regulated public needs to be aware of the need to resubmit all registering information annually, so that the Department may keep track of all such devices. Monitoring of devices helps to ensure public health and safety. Monitoring for proper use of such

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			devices is part of the Department's responsibility for radiation control and safety as an Agreement State agency. Subsection (c) is needed to ensure that the Department maintains current information on the registrant, and on the use and location of a device. This is important in case notification is needed relating to any defects in devices and sources that could result in harm to the health of the public or workers. The NRC requires all changes in the location or use information provided to it and to Agreement States to be updated within 30 calendar days of any change, in order to ensure public safety. (10 CFR 31.5(c)(14).) The Department agrees with this requirement and finds it is compatible with notification requirements for all changes in registration information, as specified in current regulation in section 30115.
30115			NE. This section is proposed to be amended to exempt persons possessing devices pursuant to sections 30192.1 or 30192.6 from these reporting requirements, as they must comply instead with reporting requirements of 30108.1. The term "registrant" is added to specify whose address is required to be reported. Commas are added as nonsubstantial grammatical changes.
30125			NE. This section is proposed to be amended to add that a person possessing devices pursuant to section 30192.6 is not excluded from registration requirements. This change is needed for consistency with section

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			30100(t) and the proposed changes in section 30192.6(b)(1). A capitalization change is made to the word "section" and it is made plural to be grammatically correct in the amended sentence.
30145			NE. This section is proposed to be amended to specify the fees for registering devices described in section 30192.1, and to specify other provisions in the section due to the proposed addition of specified fees. Proposed subsection (c) is needed to specify the registration fee for general licensees that covers the costs of the following functions, based on similar functions performed for registration of X-ray machines: 1. Processing registration forms containing submitted information; 2. Processing data input, transferring data, processing informational change requests, billing and cashiering, developing forms and website, and maintaining correspondence and documentation; 3. Conducting routine and verification inspections including scheduling, travel, site visit, correspondence, follow-up as needed, and documentation; and 4. Performing investigations and complaint inspections to evaluate allegations or complaints. Performance includes scheduling, travel, site visit, correspondence with general licensee and (when needed) complainant, follow-up, and documentation. The proposed registration fee of $70 for each

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			device covers the cost of the above functions by program support staff ($40) and program health physicist staff ($30) [$40 + $30 = $70] as follows: • Program support staff (management services technicians (MST)) perform items 1 and 2. Total annual program costs for these staff are about $86,410, resulting in an hourly rate, accounting for staff-leave time, of about $48 ($86,410 ÷ 1800 hours = $48.01). Based on Department information on the number of such devices, there are approximately 4,500 devices subject to registration in about 2,500 locations. Estimated time to perform all activities for a given device is 50 minutes (0.83 hour) resulting in a cost of $40 per device ($48 per hour X 0.83 = $39.84). • Program Health Physicist (HP) staff perform items 3 and 4. Total annual program cost for HP staff is about $135,000. Based on staff experience and the following estimated workload, it is estimated that one HP staff (i.e. one full-time equivalent) is needed to perform this workload resulting in a cost of $30 per device ($135,000 ÷ 4,500 = $30): ○ 500 routine annual inspections. Pursuant to Health and Safety Code section 115070 inspection priorities are based on priorities established by NRC. NRC's applicable designated priority is five, meaning an inspection is performed once every five years. (Reference 4.) Thus, inspections are set at five year intervals, resulting in about 500

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			annual inspections. The estimated average number of devices at each location is 2 (4,500 devices divided by 2,500 locations = 1.8). ○ An annual average of 12 investigations at 16 hours each. ○ 2,500 verification inspections in which each general licensee (2,500) is contacted by phone to verify device and personnel contact information. New subsection (c) exempts persons holding a specific license for a device from the requirement to pay this registration fee. This exemption is proposed because a specific licensee pays annual fees as specified in section 30230, which cover Department costs of license issuance, license maintenance, and inspecting the licensee's activities related to radiation safety. Thus, charging specific licensees for a general license would result in payment of duplicate fees. Former subsections (c) through (i) are redesignated (d) through (j) to accommodate proposed new subsection (c). In redesignated subsection (d), former (c), the word subsection is added as a grammatical clarification, and the reference to former (d) is changed to redesignated (e). Newly redesignated subsection (f) is amended to add two references to a device. These additions provide consistency in extending the same transfer of registration allowances to devices as to radiation machines. In newly redesignated subsection (g), the

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			reference to former subsection (d) is changed to newly redesignated (e).
30190	30.31	C	EI. Subsection (b) is amended to specify that applications are not required for general licenses except for general licenses requested for devices under sections 30192.1 and 30192.6, which have their own registration requirements. Subsection (c) is amended to delete references to sections 30181 and 30182, which were repealed in 1986 and 1985, respectively. References to sections 30192.1 through 30192.6, consecutive, and 30226 are added because all of those sections concern registration requirements for the possession of material not requiring a specific license. Capitalization corrections are made to the words Department and sections. The authority and reference note is added since it is missing in the existing section.
30191	40.22	B	EI. In subsection (a), changes are made for consistency with NRC's provision regarding the word "transfer." This also provides clarity as the current wording could be construed to exclude transferring of source material and thereby failing to meet compatibility category B. By including the word "transfer" the licensee is informed that the general license allows the transferring of the material as is clearly allowed under NRC's provision. Nonsubstantial grammatical changes are made by changing "education" to "educational" and adding "institutions," for ease of reading. Commas are

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			deleted as grammatical corrections. Additional nonsubstantial grammatical changes are made in the last sentence, and a capitalization correction is made to the word "sections." The reference to section 30253 is deleted. Prior to 1994, section 30253 contained a general requirement limiting radiation exposures and releases of radioactive material in effluents to uncontrolled areas, with exposures and releases to be as low as reasonably achievable. The reference in existing section 30191 (and in most other sections dealing with general licensing of devices containing radioactive materials) to this exception from exemption for section 30253 was specified in regulation prior to 1994. In 1994, the Department amended section 30253 to incorporate by reference NRC's regulations, 10 CFR 20, which address broader standards for protection against radiation. These broader standards are not applicable to possessors of radioactive material licensed under general licenses, such as the general license issued in section 30191, because the radioactive materials in the amounts specified that are so licensed can be handled safely without the restrictions specified in 10 CFR 20. The NRC specified the exemption from the 10 CFR 20 requirements in its regulations in order to minimize the regulatory burden on general licensees, as it is truly not a public health and safety issue. The Department agrees with this rationale, including this exemption in its general licensing regulations. In subsection (b), "Section 30191" is replaced by "subsection (a)," because it is unnecessarily cumbersome to specify the section number when referring to a subsection within the same section. Semi-colons are

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			changed to commas as nonsubstantial grammatical corrections. This amendment also contributes to consistency in the subsection references in the regulations contained in title 17, Division 1, Chapter 5, Subchapter 4.
30192	31.3	B	EI. Subsection (a) is amended by inserting the terms “tested” and “labeled” to maintain consistency with the NRC provision. This amendment informs general licensees that testing and labeling of static eliminators and air ionization devices is required to be conducted by the specific licensee prior to distribution of the devices. The NRC requires that the specific licensee conduct this activity prior to distribution, because general licensees do not have the knowledge or expertise to address the testing and labeling of items containing radioactive material. The general license is only to be issued if the static eliminator and air ionization devices containing the radioactive material have been tested and labeled by a specific licensee prior to the general licensee receiving it. Subsections (a)(1) and (a)(2) are amended by inserting a hyphen between the name of a radionuclide (polonium) and its mass number (210). In (a)(2) the name of the “hydrogen 3” radionuclide is changed to its more common name, “tritium.” These changes are nonsubstantial and made for consistency with existing title 17, Division 1, Chapter 5, Subchapter 4 regulations. Subsection (b) is amended to delete the reference to section 30253 for the same reason

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			stated regarding section 30191(a).
30192.1	31.5	B	EI. This section is proposed to be amended to maintain compatibility with the final rules issued by the NRC regarding general licenses. (65 Fed.Reg. 79161 (Dec. 18, 2000) & 72 Fed.Reg. 58473 (Oct. 16, 2007).) Existing language is deleted and replaced with NRC-equivalent provisions. Also, the section is reorganized to more closely, though not exactly, follow the provision order in 10 CFR 31.5. Further, the term “byproduct material” as used in 10 CFR 31.5 is changed to “radioactive material” in this proposal because, within the State, CDPH has regulatory authority over types of material not subject to federal law. Under NRC’s policies (Reference 3d, Appendix B), this change is a nonsubstantial difference.
(a)	(a)	B	EI. Existing subsection (a) is amended to more closely resemble and follow the NRC’s provision as required under compatibility category B. Existing subsections (a)(1) and (a)(2) are recodified and apportioned to proposed subsections (b) and (d)(2), respectively. Existing subsection (a)(3) is recodified to subsection (d)(2).
(b)	(b)(1)	B	EI. Portions of existing subsections (a), (a)(1) & (2) are recodified to proposed subsection (b). The phrase “when such devices are manufactured pursuant to a specific license authorizing distribution to general licensees provided that each such device:” found at the end of existing subsection (a) and just prior to

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			existing subsection (a)(1) is placed in this subsection. The proposal rewords the conditional language of the existing phrase to be a statement and is nonsubstantial. The subsection is formatted to clearly present the items. The reference to federal regulations in subsection (b)(3) only provides a cross-reference to NRC regulations and is not incorporated by reference.
(c)	(b)(2)	B	EI. Proposed subsection (c) is needed to clearly inform the regulated community that, because radioactive material can present a hazard to people and the environment, these devices must be received or transferred in controlled ways. Differences between NRC's provision and this proposal are nonsubstantial.
(d)	(c)	B	EI. Existing subsection (b) is recodified into proposed subsection (d) and modified for consistency with NRC's provision. Differences between NRC's provision and this proposal are nonsubstantial.
(d)(1)	(c)(13)(i)	B	EI. Existing subsection (b)(1) is recodified to proposed subsection (d)(1) and modified for consistency with NRC's provision. Currently, any person possessing a device used for those purposes specified in subsection (a) must register. This proposal narrows that provision by requiring registration of only those devices meeting the specified criteria. Differences between NRC's provision and this proposal are nonsubstantial.

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(d)(2)	(c)(1)	B	EI. Existing subsection (b)(4) is recodified to proposed subsection (d)(2) and modified for consistency with NRC's provision. Differences between NRC's provision and this proposal are nonsubstantial.
(d)(3)	(c)(2)	B	EI. Existing subsection (b)(5) is recodified to proposed subsection (d)(3) and modified for consistency with NRC's provision. The phrase "at the time of installation of the device or replacement of radioactive material on the premises of the general licensee" found in existing subsection (b)(5) is recodified to proposed subsection (d)(4). See that subsection for discussion. Differences between NRC's provision and this proposal are nonsubstantial.
(d)(4)	(c)(3)	B	EI. Existing subsection (b)(6) is recodified to proposed subsection (d)(4) for consistency with NRC's provision and to consolidate provisions. Differences between NRC's provision and this proposal are nonsubstantial.
(d)(5)	(c)(4)	B	EI. Existing subsection (b)(7) is recodified to proposed subsection (d)(5) for consistency with NRC's provision. Currently, existing subsection (b)(7) requires retention of addresses. This proposal removes this additional record retention requirement because it is not necessary for ensuring required tests are performed properly. This removal is consistent with NRC's provision. Differences between NRC's provision and this

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			proposal are nonsubstantial.
(d)(6)	(c)(5)	B	EI. Existing subsection (b)(8) is recodified to proposed subsection (d)(6) and modified for consistency with the first three sentences of NRC's provision relating to suspension of operation. Differences between NRC's provision and this proposal are nonsubstantial.
(d)(7)	(c)(5)	B	EI. Existing subsection (b)(9) is recodified to proposed subsection (d)(7) and modified for consistency with the reporting provision in NRC's provision. Differences between NRC's provision and this proposal are nonsubstantial.
(d)(8)	(c)(6)	B	EI. Existing subsection (b)(2) relating to the prohibition of abandonment is recodified to proposed subsection (d)(8) for consistency with NRC's provision and to emphasize the prohibition. Differences between NRC's provision and this proposal are nonsubstantial.
(d)(9)	(c)(7)	B	EI. Proposed subsection (d)(9) is needed to address NRC's provision. Under the federal Atomic Energy Act of 1954, as amended, Agreement States are not authorized to issue export licenses. (42 U.S.C. section 2021(c).) The reference to NRC's regulations relating to export is for clarity and consistency and is not incorporated in this proposal. The sentence "This provision shall not be constructed to incorporate by reference 10 CFR 110" is needed to inform licensees that 10 CFR 110 is not incorporated by reference.

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			Differences between NRC's provision and this proposal are nonsubstantial.
(d)(10)	(c)(8)(i) & (iii)	B	EI. This proposed subsection clarifies and combines issues of transfer found in existing subsections (b)(2) and (b)(8) (recodified to proposed subsections (d)(12) and (d)(10), respectively). This consolidation results in consistency with NRC's provision. Subsection (d)(10) is needed for clarity so the general licensee can easily find the requirements for transfer or disposal of the device. Subsection (d)(10)(C) also addresses NRC changes regarding reporting requirements (72 Fed.Reg. 58473 (Oct. 16, 2007)). Differences between NRC's provision and this proposal are nonsubstantial.
(d)(11)	(c)(8)(ii)	B	EI. Existing subsection (b)(1) addressing transfer notification required by Group 1.5, Registration of Radiation Sources, (i.e. sections 30108 through 30146) is recodified to proposed subsection (d)(11) for consistency with NRC's provision. Differences between NRC's provision and this proposal are nonsubstantial.
(d)(12)	(c)(9)	B	EI. Existing subsection (b)(3) is recodified to proposed subsection (d)(12) for consistency with NRC's provision. Existing subsection (b)(3)(A) requires the transferor to give the transferee a copy of section 30192.1 and any safety documents identified in the label of the device. The proposal modifies this requirement to include all cited sections for

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			consistency with NRC's provision (10 CFR 31.5(c)(9)(i)). This ensures the general licensee is aware of those provisions applicable to possession of the device under the general license. Differences between NRC's provision and this proposal are nonsubstantial.
(d)(13)	(c)(10)	B	EI. Existing subsection (c) is recodified to proposed subsection (d)(13) for consistency with NRC's provision. The inclusion of section 30257 is needed to inform the regulated community that licensees must notify the Department of bankruptcy proceedings. See section 30257 for further discussion. Differences between NRC's provision and this proposal are nonsubstantial.
(d)(14)	(c)(11)	B	EI. Proposed subsection (d)(14) is added to address NRC's provision. The NRC adopted this provision to institute an annual registration program for certain devices. The registration program ensures that general licensees are aware of and understand the requirements for the possession of these devices. The registration process allows NRC to account for devices that have been distributed for use under the general license. The NRC believes that if general licensees are aware of their responsibilities, then they will comply with the requirements for proper handling and disposal of these devices. This would help reduce the potential for incidents that could result in unnecessary radiation exposure to the public, as well as contamination of property. (63 Fed.Reg. 66492 (Dec. 2, 1998); 64 Fed.Reg. 42269 (Aug. 4, 1999).)

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			The Department has an equivalent registration program with many of the same oversight issues. Therefore, the Department proposes to adopt this provision for the reasons stated by NRC. Differences between NRC's provision and this proposal are nonsubstantial.
(d)(15)	(c)(12)	B	EI. Proposed subsection (d)(15) is added to address NRC's provision. The NRC conducted a 3-year sampling (1984 through 1986) of general licensees to assess the effectiveness of the general license program. The sampling revealed several areas of concern regarding the use of generally licensed devices. In particular, the NRC concluded that many general licensees were: • Unaware of the regulations that apply to the possession of a generally licensed device; and • Were unable to account for their devices. Approximately 15 percent of the general licensees sampled could not account for all of their generally licensed devices. The NRC concluded that these problems could be resolved by more frequent and timely contact between general licensees and the NRC. (64 Fed.Reg. 40295 (July 26, 1999).) The Department continues to find that these devices are being improperly disposed of. Thus, this proposed subsection would ensure that the general licensee is more aware of the regulatory provisions, and should reduce the rate of improper disposal or transfer of these devices. Differences between NRC's provision and this

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			proposal are nonsubstantial.
	(c)(13)(ii), (iii), & (iv)	B	EI. Regarding 10 CFR 31.5(c)(13)(iii), see discussion of proposed section 30108.1. NRC's reference to bankruptcy provisions in 10 CFR 31.5(c)(13)(ii) is addressed in proposed subsection (d)(13). Regarding 10 CFR 31.5(c)(13)(iv), see discussion of proposed section 30226.
	(c)(14)	B	EI. See section 30108.1 for discussion.
(d)(16)	(c)(15)	B	EI. Proposed subsection (d)(16) is needed to address NRC's provision. Differences between NRC's provision and this proposal are nonsubstantial.
(e)	(d)	B	EI. The term "byproduct" used in the NRC provision is changed to "radioactive" in the proposal since the Department regulates all radioactive material, not just byproduct material. Under the NRC's procedures (Reference 3d, Appendix B), this is a nonsubstantial difference.
30192.2	31.7	B	EI. This section is amended to maintain consistency with the corresponding NRC provision regarding general licenses for possession of source material contained in aircraft safety devices in 10 CFR 31.7. Subsection (a) is amended by inserting a hyphen between the name of a radionuclide (promethium) and its mass number (147) for consistency with existing title 17, Division 1, Chapter 5, Subchapter 4 regulations, and other nonsubstantial grammatical and punctuation changes are also made.

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			In subsection (b) the reference to "Section 30192.2" is replaced with a reference to "subsection (a)" because it is unnecessarily cumbersome to specify the section number when referring to a subsection within the same section. Nonsubstantial grammatical and punctuation changes are made. Subsection (b) is also amended by inserting a hyphen between the name of a radionuclide (promethium) and its mass number (147) for consistency with existing title 17, Division 1, Chapter 5, Subchapter 4 regulations. In subsection (c) the reference to "Section 30192.2" is replaced with a reference to "subsection (a)" because it is unnecessarily cumbersome to specify the section number when referring to a subsection within the same section. Nonsubstantial grammatical and punctuation changes are made. The reference to section 30253 is deleted for the reasons stated regarding section 30191(a). The NRC still requires the general licensee who possesses aircraft safety devices containing promethium-147 to adhere to the requirements of reports of theft and loss of such devices, and notification of incidents involving those devices is required for the purpose of ensuring public safety. Such reports are not considered by the NRC to be excessively burdensome to the general licensee, and the Department agrees with this determination in the interest of minimizing radiation exposure due to device theft or loss, or an incident involving the device, so as to help ensure public safety.
30192.3	31.8	D	EI. Though the NRC has designated 10 CFR

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			31.8 as compatibility category D, meaning the provision is not required for compatibility purposes, section 30192.3 was originally adopted when California became an Agreement State to maintain consistency with federal regulation. This section is proposed to be amended to maintain consistency with the corresponding NRC provision regarding general licenses for the possession of source material contained in calibration or reference sources in 10 CFR 31.8. Further, these amendments are made to maintain consistency with other states, such as those identified below. Subsection (a) is amended to add radium–226 as a source subject to this general license category. These changes provide consistency with other states, such as Texas (25 TAC 289.251(f)(4)(D), Washington (WAC 246-233-035(5)(a), Oregon (OAC 333-102-0125), Colorado (6 CCR 1007-1, 3.6.7.5), and Louisiana (LAC 33:XV:322.G.5.), and are consistent with state law (Health & Saf. Code, sections114965(c) and 114970). Nonsubstantial grammatical and punctuation changes are made to the section and to the language in the specified label statement. In subsection (b) the reference to “Section 30192.3” is replaced with a reference to “subsection (a)” because it is unnecessarily cumbersome to specify the section number when referring to a subsection within the same section, and a nonsubstantial grammatical change is made. In subsection (b)(1) the phrase “5 microcuries of radium-226” is added to be consistent with the amendment made to subsection (a).

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			Nonsubstantial grammatical and punctuation changes are also made. Subsection (b)(3): a nonsubstantial grammatical change is made. In subsection (c) the reference to "Section 30192.3" is replaced with a reference to "subsection (a)" because it is unnecessarily cumbersome to specify the section number when referring to a subsection within the same section, and nonsubstantial grammatical and punctuation changes are made. The reference to section 30253 is deleted for the reasons stated regarding section 30191(a). Subsection (d) contains nonsubstantial grammatical changes. The number "241" is added to "americium," and "radium-226" is added, to be consistent with the radioisotope references in subsection (a).
30192.4	31.10	B	EI. This section is proposed to be amended to maintain consistency with the corresponding NRC provision regarding general licenses for possession of source material contained in ice detection devices in 10 CFR 31.10. Subsections (a) and (d) are amended by inserting a hyphen between the name of a radionuclide (strontium) and its mass number (90) for consistency with such designations in existing Title 17, Division 1, Chapter 5, Subchapter 4 regulations. Subsection (a) also contains a nonsubstantial grammatical change. In subsection (b) the reference to "Section 30192.4" is replaced with a reference to "subsection (a)" because it is unnecessarily

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			cumbersome to specify the section number when referring to a subsection within the same section, and nonsubstantial grammatical changes are made. Subsection (b)(1) contains nonsubstantial grammatical and punctuation changes. In subsection (b)(2), the term “immediately” is added to emphasize that the device, if damaged, may not be used during the interval from when the damage occurred to when it is inspected, tested for leakage, and repaired if needed. This emphasis is needed because the radioactive material could be leaking from the device. If the material is leaking and the device continues to be used, equipment, personnel, and the surrounding facilities could become contaminated requiring major and expensive clean up efforts. Thus, removing the damaged device from service minimizes exposure to radiation and contamination. Lastly, a comma is added as a nonsubstantial punctuation change. Subsection (c) is amended to delete the reference to section 30253 for the reasons stated regarding section 30191(a). The NRC still requires the general licensee who possesses ice detection devices containing strontium-90 to adhere to the requirements regarding reports of theft and loss of such devices, and notification of incidents involving those devices, for the purpose of ensuring public safety. Such reports are not considered by the NRC to be excessively burdensome to the general licensee, and the Department agrees with this determination in the interest of minimizing radiation exposure due to theft or loss or incidents involving the devices, to help ensure public safety.

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			In addition, the reference to "Section 30192.4" is replaced with a reference to "subsection (a)" because it is unnecessarily cumbersome to specify the section number when referring to a subsection within the same section, and nonsubstantial grammatical and punctuation changes are made. This amendment also contributes to consistency in the subsection references in the regulations contained in Title 17, Division 1, Chapter 5, Subchapter 4.
30192.5	31.11	D	EO. Though NRC has designated 10 CFR 31.11 as compatibility category D, meaning the provision is not required for compatibility purposes, section 30192.5 was originally adopted when California became an Agreement State to maintain consistency with federal regulation. In subsection (a) the reference to section 30236 is deleted, as that section itself is being deleted. Table in existing section 30236 is being added to this section, because it is related only to in vitro clinical tests. The term "Tritium," also known as "Hydrogen-3," is being used in this section, for consistency with other references to that name for the radionuclide in title 17, Division 1, Chapter 5, Subchapter 4 regulations. A nonsubstantial grammatical change is added. In subsection (b) the reference to "this section" is replaced with a reference to "subsection (a)" because it is unnecessarily cumbersome to refer to a section within the same section. And nonsubstantial grammatical changes are made.

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			Subsections (b)(1) and (b)(2): nonsubstantial grammatical and punctuation changes are made. Subsection (c) is amended to delete the reference to section 30253 for the reasons stated regarding section 30191(a). The NRC still requires the general licensee who possesses in vitro testing devices containing Mock Iodine radionuclide to adhere to the requirements of specific disposal, reports of theft and loss of such devices, and notification of incidents involving those devices, for the purpose of ensuring public safety. Such disposal requirements and reports are not considered by the NRC to be excessively burdensome to the general licensee, and the Department agrees with this determination in the interest of minimizing radiation exposure and so helping to ensure public safety. The reference to “Section 30192.5” is replaced with a reference to “subsection (a)” because it is unnecessarily cumbersome to specify the section number when referring to a subsection within the same section, and nonsubstantial grammatical and punctuation changes are made.
30192.6	40.25	C	EI. This section is proposed to be amended to maintain consistency with the corresponding NRC provision in 10 CFR 40.25. Subsection (a): commas are added as nonsubstantial punctuation additions. In subsection (b) the reference to “Section 30192.6” is replaced with a reference to “subsection (a)” because it is unnecessarily

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			cumbersome to specify the section number when referring to a subsection within the same section. Nonsubstantial grammatical changes are also made. Subsection (b)(1) is amended to clearly identify where registration requirements are found. Subsection (b)(2) contains nonsubstantial grammatical and punctuation changes. Subsection (b)(3) is amended for consistency with 10 CFR 40.25(c)(1)(ii), and to specify that the procedures must not only be maintained but that there is also a requirement to develop and implement them. The phrase “in any form, including scrap metal” is added for consistency with NRC’s provision. New subsection (b)(4) is added to address 10 CFR 40.25(c)(1)(iii), which requires the general licensee, when registering, to identify an individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in 40.25(c)(1)(ii). It is noted that the NRC’s registration process for these devices is similar to the process for devices possessed under 10 CFR 31.5. In 10 CFR 31.5(c)(12), corresponding to proposed section 30192.1(d)(15), NRC requires the general licensee to appoint an individual responsible for having knowledge of required actions and authority for taking required actions. This appointed individual serves to ensure compliance with the specific requirements. The individual referenced in 10 CFR 40.25(c)(1)(iii) is acting in a similar capacity to ensure procedures designed to establish physical control over the depleted uranium are followed so as to prevent

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			unauthorized use or transfer. Therefore, the Department proposes to require appointment of an individual to oversee control and use of the material as presented in 10 CFR 31.5(c)(12), which is equivalent to proposed section 30192.1(d)(15). The Department believes this will assist licensees in complying with the requirements, provide consistency in registration processes, and meets NRC's compatibility category C. Proposed subsection (b)(5), recodified from existing subsection (b)(4), is added for consistency with 10 CFR 40.25(d)(2). Further, by separating the prohibition of abandonment from transfer or disposal requirements, a general licensee becomes more aware of their responsibility over the radioactive material for protection of the public. Former subsection (b)(4), redesignated to subsection (b)(6), is amended for consistency with 10 CFR 40.25(d)(3), which references 10 CFR 40.51. That federal provision addresses transfer of source or byproduct material and verification of receipt of those sources, those requirements are stated in sections 30210 and 30210.1. The requirement in subsection (b)(7) is added to be consistent with 10 CFR 40.25(c)(2). Subsection (b) is amended for consistency with 10 CFR 40.25(e). Further, in subsection (c) the reference to "this section" is replaced with a reference to "subsection (a)" because it is unnecessarily cumbersome to refer to a section within the same section. And nonsubstantial grammatical and punctuation changes are made. This amendment also

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			contributes to consistency in the subsection references in the regulations contained in title 17, Division 1, Chapter 5, Subchapter 4.
30225	31.6 & 150.20	B & C, respectively.	EO. In subsections (a) and (b), nonsubstantial grammatical, capitalization, and punctuation changes are made, and acronyms are added for existing titles. Subsection (b) is amended for consistency with NRC's provision in 10 CFR 31.6. Regarding compatibility, NRC redesigned 10 CFR 31.6 from compatibility category C to category B during rulemaking (65 Fed.Reg. 79161 (Dec. 18, 2000)) without a concurrent review of 10 CFR 31.6 and its implementation by all Agreement States. That redesignation made subsection (b) incompatible with NRC's provision. However, in 2005, NRC received a petition for rulemaking from the Organization of Agreement States, Inc. and a request from the State of Florida to change the compatibility category of 10 CFR 31.6 from B to C. In response, NRC directed staff to hold in abeyance any determination on this rule and compatibility of those rules if the Agreement State rule met the essential elements of NRC's rule so NRC staff could complete review of and respond to the petition. (Reference 12.) NRC, in 2007, informed all Agreement States they would continue this abeyance and that they were granting the request by incorporating the request into its rulemaking initiated in 2007. (Reference 13.) NRC's proposal was recently published (74 Fed.Reg. 38372 (Aug. 3, 2009)) and would change the compatibility category for 10 CFR 31.6 from B to C. That proposal will be addressed in future Department

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			rulemaking. Currently, subsection (b) meets the essential elements of 10 CFR 31.6 so it is not being amended for purposes of meeting compatibility category B. Subsection (b)(4) is amended to add section 30257 to the list of regulation sections required to be furnished, to address the NRC's changes to 10 CFR 31.5(c)(13)(ii) and 10 CFR 30.34(h), and the NRC's redesignation of 10 CFR 31.6 from compatibility category C to category B (65 Fed.Reg. 79161 (Dec. 18, 2000)). Since 10 CFR 31.5 and 31.6 are a compatibility category "B" requirement, the components of those NRC regulations that impact this regulation section must meet the requirement of being essentially identical to the federal regulation. Further, the Department agrees that persons licensed by other agencies that provide devices to recipients in California should provide those recipients with copies of the bankruptcy reporting regulation in section 30257, as all holders of such devices need to be aware of the need to report bankruptcy filings to the Department so as to help the Department ensure that devices are transferred or disposed of safely. Lastly, though 10 CFR 31.6 does not require the general licensee to provide certain documents, subsection (b)(4) is needed to ensure the recipient is aware of the regulations. Often, it is the manufacturer that performs installation or servicing of devices, and thus the manufacturer would ordinarily be most aware of the applicable regulations. In subsection (c) the reference to "sections 30225" is replaced with a reference to "subsections" because it is unnecessarily cumbersome to specify the section number

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			when referring to subsections within the same section. A nonsubstantial capitalization change is also made. Subsection (d) is added for the same reason stated regarding section 30226(b).
30226	31.5 & 150.20	B & C, respectively.	EI. Subsection (a) is proposed to be added so that California's reciprocity oversight is made essentially identical to the NRC provision found in 10 CFR 31.5(c)(13)(iv). Subsection (b) is needed to address NRC's changes in 10 CFR 150.20(a) & (b), [62 Fed.Reg. 1662 (Jan. 13, 1997)], which are designated as compatibility category C. (Reference 3c.) Prior to those changes, 10 CFR 150.20 created confusion for Agreement State licensees operating in areas of exclusive Federal jurisdiction within Agreement States. Thus, subsection (b) is added to clarify that reciprocity granted under this section does not authorize the person to work in areas within this State that are under exclusive federal jurisdiction.
30236			This section is repealed and the table of information is being added to section 30192.5, because the table is related only to in vitro clinical tests, which is discussed in section 30192.5.
30257	30.34(h)	H&S	EI. This section is proposed to be amended to maintain compatibility with NRC's provision (65 Fed.Reg. 79161 (Dec. 18, 2000)). Subsection (a) is amended to specify which licensees are required to make the notification.

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			This section is equivalent to the NRC's bankruptcy notification in 10 CFR 30.34(h). The NRC has designated that requirement as compatibility category “Health & Safety” and the Department is required to meet the essential objective of the NRC’s equivalent regulation. Though the Department can adopt a regulation that is stricter or accomplishes the essential objective in some other way, the Department is adopting this provision in an essentially identical way to maintain consistency with the NRC requirements. This allows those licensees holding a Department and NRC license to comply with both jurisdictions, federal and State, and this also maintains consistency with state law (Health & Saf. Code, section 114965(a)). In addition, nonsubstantial grammatical and punctuation changes are made in (a), (a)(1), (a)(3), and (b). Non-substantive changes and corrections are made to the Authority and Reference note. (HSC sections “28501” and “28502” were typographical errors, and should have been 25801 and 25802, now recodified to 114965 and 114970.)

STATEMENTS OF DETERMINATIONS

The Department of Public Health ("Department") has determined that the proposed regulatory action would have no significant adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states. Thus, there will be no significant adverse economic impact on California businesses.

The Department has determined that the regulation would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code.

The Department has determined that the regulation would not significantly affect the following:

1. The creation or elimination of jobs within the State of California.
2. The creation of new businesses or the elimination of existing businesses within the State of California.
3. The expansion of businesses currently doing business within the State of California.

The Department has determined that there would be an effect on small business because they will be legally required to comply with the regulation and may incur a detriment from the enforcement of the regulation.

Alternatives have been considered in those areas not subject to or specifically limited by the adequacy and compatibility criteria under the State of California agreement with the United States Atomic Energy Commission, the predecessor to the United States Nuclear Regulatory Commission (HSC sec. 115230). According to the agreement, the state is to use its "best efforts to maintain continuing compatibility between its program and the program of the [United States Atomic Energy] Commission for the regulation of like materials..." (HSC sec. 115235, art. V).