

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 §30192.6(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.