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 30192.6:

• Subsection (b) was revised to identify the Part number (40) of the cited federal provision, resulting in no regulatory effect, because federal provisions are structured (e.g., "40.34") with the provisions' Part number shown by the digit(s) preceding the decimal.

Section 30210:

- Subsection (b)(3) was revised for consistency with NRC's provisions found in 10 CFR 30.41(b)(2) and 40.51(b)(2), and to present federal language from the States' perspective, not the NRC's. The presented language is based on NRC's provision and 17 CCR 30100(b).
- Subsection (b)(4) was revised to clarify where exemptions to licensing requirements are located.
- Subsection (b)(6) was revised to delete unneeded duplication of a defined acronym's meaning.

Section 30220:

- Due to comments, subsection (a)(2) was revised so that the term "fingerprint orders" is adopted by reference in subsection (a). The term "government agency," designated by NRC as compatibility category D, remains as initially proposed to not be adopted.
- Due to the revision of subsection (a)(2), subsection (a)(4) was revised for clarity by:
 - Adding new subparagraphs (A) and (B) to address references to the NRC in the cited provisions. Subparagraph (B) is needed to clarify that "security orders," as defined in the cited CFR, refers only to orders issued by NRC under its authority to protect the common defense and security (ISR: pp. 9 &10; Reference 7, pp. 1-6):
 - Recodifying initially proposed subparagraphs (A) and (B) to subparagraphs (C) and (D), respectively, to maintain a coherent structure; and
 - Deleting reference to paragraph (9) in subparagraph (C), as recodified, since it is proposed to be deleted.
- Subsection (a)(6) was revised to clarify that the terms in the presented table are for purposes of the material incorporated by reference in subsection (a).
- Subsections (a)(7) and (a)(9) are deleted due to the revision of subsection (a)(2) that would result in adoption by reference of the term "fingerprint orders" in subsection (a).
- Subsection (a)(8) is deleted due to adoption of the term "fingerprint orders" and the reference clarification in newly proposed paragraph (4)(B) regarding the term "security orders."

• Subsection (a)(10) is recodified to subsection (a)(7) due to the deletion of subsections (a)(7), (a)(8) and (a)(9).

The phrase "Group 3. Standards for Protection Against Radiation" is added preceding the presentation of section 30293 to clearly indicate the structural location of Article 3.1 under which section 30293 is located, as shown in the CCR. This addition results in no regulatory effect.

Section 30293:

- Due to comments regarding subsection (a)(2), subsection (a)(2) is amended for consistency with NRC's provision in 10 CFR 40.61(a)(2). However, the phrase "byproduct material" found within 10 CFR 40.61(a)(2), and defined in 10 CFR 40.4, is excluded because California has no licensees possessing that defined material. Under NRC's policy, a State need not adopt a specific regulation if the State has no licensees that would be subject to that regulation. (Reference 3a: Appendix E, footnote 4.)
- Section 115230 of the Health and Safety Code is added to the Reference note for consistency with other section notes citing to the codified Agreement with the federal government. This results in no regulatory effect.

Section 30373:

- Due to comments, the following revisions are made:
 - Subsection (a)(1) is revised to remove 10 CFR 71.8 and 71.13 from those provisions not being incorporated to clarify that the equivalent provisions are located as specified in newly proposed subsections (a)(7) and (a)(8), respectively.
 - Subsection (a)(2) (presented initially as "no change to text") is revised to identify those provisions for which the reference to the NRC must remain a reference to the NRC. Comments, in part, indicated that the reference to NRC in 10 CFR 71.101(c)(1) should remain a reference to NRC since that provision contained "certificate of compliance (CoC), certificate holder, and applicant for a CoC." However, it appears the commenter intended 71.101(c)(2), not 71.101(c)(1) since 71.101(c)(1) does not contain those terms. Because 71.101(c)(2) is designated as compatibility category NRC, agreement states may not adopt that provision. Thus, the reference to NRC in 71.101(c)(1) should be adopted by replacing "NRC" with the Agreement State's applicable department name. Only those provisions being incorporated by reference in subsection (a) to which the reference to NRC must so remain are identified.
 - Subsections (a)(5) and (a)(6): Due to additionally proposed provisions, the word "and" is deleted and the punctuation at the end of this provision is revised for consistency with existing regulatory structure, resulting in no regulatory effect.
 - Subsection (a)(7) is newly added to clarify where the equivalent provision to 10 CFR 71.8 is found.

- Subsection (a)(8) is newly added to clarify where the equivalent provision to 10 CFR 71.13 is found.
- Subsections (a)(3), (b) and (c), initially presented as "no change to text," is now presented fully without change, resulting in no regulatory effect.
- As found in the second section note, the underlined period at the end of the proposed internet address is changed to a non-underlined period to clearly indicate that the period currently exists in the note's text. This results in no regulatory effect.

Incorporation by Reference: Federal documents incorporated by reference in:

- Section 30220 contain extensive provisions governing procedures for the physical protection of certain quantities of radioactive material making it cumbersome, duly expensive and impractical to publish the documents in the California Code of Regulations. Further, the documents are readily available from federal internet sources as identified in the second Note to section 30220.
- Section 30373(a) and (a)(5) contain extensive tables, graphics, definitions, and provisions for safe packaging and transportation of radioactive material making it cumbersome, duly expensive and impractical to publish the documents in the California Code of Regulations. Further, the documents are readily available from federal internet sources as identified in the second Note to section 30373.

<u>SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE INITIAL NOTICE PERIOD OF FEBRUARY 23, 2018 TO APRIL 9, 2018.</u>

Following is the list of persons who commented on the initial proposed regulations (DPH-13-001) during the 45-day public comment period beginning on February 23, 2018 and ending at 5:00 p.m. on April 9, 2018. The Department received one letter of comment as identified below. A request to hold a public hearing was not received so no public hearing was held. A 15-day public availability comment period was conducted beginning on June 1, 2018 and ending at 5:00 p.m. on June 16, 2018. The Department received no comments during the first 15-day public availability comment period. A second 15-day public availability comment period was conducted beginning on November 16, 2018 and ending at 5:00 p.m. on December 1, 2018. The Department received one letter of comment during the second 15-day public availability comment period.

<u>List of Commenters during Initial 45-day Proceeding held from February 23, 2018</u> through April 9, 2018. (Written testimony)

1. Linda Howell, Acting Deputy Director, Division of Materials Safety, Security, State and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission (NRC).

No comments were received during the first 15-day Proceeding held from June 1, 2018 through June 16, 2018.

<u>List of Commenters during second 15-day Proceeding held from November 16, 2018</u> <u>through December 1, 2018.</u> (Written testimony)

2. Kevin Williams, Deputy Director, Division of Materials Safety, Security, State and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission.

Summary of comments and responses

Note: The digit or digit and letter before the decimal point designation identifies the Commenter as listed above. The digit(s) after the decimal point indicate the identified comment from that commenter.

1.1. The proposal fails to adopt the specified 10 CFR 71 provisions required for compatibility.

Response: The commenter indicated that the NRC compatibility categories for 10 CFR 71.127, 71.129 & 71.131 are "C." However, based on 69 FR 3698 (Jan. 26, 2004) for those provisions, it appears that the published compatibility categories are "[C]." Due to this disparity, the Department confirmed with the commenter (Reference 5) that the designated compatibility category was "[C]," and that, if 10 CFR 71.105 was adopted, it was not necessary to adopt 71.127, 71.129 & 71.131. Because 10 CFR 71.105 is already adopted by reference in existing section 30373(a), and is not affected by this proposal, no changes are made to the proposal due to the comment.

To address comments regarding 10 CFR 71.8 and 71.13, a second 15-day public comment period was held. Section 30373, subsection (a)(1), was revised to remove 10 CFR 71.8 and 71.13 from the list of provisions not incorporated by reference and to insert new subsections (a)(7) and (a)(8), respectively, to provide reference to 17 CCR 30105 that addresses 10 CFR 71.8 and 17 CCR 30373(c) that addresses 10 CFR 71.13. Commenter two (NRC) indicated they had no additional comments on this revision.

The comment regarding 10 CFR 71.103(a) is addressed in the proposed regulation text for section 30373(a)(1), in that the phrase "71.103(a)," is shown as "71.103(a)," ensuring that 71.103(a) is removed from the list of provisions not being incorporated and placed in the section's structure as being incorporated by reference. Thus, the

commenter's concern is already addressed and no changes are made to the proposal due to this comment.

1.2. Because the general license in 10 CFR 71.20 expired, section 30373 should be amended to remove 10 CFR 71.20 from the list of regulations adopted by reference.

Response: The proposal adopts by reference 10 CFR 71 as published on January 1, 2016, and because 71.20 does not exist within the 2016 publication, 71.20 is effectively removed. No change to the proposal was made due to this comment.

1.3, 1.7, 1.8, & 1.9.

To meet the required compatibility category, section 30373 should be amended to substitute the State's corresponding agency information for NRC's.

Response: The initially proposed text for section 30373 identified some existing provisions not being amended by use of the phrase "no change to text." The proposal now fully presents those existing provisions for review.

Section 30373(a)(2) is amended as follows:

- For provisions referencing "certificate of compliance (CoC), certificate holder or applicant for a CoC," the following provisions indicated in the comment are either included or not included for the indicated reason:
 - 10 CFR 71.5(b) is included in section 30373(a)(2)(B) as recommended;
 - 10 CFR 71.10 is not included since it is compatibility category D, is not required to be adopted, and is not being adopted;
 - 10 CFR 71.17(c)(3) & (e) are included section 30373(a)(2)(B) as recommended;
 - 10 CFR 71.85(c) is not included but is listed in section 30373(a)(1) as not being adopted because it is compatibility category NRC, may not be adopted, and is not being adopted;
 - 10 CFR 71.88(a)(4) is included in section 30373(a)(2)(B) as recommended;
 - 10 CFR 71.93(c) & 71.95 are not included since both are compatibility category D, are not required to be adopted, and are not being adopted; and
 - 10 CFR 71.91(c), (c)(3)(iii) & (f) are included in section 30373(a)(2)(B) as recommended.
 - Regarding the reference to NRC in 10 CFR 71.101(c)(1), it appears the commenter intended 71.101(c)(2), not 71.101(c)(1) since 71.101(c)(1) does not contain terms applicable only to NRC. Because 71.101(c)(2) is designated as compatibility category NRC, agreement states may not adopt that provision. Thus, the reference to NRC in 71.101(c)(1) is replaced with "Department" as recommended.

Commenter two (NRC) indicated they had no additional comments on these revisions.

1.4. To meet the required compatibility category, section 30293(a)(2) should be amended to meet the Compatibility Category C designation assigned to 10 CFR 40.61(a)(2).

Response: The proposal was revised to include section 30293(a)(2) as indicated. Currently, the existing provision applies to users, as defined in 17 CCR 30100(z), of both radiation machines and radioactive materials. Because the NRC does not regulate radiation machines, section 30293(a)(2) is revised for consistency with 10 CFR 40.61(a)(2) by providing an exception specific to source material, a subset of radioactive material as defined in 17 CCR 30100(q). NRC has designated 10 CFR 40.61(a)(2) as compatibility category C, requiring agreement states to adopt the essential objectives. Additionally, because the existing provision applies to all users of radioactive materials, 10 CFR 30.51(a)(2) was reviewed, and the existing provision deemed equivalent, to ensure the proposal did not change the regulatory effect for radioactive material users not possessing source material.

However, this proposal excludes reference to "byproduct material," as defined in 10 CFR 40.4, found within 10 CFR 40.61(a)(2), because California has no licensees possessing that defined material. Under NRC's policy, a State need not adopt a specific regulation if the State has no licensees that would be subject to the regulation. (Reference 3a: Appendix E, p. 5.) Commenter two (NRC) indicated they had no additional comments on this revision.

1.5 To meet the required compatibility category, section 30220 should be amended to meet the Compatibility Category C designation for the definitions of "Fingerprint Orders" and "Government Agency" found in 10 CFR 37.5.

Response: The comment regarding the term "fingerprint orders" is accepted resulting in completion of a second 15-day comment period. Section 30220(a)(2) is revised so that the term "fingerprint orders" is adopted by reference in subsection (a). The term "government agency," compatibility category D as indicated in 78 FR 17002 (Mar. 19, 2013), remains, as initially proposed, to not be adopted. Proposed subsection 30220(a)(4) is revised to clarify references to NRC in the cited provisions, and subsections 30220(a)(7) through (a)(9) are deleted as unnecessary. Commenter two (NRC) indicated they had no additional comments on this revision.

1.6. To meet the required compatibility category, section 30220(a)(4)(B) should be amended to include the "NRC, the Department, and any Agreement State."

Response: The comment was accepted resulting in completion of the first 15-day public comment period. No comments were received during that comment period. Commenter two (NRC) indicated they had no additional comments on this revision.

1.10. The word "Standards" in 30332(a)(1) and in the notes section is singular when it should be plural.

Response: The comment is rejected because the document incorporated by reference in 17 CCR 30332(a)(1) is a published document and titled using the word "Standards." Thus, the regulation, and its note, quote the title of the document verbatim for clarity. No change to the proposal was made due to this comment.

2.1. The commenter had no comments on the proposed revisions.

Response: The Department appreciates the NRC's additional review.

<u>ALTERNATIVES DETERMINATION:</u> In accordance with Government Code Section 11346.9(a)(4), the Department has determined that no alternative would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

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.