

## **INITIAL STATEMENT OF REASONS**

### **SUMMARY OF THE PROPOSED REGULATIONS**

The California Department of Public Health (Department) proposes to amend, adopt or repeal sections of Title 17 of the California Code of Regulations (CCR) that address radioactive material (RAM), in accordance with the United States Nuclear Regulatory Commission's (NRC) adoption of Title 10, Code of Federal Regulations, part 37 (10 CFR 37), Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material, and part 71 (10 CFR 71), Transportation of Licensed Material. These proposed regulations also address the NRC's provisions in 10 CFR parts 30, 40, and 70.

These proposed regulations incorporate by reference the January 2016 versions of 10 CFR 37 and 10 CFR 71, and the U.S. Department of Transportation's (DOT) provisions in 49 CFR parts 107, 171 through 180, and 390 through 397 - which are referenced in 10 CFR 71's provisions - effective as of January 1, 2016. These proposed regulations also correct inconsistencies in existing regulations that correspond to the NRC's provisions, and make other nonsubstantial corrections.

### **AUTHORITY AND REFERENCE**

The Department proposes to adopt, amend, or repeal, as applicable, sections 30108.1, 30192.6, 30194, 30210, 30210.1, 30220, 30257, 30295, and 30373 of 17 CCR, under the authority provided in sections 114820, 114970, 114975, 115000, 115091, and 131200 of the Health and Safety Code (H&S Code). This proposal implements, interprets and makes specific sections 114740, 114765, 114960, 114965, 114970, 114985, 114990, 115000, 115060, 115065, 115091, 115105, 115110, 115120, 115165, 115175, 115205, 115230, 115235, 131050, 131051, and 131052 of the H&S Code.

### **POLICY STATEMENT OVERVIEW**

*Problem Statement:* Existing Department regulations that address radioactive material do not address recent NRC regulatory changes, contain provisions that are out-of-date, and contain incorrect addresses, inconsistencies, and grammatical and capitalization errors.

*Objectives:* The broad objectives of this proposed regulatory action are to:

- Ensure that the Department's regulations are compatible with those of the NRC and the DOT.
- Update and clarify existing regulations.

*Benefits:* Anticipated benefits from this proposed regulatory action are:

- Continued protection of the public health and safety, worker safety, and the environment, as provided for by the Legislature in the following provisions:

- H&S Code sections 114705, 114740, 114755, 114965, 114970, 115000, 115230, and 115235.
- Continued compatibility with the standards and regulatory programs of the NRC, as specified in H&S Code sections 114965(a),<sup>1</sup> 115000(b), and 115235 (article V).
- Consistency with the regulatory programs of other States, as specified in H&S Code section 114965(c).
- Continued maintenance of an orderly regulatory pattern within the State, among the States, and between the federal government and the State, as specified in H&S Code section 114965(b).
- An updating and clarification of existing regulations, and a deletion of unnecessary regulations.

### **EVALUATION AS TO WHETHER THE PROPOSED REGULATIONS ARE INCONSISTENT OR INCOMPATIBLE WITH EXISTING STATE REGULATIONS**

The Department evaluated this proposal to determine whether the proposed regulations are inconsistent or incompatible with existing State regulations. This evaluation included a review of both the Department's existing general regulations and those regulations specific to the regulatory control of radioactive material. Some inconsistencies in those specific regulations were found, and are addressed in this proposal. An Internet search of other state agency regulations was also performed. It was determined that no other state regulation addressed the same subject matter, and that this proposal was not inconsistent or incompatible with other state regulations. Therefore, the Department has determined that this proposal, if adopted, would not be inconsistent or incompatible with existing State regulations.

### **PROGRAM BACKGROUND/AUTHORITY**

Radioactive Material (RAM) is widely used in many industries, including: the healing arts, for diagnostic and therapeutic purposes; industrial radiography, for nondestructive testing of objects to ensure structural integrity; well logging, for the purpose of obtaining information about the well or adjacent formations that may be used in oil, gas, mineral, groundwater, or geological exploration; and, manufacturing and distribution, for designing, building, and supplying radioactive sources for use in medicine and by other industries. The Department issues licenses authorizing such uses, and conducts inspections of users to ensure compliance with applicable laws and regulations.

The Radiation Control Law (RCL) (H&S Code §§ 114960 through 115273) requires that the Department develop programs for licensing and regulating radioactive materials. (H&S Code § 115000(b).) The Department is the successor of the California

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<sup>1</sup> This short format "H&S Code section 131055" for a given Health and Safety Code section will be used throughout this document for brevity.

Department of Health Services and as such has the authority to license and regulate radioactive material under the California Public Health Act of 2006. (Chapter 241, Statutes of 2006; SB 162, Ortiz.)

In 1962, the State of California ratified and approved an agreement with the United States Atomic Energy Commission, the predecessor of the United States Nuclear Regulatory Commission (NRC), by which the federal agency discontinued its regulatory authority over certain radioactive materials. (H&S Code § 115230.) By such action, California became an “Agreement State.”

California, as an Agreement State, has regulatory authority over the possession and use of RAM by any person subject to state jurisdiction. A person, as defined in H&S Code section 114985(c), is “any individual, corporation, partnership, limited liability company, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, other than the United States Nuclear Regulatory Commission, the United States Department of Energy, or any successor thereto, and other than federal government agencies licensed by the United States Nuclear Regulatory Commission, under prime contract to the United States Department of Energy, or any successor thereto.”

A provision of the agreement between California and the NRC requires that the State “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.” (H&S Code § 115235, art. V.) The NRC's stated policy is “to evaluate Agreement State programs established pursuant to Section 274 of the Atomic Energy Act (AEA) of 1954, as amended, to ensure they are adequate to protect public health and safety and compatible with NRC's regulatory program.”<sup>2</sup>

To determine a state's compatibility, the NRC uses Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*, Handbook 5.9. (Reference 1.) This handbook describes the specific criteria and process that are used to determine which NRC program elements should be adopted and implemented by an Agreement State for purposes of maintaining compatibility, and which NRC program elements have a particular health and safety significance. The NRC rates the elements according to the degree of compatibility required. The NRC requires that some elements be adopted by the States in a form identical to the NRC's. Other elements need not be adopted in identical form, but are still required to meet the “essential objective” of the program element. The NRC's overall determination of the adequacy and compatibility of an Agreement State's program is made pursuant to Management

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<sup>2</sup> *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 and Tribal Programs website: <https://scp.nrc.gov/procedures/md0509.pdf> (Reference 1.)

Directive 5.6, *The Integrated Materials Performance Evaluation Program (IMPEP)*.<sup>3</sup> The NRC evaluates Agreement State programs 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 and assume direct regulation and control of byproduct, source, and special nuclear material within the State.

In conjunction with the NRC's IMPEP review every four years, the NRC procedures (SA-200<sup>4</sup>) require that Agreement States, when adopting regulations required for meeting the adequacy and compatibility determinations, submit proposed regulations to the NRC for review. The NRC then reviews the proposal to ensure that the proposed regulations meet the applicable NRC compatibility category, defined as follows:

**NRC Compatibility Categories<sup>5</sup> (underlined words are defined below)**

**Category A:** Basic radiation protection standard, or related definitions, signs, labels or terms that is necessary for a common understanding of radiation protection principles. The State program element should be essentially identical to that of NRC.

**Category B:** Program element with significant direct transboundary implications. The State program element should be essentially identical to that of NRC.

**Category C:** Program element, the essential objectives of which should be adopted by the State to avoid conflicts, duplications, or gaps. The manner in which the essential objectives are addressed need not be the same as NRC provided the essential objectives are met.

**Category D:** Not required for purposes of compatibility.

**Category NRC:** Not required for purposes of compatibility. These are NRC program elements that address areas of regulation that cannot be relinquished to Agreement States pursuant to the AEA or provisions of Title 10 of the Code of Federal Regulations. The State should not adopt these program elements.

**Category Health & Safety (H&S):** Program elements identified as H&S are not required for purposes of compatibility; however, they do have particular health and safety significance. The State should adopt the essential objectives of such program elements in order to maintain an adequate program.

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<sup>3</sup> *Integrated Materials Performance Evaluation Program (IMPEP), Management Directive 5.6*. The document is available at the Nuclear Regulatory Commission, Office of State, and Tribal Programs website: <https://scp.nrc.gov/procedures/md0506.pdf> (Reference 2).

<sup>4</sup> SA-200 is available at <http://nrc-stp.ornl.gov/procedures/sa200.pdf> (Reference 3).

<sup>5</sup> Volume 5, Governmental Relations and Public Affairs, *Adequacy and Compatibility of Agreement State Programs*, February 27, 1998, Handbook 5.9, Part II, pp. 4-7. (Reference 1).

[ ] = A bracket around a category (e.g. [B]) means that the Section may have been adopted elsewhere and it is not necessary to adopt it again.

### **Definitions**<sup>6</sup>

**Conflict** means that the essential objectives of regulations or program elements are different and an undesirable consequence is likely to result in another jurisdiction or in the regulation of agreement material on a nationwide basis.

**Duplication** means that identical regulations or program elements apply to the same material at the same time. Note: this definition applies primarily to review of Agreement State regulations.

**Essential objective** of a regulation or program element means the action that is to be achieved, modified, or prevented by implementing and following the regulation or program element. In some instances, the essential objective may be a numerical value (e.g., restriction of exposures to a maximum value) or it may be a more general goal (e.g., access control to a restricted area).

**Essentially Identical** means the interpretation of the text must be the same, regardless of the version (NRC or Agreement State) that is read.

**Gap** means that the essential objectives of NRC regulations or program elements are absent from the Agreement State program, and an undesirable consequence is likely to result in another jurisdiction or in the regulation of agreement materials on a nationwide basis.

To ensure compliance with the NRC agreement and to maintain compatibility of State regulations, this proposal amends existing regulations relating to radioactive material and addresses those changes made by the NRC, as noted in the following volumes of the Federal Register (FR):

- 77 FR 34194 (June 11, 2012)<sup>7</sup>
- 77 FR 39899 (July 6, 2012)
- 78 FR 16922 (March 19, 2013)
- 79 FR 58664 (September 30, 2014)
- 80 FR 33987 (June 12, 2015)
- 80 FR 45841 (August 3, 2015)

The authority and reference citations of sections being amended, resulting in no regulatory effect pursuant to 1 CCR section 100, reflect the:

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<sup>6</sup> *Ibid*, pg. 17.

<sup>7</sup> The citation format 77 FR 34194 (June 11, 2012) means the June 11, 2012 publication of Volume 77, commencing at page 34194, of the Federal Register. This short format for any given federal register will be used throughout this document for brevity.

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

### **SPECIFIC DISCUSSION OF PROPOSED CHANGES**

The regulations that implement, interpret, and make specific the provisions of the Radiation Control Law are identified in Title 17, California Code of Regulations, sections 30100 through 30395. The proposed changes to existing state regulations are explained as follows:

**Amend Section 30108.1, Registration and General Provisions for Persons Possessing Devices Under Sections 30192.1 and 30192.6.** This section is amended for consistency with proposed changes to section 30192.6. These changes are without regulatory effect.

**Amend Section 30192.6, General Licenses - Depleted Uranium.** This section is amended to ensure consistency with 10 CFR 40.25. The NRC has designated that section as Compatibility Category C, requiring Agreement States to adopt the essential objective of the regulation. Although the Department may adopt a regulation that is stricter or accomplishes the essential objective in some other way, the Department is adopting these provisions in an essentially identical way in order to maintain consistency with the NRC requirements.

Subsection (a) is repealed and replaced with proposed subsections (a) and (b), to maintain consistency with 10 CFR 40.25(a) and (b).

Subsection (b) is redesignated as subsection (c) to maintain a coherent structure, resulting in no regulatory effect. Proposed subsection (c)(6), as redesignated, is amended for consistency with the repeal of section 30210.1, and for consistency with 10 CFR 40.25(d)(3).

Subsection (c) is redesignated as subsection (d) to maintain a coherent structure, resulting in no regulatory effect.

**Amend Section 30194, Approval of Applications and Specific Terms and Conditions for Specific Licenses.** This section is amended to provide citations to other provisions that may apply to applicants. Subsection (g) is amended to ensure that applicants are aware of other regulatory provisions that must be addressed in an application. The cited sections currently apply to applicants, but section 30194 fails to clearly inform applicants of the requirements. By citing the other provisions, applicants become more aware of what must be addressed in the initial application, and delays in license issuance due to additional correspondence efforts are reduced.

**Amend Section 30210, Transfer of Radioactive Material.** This section is amended for clarity and consistency with the corresponding NRC regulations found in 10 CFR 30.41 and 40.51. The NRC has designated:

- 10 CFR 30.41(a), (b)(1)-(b)(5), (b)(7), (c) and (d) as compatibility category C, requiring Agreement States to adopt the essential objective of the regulation. 10 CFR 30.41(b)(6) is designated as compatibility category NRC, meaning Agreement States may not adopt the provision.
- 10 CFR 40.51(a), (b)(1)-(b)(5), (b)(7), (c) and (d) as compatibility category C, requiring Agreement States to adopt the essential objective of the regulation. 10, CFR 40.51(b)(6) is designated as compatibility category NRC, meaning Agreement States may not adopt the provision.

Except as discussed below, this section is proposed to be amended to be essentially identical to 10 CFR 30.41 and 40.51, in order to maintain consistency and uniformity:

- References to the term “byproduct material” are replaced with the term “radioactive material” because within the State, the Department has regulatory authority over types of material not subject to federal law. However, although “radioactive material” means any material that emits radiation spontaneously pursuant to 17 CCR section 30100, this proposal, and replacement of terms, excludes the meaning of “byproduct material” as defined in 10 CFR 40.4. The NRC defines byproduct material, only for purposes of 10 CFR 40.51, to mean the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. The term is used to address the federal Uranium Mill Tailings Radiation Control Act of 1978, as amended. Pursuant to California’s agreement under the federal Atomic Energy Act, authority to regulate uranium mills is excluded. Therefore, the NRC would maintain authority over any such mills in the State. Currently, there are no uranium mills in California.
- References to the “Commission” are replaced with the acronym NRC.
- Proposed subsection (c) addresses 10 CFR 30.41(c) and (d) and 10 CFR 40.51(c) and (d). The NRC includes in its provisions the phrases, “a general licensee who is required to register.....prior to receipt of the [applicable] material,” “registration certification” and “registration certification number.” As discussed below, these phrases are excluded, because the Department does not issue any general license requiring registration prior to receipt of the material, or issue to a general licensee a registration certificate or number:
  - 10 CFR 30.41(c): A review of the NRC’s part 31 provisions addressing general licenses<sup>8</sup> (GL) indicates that the only applicable GL is found in 10 CFR 31.11, which allows use of certain quantities of radioactive material

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<sup>8</sup> General License means a license, pursuant to regulations promulgated by the department, effective without the filing of an application, to transfer, acquire, own, possess or use quantities of, or devices or equipment utilizing, byproduct, source, or special nuclear materials or other radioactive material occurring naturally or produced artificially. (H&S Code § 114985(g).)

- for *in vitro* testing. The NRC has designated 10 CFR 31.11 as compatibility category D; meaning agreement states are not required to adopt the provision. The Department's equivalent regulation is found in 17 CCR section 30192.5<sup>9</sup> and does not require registration prior to receipt.
- 10 CFR 40.51(c): A review of the NRC's part 40 provisions addressing GLs indicates that the NRC does not issue any GL requiring registration prior to receipt of the material.
  - References to registration certificates and numbers are excluded, since they are not issued.

Proposed subsection (d), redesignated from existing subsection (b) provides clarification regarding commercial distribution. The list of cited sections is amended to include existing section 30192.7.

**Repeal Section 30210.1, Verification Required.** This section is repealed and the content redesignated to section 30210. See section 30210 for discussion.

The title of **Article 6** of Group 2 of subchapter 4.0 is proposed to be amended to clearly identify the contents of the article.

**Adopt Section 30220, Special Requirements for Issuance of Specific Licenses—Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.** This section is adopted to achieve compatibility with the new NRC physical protection standards found in 10 CFR 37. The January 1, 2016, version of 10 CFR 37 is proposed to be incorporated by reference with exceptions.

Following, in part, is the NRC's background discussion of the part 37 final rule, as published at 78 FR 16922-16924 (March 19, 2013):

The NRC has long participated in efforts to ensure radioactive source protection and security. The terrorist attacks of September 11, 2001, heightened concerns about the use of risk-significant radioactive materials in a malevolent act. Such an attack is of particular concern because of the widespread use of radioactive materials in the United States by industrial, medical, and academic institutions. The theft or diversion of risk-significant quantities of radioactive materials could lead to their use in a radiological dispersal device (RDD) or a radiological exposure device (RED). The NRC's current regulations provide requirements for the safe use, transportation, and control of licensed radioactive material. Loss of control of risk-significant radioactive material, whether inadvertent or through a deliberate act, could result in significant adverse impacts that could reasonably constitute a threat to the public health and safety or the common defense and

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<sup>9</sup> The citation format "17 CCR section 30192.5" means Title 17, California Code of Regulations, section 30192.5. This short format for any given State regulation will be used throughout this document for brevity.

security of the United States. In the changed threat environment after the attacks of September 11, 2001, the Commission determined that certain licensed material should be subject to enhanced security requirements and safeguarded during transport, and that individuals with unescorted access to risk-significant quantities of radioactive material should be subject to background investigations.

As part of the development of the enhanced security measures, the NRC performed threat and vulnerability assessments to identify gaps or vulnerabilities in security and the effectiveness and costs of certain physical protection enhancements at various licensed facilities. The results of these assessments were used in the development of security enhancement orders that were issued to licensees using a graded approach based on the relative risk and quantity of material possessed by the licensee.

The NRC issued the first series of orders to certain panoramic and underwater irradiator licensees that possessed more than 370 Terabequerels (TBq) (10,000 curies (Ci)) of radioactive material (EA-02-249; June 6, 2003) (68 FR 35458; June 13, 2003). The next series of orders were issued to certain manufacturing and distribution (M&D) licensees (EA-03-225; January 12, 2004) (69 FR 5375; February 4, 2004). These orders require the implementation of additional security measures and the protection of the licensee's physical protection information as Safeguards Information--Modified Handling (SGI-M). The original orders are not publicly available because they contain detailed security requirements that are designated as SGI-M. However, redacted versions of these orders have been made available to the public (73 FR 33859; June 13, 2008, and 73 FR 49714; August 22, 2008). These orders were issued to both NRC and Agreement State licensees under the NRC's authority to protect the common defense and security.

Subsequently, the NRC issued Increased Control Orders (EA-05-090; November 14, 2005) (70 FR 72128; December 1, 2005) to other licensees authorized to possess certain risk-significant quantities of radioactive material (category 1 and category 2 quantities). The Increased Control Orders do not contain safeguards information (SGI) or SGI-M, and are available on the NRC's public Web site: [U.S.NRC Security Orders and Requirements - Increased Controls](#) These orders were issued under the NRC's authority to protect public health and safety, and require licensees to implement enhanced security measures known as Increased Controls. To effect nationwide implementation of the Increased Control Orders, each Agreement State issued legally binding requirements to impose enhanced security measures, identical to the Increased Controls, for licensees under that State's regulatory jurisdiction.

All of the orders described above specifically address the security of byproduct material possessed in quantities equal to or greater than category 1 or category 2 quantities. The orders provide for enhanced security measures for such things

as license verification before the transfer of these materials, access control, intrusion detection and response, and coordination with local law enforcement authorities (LLEAs). The orders also contain requirements for the licensee to determine the trustworthiness and reliability of individuals permitted unescorted access to risk-significant radioactive materials. The determination involves a background investigation of the individual. The background investigations were originally limited to local criminal history records checks with law enforcement agencies, verification of employment history, education, personal references, and confirmation of employment eligibility (legal immigration status).

In 2005, Congress passed, and the President signed, the Energy Policy Act of 2005 (EPAAct). The EPAAct amended Section 149 of the Atomic Energy Act (AEA) to authorize the Commission to require to be fingerprinted any individual who is permitted unescorted access to radioactive material or other property subject to regulation by the Commission that the Commission determines to be of such significance to the public health and safety or the common defense and security as to warrant fingerprinting and a Federal Bureau of Investigation (FBI) criminal history records check. With this new authority, the Commission determined that individuals who have access to category 1 and category 2 quantities of radioactive material warrant fingerprinting and FBI criminal history records checks.

On October 17, 2006, the NRC issued orders to panoramic and underwater irradiator licensees (EA-06-248) (71 FR 63043; October 27, 2006), M&D licensees (EA-06-250) (71 FR 63046; October 27, 2006), and licensees making shipments of category 1 quantities of radioactive material (EA-06-249) (71 FR 62302; October 24, 2006) to require fingerprinting and FBI criminal history records checks for unescorted access to risk-significant quantities of radioactive material at their facilities. In issuing these orders, the NRC noted that a malevolent act by an individual with unescorted access to these materials could result in significant adverse impacts to the public health and safety or the common defense and security and, thus, necessitated expedited implementation of fingerprinting requirements. The orders were issued to both the NRC and Agreement State licensees under the NRC's authority to protect the common defense and security. On December 5, 2007, the NRC issued orders to all other NRC licensees that possessed category 1 or category 2 quantities of radioactive material (EA-07-305) (72 FR 70901; December 13, 2007) to require fingerprinting and FBI criminal history records checks for unescorted access to category 1 or category 2 quantities of radioactive material. These orders were issued under the NRC's authority to protect the public health and safety and are available on the NRC's public Web site: [U.S.NRC Security Orders and Requirements](#). To effect nationwide implementation, each Agreement State issued legally binding requirements consistent with the Increased Control Orders to licensees under their regulatory jurisdiction.

In 2005, the NRC issued two sets of orders to licensees transporting radioactive material in quantities of concern. The first set of transportation security orders was issued to certain licensees that might be expected to transport radioactive materials in category 1 quantities (EA-05-006; July 19, 2005) (70 FR 44407; August 2, 2005). These orders require the implementation of additional security measures and the protection of the licensee's physical protection information as SGI-M. The original orders are not publicly available because they contain detailed security requirements that are designated as SGI-M. However, a redacted version of the order is publicly available (73 FR 51016; August 29, 2008). These orders were issued to both NRC and Agreement State licensees under the NRC's authority to protect the common defense and security.

Subsequently, the NRC issued orders (EA-05-090; November 14, 2005) (70 FR 72128; December 1, 2005) to specifically address the transportation security of byproduct material transported in quantities equal to or greater than category 2. The Increased Control Orders mentioned earlier also contain requirements for transporting category 2 quantities of radioactive material. The additional security measures contained in these two sets of orders provide for enhanced security measures during transportation that are beyond the regulations then applicable, and include: Enhanced security in preplanning and coordinating shipments; advance notification of shipments to the NRC and States through which the shipment will pass; control and monitoring of shipments that are underway; trustworthiness and reliability of transport personnel; information security considerations; and control of mobile or portable devices such as radiography cameras and well-logging devices.

In November 2009, the NRC issued the Increased Control Order and the Fingerprint Order to power reactor licensees that are undergoing decommissioning (EA-09-204 and EA-09-205; November 23, 2009) (74 FR 66168 and 74 FR 66164; December 14, 2009). The orders required these licensees to implement the Increased Controls and to obtain fingerprints and criminal history records checks for individuals to have or continue having unescorted access to aggregated category 1 or category 2 quantities of radioactive material.

In December 2009, the NRC issued orders to service provider licensees that were not manufacturers or distributors (EA-09-293; December 16, 2009 (75 FR 160; January 4, 2010). The order required service provider licensees to implement specific measures to ensure the trustworthiness and reliability of their service representatives that have unescorted access to category 1 or category 2 quantities of radioactive materials.

The requirements put in place by all these above-described orders supplement the existing regulatory requirements. These additional requirements are primarily intended to provide reasonable assurance of preventing the theft or diversion of

risk-significant radioactive material. These requirements provide the Commission with reasonable assurance that public health and safety and the common defense and security continue to be adequately protected.

As indicated in the above excerpt regarding Agreement States' issuance of legally binding security requirements, California issued two sets of orders; namely, the Increased Control Order (November 2005) (Attachment 1); and the Fingerprint/Criminal History Record Check Order (June 2008) (Attachment 2). Therefore, this proposal also ensures that the provisions of those orders, as encompassed by part 37, are applied universally to existing licensees, new licensees, and applicants.

The January 2016 version of 10 CFR 37 is incorporated by reference. The following table identifies each subsection of proposed section 30220 and its corresponding federal regulation, if applicable, as found in 10 CFR 37. The table also identifies the required level of compatibility with the NRC, describes any difference between the NRC and state regulation, and explains the reasons for the difference.

Section 30220 (subsection)	10 CFR 37 (section)	Compatibility Category	Description & Rationale EI = Essentially Identical, NA = Not Adopted, NE = No Equivalent.
(a)			NE. Subsection (a) is adopted to: <ul style="list-style-type: none"> <li>• Inform applicants and users that issuance of licenses is subject to other provisions. This is needed to ensure applicants are aware that other provisions must be addressed.</li> <li>• Incorporate by reference the NRC's regulations governing the physical protection of category 1 and category 2 quantities of radioactive material in 10 CFR 37, January 1, 2016, with exceptions. California, as an Agreement State, has regulatory authority over the radioactive material within the state. This incorporation is necessary to maintain California's continued compatibility with federal regulations.</li> <li>• To inform applicants that, if a license is issued, the applicant must also maintain compliance</li> </ul>

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Section 30220 (subsection)	10 CFR 37 (section)	Compatibility Category	Description & Rationale EI = Essentially Identical, NA = Not Adopted, NE = No Equivalent.
			with the adopted regulations. This is needed to ensure that the applicants clearly understand that they not only must be capable of initially complying with the adopted regulations, but that they must also maintain compliance with the adopted regulations after issuance of the license.
(a)(1)	37.1	D	NE. These sections of 10 CFR 37 are not adopted, as discussed regarding subsection (a)(1).
(a)(1)	37.3	D	
(a)	37.5		Each defined term is addressed below.
(a)	Access control	C	EI. This term is proposed to be adopted to maintain consistency with the NRC's provisions.
(a)(6)	Act	D	NE. See subsection (a)(6) for discussion.
(a)	Aggregated	C	EI. This term is proposed to be adopted to maintain consistency with the NRC's provisions.
(a)(6)	Agreement State	[B]	NE. See subsection (a)(6) for discussion.
(a)	Approved individual	B	EI. These terms are proposed to be adopted to maintain consistency with the NRC's provisions.
(a)	Background investigation	C	
(a)(6)	Becquerel (Bq)	[A]	NE. See subsection (a)(6) for discussion.
(a)(6)	Byproduct material	[H&S]	
(a)	Carrier	[B]	EI. These terms are proposed to be adopted to maintain consistency with the NRC's provisions.
(a)	Category 1 quantities of radioactive material	B	
(a)	Category 2 quantities of radioactive material	B	
(a)(4)	Commission	D	NE. See subsection (a)(4) for discussion.

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<b>Section 30220</b> (subsection)	<b>10 CFR 37</b> (section)	<b>Compatibility Category</b>	<b>Description &amp; Rationale</b> EI = Essentially Identical, NA = Not Adopted, NE = No Equivalent.
(a)(6)	Curie	[A]	NE. See subsection (a)(6) for discussion.
(a)	Diversion	C	EI. These terms are proposed to be adopted to maintain consistency with the NRC's provisions.
(a)	Escorted access	B	
(a)(2)	Fingerprint orders	C	NE. See subsection (a)(2) for discussion.
(a)(2)	Government agency	D	NE. See subsection (a)(2) for discussion.
(a)(6)	License	D	NE. See subsection (a)(6) for discussion.
(a)	License issuing authority	D	EI. Though the term is not required to be adopted, it is proposed to be adopted in order to maintain consistency with the NRC's provision, and for coherency. The term is used often within 10 CFR 37, and is maintained for clarity.
(a)	Local law enforcement agency (LLEA)	C	EI. These terms are proposed to be adopted to maintain consistency with the NRC's provisions.
(a)	Lost or missing licensed material	[B]	
(a)	Mobile device	B	
(a)	Movement control center	B	
(a)	No-later-than arrival time	B	
(a)(6)	Person	[C]	NE. See subsection (a)(6) for discussion.
(a)	Reviewing official	C	EI. These terms are proposed to be adopted to maintain consistency with the NRC's provisions.
(a)	Sabotage	C	
(a)	Safe haven	B	
(a)	Security zone	C	
(a)	State	D	Though the term "State" need not be adopted, it is proposed to be adopted to maintain consistency with the NRC's provision, and for coherency. The term is used extensively within 10 CFR 37, and is maintained for clarity.

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Section 30220 (subsection)	10 CFR 37 (section)	Compatibility Category	Description & Rationale EI = Essentially Identical, NA = Not Adopted, NE = No Equivalent.
(a)	Telemetric position monitoring system	B	EI. These terms are proposed to be adopted to maintain consistency with the NRC's provisions.
(a)	Trustworthiness and reliability	B	Though the term "United States" need not be adopted, it is proposed to be adopted to maintain consistency with the NRC's provision, and for clarity.
(a)	Unescorted access	B	
(a)	United States	D	
(a)(1)	37.7	D	NE. These provisions are not adopted, as discussed regarding subsection (a)(1).
(a)(1)	37.9	D	
(a)(1)	37.11(a) & (b)	D	
(a)	37.11(c)	B	EI. This provision is proposed to be adopted to maintain consistency with the NRC's provisions.
(a)(1)	37.13	D	NE. This provision is not adopted, as discussed regarding subsection (a)(1).
(a)	37.21(a)	C	EI. These provisions are proposed to be adopted to maintain consistency with the NRC's provisions. Regarding those provisions that are designated Compatibility Category C, although the Department can adopt a regulation that is stricter or accomplishes the essential objective in some other way, the Department is adopting those provisions that are Compatibility Category C in an essentially identical way, in order to maintain consistency with the NRC requirements. This allows those licensees holding a Department and an NRC license to more easily comply with both federal and state jurisdictions, and this also maintains consistency with
(a)	37.21(b) & (c)	B	
(a)	37.23(a), (b)(1), (b)(2), (b)(4), (b)(5), (c), (d), (e) & (g)	B	
(a)	37.23(b)(3), (f) & (h)	C	
(a)	37.25(a) & (c)	B	
(a)	37.25(b)	C	
(a)	37.27	B	
(a)	37.29	B	
(a)	37.31(a)-(d)	B	
(a)	37.31(e)	C	
(a)	37.33	C	
(a)	37.41(a) & (b)	B	
(a)	37.41(c)	C	
(a)	37.43(a)	B	
(a)	37.43(b)	C	
(a)	37.43(c)(1)-(c)(3)	B	
(a)	37.43(c)(4) & (d)	C	
(a)	37.45(a), (b) & (d)	B	
(a)	37.45(c)	C	

DPH-13-001  
 Compatibility Maintenance with NRC Regulations  
 Initial Statement of Reasons  
 October 30, 2017

Section 30220 (subsection)	10 CFR 37 (section)	Compatibility Category	Description & Rationale EI = Essentially Identical, NA = Not Adopted, NE = No Equivalent.
(a)	37.47	B	legislative policy (H&S Code § 114965).
(a)	37.49	B	
(a)	37.51	C	
(a)	37.53	B	
(a)	37.55	C	
(a)	37.57	C	
(a)	37.71(a)-(c)	B	
(a)	37.71(d)	C	
(a)	37.73(a), (b), (d) & (e)	D	
(a)	37.73(c)	B	
(a)	37.75(a)-(d)	B	
(a)	37.75(e)	C	
(a)	37.77(a)-(d)	B	
(a)	37.77(e) & (f)	C	Regarding those provisions that are Compatibility Category D, though the Department is not required to adopt the provisions, those provisions are proposed to be adopted to ensure licensees are fully aware of applicable provisions so they can more easily comply with the requirements.
(a)	37.79	B	

Section 30220 (subsection)	10 CFR 37 (section)	Compatibility Category	Description & Rationale EI = Essentially Identical, NA = Not Adopted, NE = No Equivalent.
(a)	37.81(a)-(f)	B	EI. These provisions are proposed to be adopted to maintain consistency with the NRC's provisions. Regarding those provisions that are designated Compatibility Category C, though the Department can adopt a regulation that is stricter or accomplishes the essential objective in some other way, the Department is adopting those provisions that are Compatibility Category C in an essentially identical way, in order to maintain consistency with the NRC requirements. This reduces the regulatory burden on those licensees holding both a Department and an NRC license, and this also maintains consistency with legislative policy (H&S Code § 114965).
(a)	37.81(g) & (h)	C	
(a)(10)	37.101	C	NE. See discussion of subsection (a)(10).
(a)(10)	37.103	C	
(a)(1)	37.105	D	NE. These sections are not adopted, as discussed regarding subsection (a)(1).
(a)(1)	37.107	D	
(a)(1)	37.109	D	
(a)	Appendix A	B	EI. These provisions are proposed to be adopted to maintain consistency with NRC's provisions.

Subsection (a)(1) lists the NRC provisions that are not incorporated because the provisions are not required for compatibility or adequacy, as follows:

- 10 CFR 37.1, 37.3, 37.7, 37.9, 37.11(a) and (b), 37.13, 37.105, 37.107, and 37.109 are compatibility category D.

Subsection (a)(2) is needed to clarify that the terms are not incorporated by reference. The term "fingerprint orders" is not adopted, as discussed regarding subsection (a)(7). The term "government agency" is not adopted because it is not needed to maintain compatibility with the NRC and is not used within the proposal. The NRC designated the term as Compatibility Category D, meaning it is not required to be adopted by Agreement States. That term is used only in NRC's definition of "Person". The NRC's

definition is written from that federal agency's perspective for consistency with federal law. The term "person", as it relates and is specific to the Department, is defined in H&S Code section 114985(c). See also the discussion regarding subsection (a)(6).

Subsection (a)(3) is needed to clarify that the Department is not adopting any of the NRC provision found in 10 CFR 73. Part 73 is reserved exclusively to the NRC, and may not be adopted by Agreement States. (Reference 3, page 4.) However, an exception is provided for consistency with the NRC's provision allowing a licensee, under the cited provisions, to meet the requirements by use of either the part 37 provisions or the provisions within part 73. This also provides clarity for licensees who may have individuals within their organization who may have already met part 73 provisions.

Subsection (a)(4) is needed to clarify that the Department, not the NRC, is the organization responsible for radiological health in California. As an Agreement State, California has regulatory authority over the possession and use of radioactive material. However, this is not the case with the provisions in paragraphs (A) and (B), addressing 10 CFR 37.27 and 37.71, for the following reasons:

- The NRC informed Agreement States that the NRC serves as the receiver of fingerprint information submitted to the U.S. Federal Bureau of Investigations for all licensees, regardless of jurisdiction. Therefore, state licensees must comply with and follow the processes specified in 10 CFR 37.27.
- The NRC has designated 10 CFR 37.71 as Compatibility Category B, because radioactive material can be transferred across jurisdictions throughout the United States. Also, the NRC designated a large majority of part 37 provisions as Compatibility Category B, in order to maintain national uniformity and consistency across jurisdictions. Therefore, this proposal is needed to clarify that the transferring licensee needs to use the appropriate verification system of the particular licensing authority.

Subsection (a)(5) is needed to identify the equivalent State provision that a licensee is not to use for purposes of 10 CFR 37.71. A licensee transferring material under part 37.71 is required to use the verification methods specified in part 37.71, instead of those methods found in part 30.41(d) (equivalent to the Department's regulation in 17 CCR section 30210.1(b), redesignated to section 30210(c) in this proposal). See also the discussion regarding section 30210.

Subsection (a)(6) is needed to clarify that any references to the identified NRC terms are references to the terms as defined in State law or regulations as indicated. The NRC's definitions are written from the NRC's perspective and apply nationally. The State's definitions are written from California's perspective or already exist in law or regulation, and the clarification is needed, since this proposal applies only to this State's jurisdiction. Further, it prevents duplication of the term's definition.

Subsections (a)(7), (a)(8), and (a)(9) are needed to clarify the grandfathering provisions of 10 CFR 37.25(b) regarding "fingerprint orders" as defined in 37.5 and "security orders" as defined within 37.25(b)(2). The NRC defines "fingerprint orders" broadly to

include both the NRC and Agreement States. Because this proposal only applies to Department jurisdiction, the term “fingerprint orders” is not used, in order to distinguish the Department’s grandfathering process from the issued Fingerprint/Criminal History Record Check Order (June 2008) (Attachment 2). These proposed subsections use the grandfathering provisions in 10 CFR 37.25(b) as the basis for the proposed substitutions, in order to ensure that the provisions of that order, as now encompassed by this proposal, are applied universally to existing licensees, new licensees, and applicants. To fully sunset the June 2008 order, the proposal includes a transition date based on the effective date of these proposed regulations, if the proposal is approved and adopted. However, because the effective date of this proposal cannot be determined, the Department proposes to authorize the Office of Administrative Law (OAL) to insert the date, for clarity.

Subsection (a)(10) is needed to clarify where the Department’s equivalent regulation to 10 CFR 37.101 and 37.103 is found. This further prevents unnecessary duplication of regulations.

**Amend Section 30257, Bankruptcy Notification.** This section is amended for consistency with changes proposed regarding section 30192.6. These changes are without regulatory effect.

**Amend Section 30295, Notification of Incidents.** This section is amended for consistency and compatibility with NRC’s reporting requirements specified in 10 CFR 30.50, 40.60, and 70.50. The NRC has designated those sections as compatibility category C, requiring agreement states to adopt regulations that meet the essential objective of the NRC’s regulation.

Existing section 30295 is identical to 10 CFR 30.50 and 40.60, except for grammatical and punctuation differences that are nonsubstantial under the NRC’s regulation review procedures (Reference 3a). However, section 30295(a) fails to include reference to events that result in releases of material that could exceed regulatory limits. Thus, subsection (a) is amended to clarify that notification of incidents includes releases of radioactive material that could exceed regulatory limits, for consistency with 10 CFR 30.50 and 40.60.

However, 10 CFR 70.50 contains the same provisions as 30.50 and 40.60, but includes additional provisions that are not addressed in existing section 30295, and are not proposed to be adopted. A review of the NRC’s adoption history of 70.50 below, shows that prior to September 18, 2000, 10 CFR 70.50 was duplicative of 30.50 and 40.60, except that each provision applied to the type of material being addressed in the applicable 10 CFR part. Therefore, the additional provisions found in 10 CFR 70.50, as compared to 30.50 and 40.60, are not proposed to be adopted, because they are reserved to the NRC. The differences found in 70.50, as compared to 30.50 and 40.60, apply only to licensees authorized to possess a critical mass of special nuclear material (SNM). Agreement states, including California, are not authorized to regulate a critical mass of SNM. (H&S Code § 115235, Art. I, C.)

- 10 CFR 70.50 (Jan. 1, 2000 edition).

- Identical to 10 CFR 30.50 and 40.60, as found in Jan. 1, 2000 edition, except as it pertains to the specific 10 CFR part.
- Sept. 18, 2000 (65 FR 56226).
  - Final rule addresses possession of a critical mass of SNM, revises 70.50(c), and adds new paragraph (d) to 70.50.
  - Adds new Subpart H, specifying additional requirements for certain licensees authorized to possess a critical mass of SNM.
  - Contains no reference to Agreement States or compatibility categories.
- Oct. 10, 2003 (68 FR 58817).
  - Final rule addresses electronic maintenance and submission of information.
  - Contains no reference to Agreement States or compatibility categories.
- Sept. 26, 2014 (79 FR 57725).
  - Final rule revised 70.50(c)(2) to remove references to 70.74 and Appendix A.
    - 70.50(c)(2) now identical to Jan. 1, 2000 edition.
  - 10 CFR 70.74 and Appendix A are designated as compatibility category NRC. Agreement States not authorized to adopt such provisions.

**Amend Section 30373, Transportation Regulations.** This section is amended for consistency and compatibility with 10 CFR 71. Also, nonsubstantial punctuation and grammatical corrections are made in subsections (a) and (a)(5) for clarity, resulting in no regulatory effect.

Subsection (a) is amended to incorporate by reference those changes that were made to 10 CFR 71 from January 1, 2007 to January 1, 2016. By changing the date, the incorporated material will include the changes to 10 CFR 71 made by the NRC in the following [Federal Register publications](#), which are available at:

<https://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR>:

- 77 FR 34194 (June 11, 2012)
- 77 FR 39899 (July 6, 2012)
- 78 FR 16922 (March 19, 2013)
- 80 FR 33987 (June 12, 2015)

The NRC amended 10 CFR 71.4 (77 FR 34194 (June 11, 2012)) to add the following definitions, which are both compatibility category B:

- “Indian tribe” means an Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a.
- “Tribal official” means the highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership.

The NRC amended 10 CFR 71.97(a), (c)(1), (c)(3), (d)(4), (e) and (f)(1); (77 FR 34194 (June 11, 2012)), which are compatibility category B, to require licensees to provide advance notification to tribal officials and to specify procedural requirements when transporting radioactive material across tribal boundaries. Currently, existing licensees

who transport the quantities of material meeting the criteria specified in 71.97(b) are subject to advance notification requirements. This proposal would require that an additional copy of that advance notification is sent to tribal officials as specified. Therefore, the costs are minimal, as it only requires submitting a duplicate copy of what is already required.

This reporting requirement is necessary for the protection of the health, safety and welfare of California residents and residents of a tribal nation, by requiring that officials be informed so that they can provide emergency assistance if needed.

The NRC amended 10 CFR 71.97(b) (78 FR 16922 (March 19, 2013)), which is compatibility category B, to delete the reference to shipments of irradiated reactor fuel in quantities less than those subject to the advance notification requirements of 10 CFR 73.37(f), since that reference was duplicative of 10 CFR 73.35. Because this change is nonsubstantial and part 73 provisions may not be adopted by Agreement States, no regulatory effect results from changing the incorporation by reference date of 2007 to 2016.

The NRC amended appendix A, Table A-1 of 10 CFR part 71 (77 FR 39899 (July 6, 2012)) to revise the values of the following radionuclides, for consistency with amended federal Department of Transportation (DOT) regulations found in 49 CFR 173.435 (77 FR 60937 (Oct. 5, 2012)). These revised values are compatibility category [B], meaning Agreement States must adopt the provision in an essentially identical manner unless it has been elsewhere adopted. Because the following radionuclides are not listed in existing State regulation, they are proposed to be adopted in an essentially identical manner, to maintain compatibility with the NRC provisions:

- Bismuth (Bi-205)
- Curium (Cm-248)
- Europium (Eu-150)
- Tellurium (Te-132)

The DOT's regulation 49 CFR 173.435 is currently incorporated by reference in subsection (a)(5). The date of January 1, 2016 is proposed to be the date of reference for the DOT regulations. This maintains consistency with the date of incorporation of the NRC's regulations. The U.S. Government Printing Office annually publishes each title of federal regulation but staggers those publications, such that Title 10 is published in January of each year and Title 49 is published in October of each year. Thus, the January 1, 2016 date in this proposal, corrects the date of effectiveness for the incorporation of DOT's regulations, so that the dates of incorporation for the NRC's and the DOT's regulations are one date: namely, January 1, 2016. This is necessary for consistency and clarity.

The NRC made additional amendments to Part 71 (80 FR 33987 (June 12, 2015)) so as to harmonize its transportation regulations with the United Nations' International Atomic Energy Agency's (IAEA) regulations. Periodically, the IAEA revises its regulations related to transportation of radioactive material. The NRC evaluated changes in the 2009 edition of the IAEA's "Regulations for the Safe Transport of Radioactive Material"

(TS-R-1) and identified a number of areas in 10 CFR part 71 that needed to be revised to maintain compatibility with the IAEA's regulations.

The NRC's final rule also revised 10 CFR part 71 to: (1) update administrative procedures for the quality assurance program requirements described in subpart H; (2) re-establish restrictions on material that qualifies for the fissile material exemption; (3) clarify the requirements for a general license; (4) clarify the responsibilities of certificate holders and licensees when making preliminary safety determinations on packaging to be used for transporting radioactive material; and (5) make editorial changes.

Following is a summary of the NRC's action for the indicated provision and the provision's Compatibility Category as designated by the NRC. The NRC's reasons for these revisions are discussed in detail in its final rule (80 FR 33987 (June 12, 2015)).

- Added or revised the following terms to 10 CFR 71.4, all of which the NRC designated as Compatibility Category [B]. These terms, as added or revised, are proposed to be adopted:
  - Contamination
  - Criticality Safety Index (CSI)
  - Low Specific Activity (LSA) material
  - Special Form radioactive material
  - Uranium – natural, depleted, enriched
- Revised 10 CFR 71.14(a)(1) and (a)(2) and added (a)(3), all of which are designated as Compatibility Category [B], addressing exemptions for low-level materials.
  - The revisions and additions are proposed to be adopted.
- Revised 10 CFR 71.15(d), addressing an exemption from classification as fissile material, designated as Compatibility Category [B].
  - The revision is proposed to be adopted.
- Revised the Compatibility Category designation of 10 CFR 71.17 from [B] to B, signifying that Agreement States should ensure that they have regulations compatible with 71.17 that are co-located with their transportation regulations. 10 CFR 71.17(c) was also revised.
  - Currently, 71.17 is incorporated by reference in section 30373 and co-location is not needed.
  - The revision of 71.17(c) is proposed to be adopted.
- Revised 71.19, designated as Compatibility Category NRC and listed in section 30373(a)(1). It is not proposed to be adopted because Agreement States may not adopt provisions designated as Compatibility Category NRC.
- Revised the Compatibility Category designation of 10 CFR 71.21 from [B] to B, signifying that Agreements states should ensure that they have regulations compatible with 71.21 that are co-located with their transportation regulations. 10 CFR 71.21(a) and (d) were also revised.
  - Currently, 71.21 is incorporated by reference in section 30373 and co-location is not needed.
  - The revisions of 71.21(a) and (d) are proposed to be adopted.

- Revised or added the following 10 CFR provisions, all of which are designated as Compatibility Category NRC. These provisions are not proposed to be adopted, as they may not be adopted by Agreement States:
  - 71.31(b).
  - 71.38.
  - 71.70.
  - 71.75.
- Revised 71.85 and changed the Compatibility Category for subdivisions (a) through (c) from Compatibility Category [B] to NRC. New subdivision (d) was added to 71.85 and is designated as Compatibility Category B.
  - Currently, 71.85 is incorporated by reference in section 30373(a). Due to this recent NRC change, 71.85(a) through (c) is not adopted, so it is listed in section 30373(a)(1). See the additional discussion regarding subsection (a)(6).
  - New 10 CFR 71.85(d) is proposed to be adopted. See the additional discussion regarding subsection (a)(6).
- Revised 71.91 and changed the Compatibility Category for 71.91, as follows:
  - 71.91(a) was revised to correctly refer to 71.14 instead of 71.10. Compatibility Category was changed from D to Compatibility Category C, requiring Agreement States to adopt a regulation meeting the essential objective.
    - This provision is currently not adopted as listed in section 30373(a)(1), but is now proposed to be adopted by reference, as specified in section 30373(a).
  - 71.91(b). Compatibility Category was changed from D to Compatibility Category NRC, prohibiting Agreement States from adopting the provision.
    - This provision is currently adopted in section 30373(a), but is now proposed to be excluded from incorporation, as specified in section 30373(a)(1).
  - The Compatibility Categories for 71.91(c) and (d) were changed from Compatibility Category D to Compatibility Category C, requiring Agreement States to adopt a regulation meeting the essential objective. Those provisions were not revised by the NRC.
    - This provision is currently not adopted as listed in section 30373(a)(1), but is now proposed to be adopted by reference, as specified in section 30373(a).
  - Revised 71.101 and changed the Compatibility Category for 71.101, as follows:
    - The Compatibility Category for 71.101(a), (b) and (c)(1) were changed for those Agreement States that have no users of Type B packages – other than industrial radiography, Compatibility Category D to C, and for those states which have users of Type B packages – other than industrial radiography, the Compatibility Category C was not changed. Thus, the NRC now requires all Agreement States to meet compatibility category C.

- The NRC revised 71.101(a) but made no changes to the provisions in 71.101(b) and (c)(1).
  - These provisions are currently incorporated by reference in section 30373(a). Because this proposal changes the date of incorporation from 2007 to 2016, the NRC's revisions to 71.101(a) are proposed to be adopted.
- Revised 71.101(c)(2), designated as compatibility category NRC, and so may not be adopted by Agreement States.
  - This provision is currently, and is proposed to remain, listed in section 30373(a)(1), excluding it from being incorporated by reference.
- Added 71.101(g), designated as compatibility category C.
  - By changing the date of incorporation by reference from 2007 to 2016, this provision is proposed to be adopted.
- Revised 71.103 and changed the Compatibility Category for 71.103, as follows:
  - 71.103(a). The compatibility category for those Agreement States that have no users of Type B packages – other than industrial radiography, was changed from Compatibility Category D to C, and for those states which do have users of Type B packages – other than industrial radiography, the Compatibility Category was changed from [C] to C, signifying that a state's regulations compatible with 71.103(a) are to be co-located with their transportation regulations. The NRC now requires all Agreement States to meet compatibility category C.
  - 71.103(a) was also revised.
    - Currently, this provision is excluded from incorporation as listed in section 30373(a)(1). In 2009, section 30373 was amended to incorporate the 2007 version of 10 CFR 71. At that time, 10 CFR 71.103(a) did not need to be adopted because its essential objective was met by adopting 71.101(b), as signified by the compatibility category [C]. Due to the compatibility category change from [C] to C, this proposal incorporates 71.103(a) by deleting reference to it in section 30373(a)(1).
  - 71.103(b). The NRC revised the compatibility category note regarding this provision, but made no changes to the provision or to the designation of this provision as compatibility category C.
    - Currently, this provision is incorporated by reference in section 30373(a). This proposal maintains the provision, thereby maintaining compatibility with the NRC's provision.
- Added 71.106. NRC designated this provision as Compatibility Category C, requiring Agreement States to adopt provisions meeting the provisions' essential objective. This provision informs the licensee what changes to the package quality assurance program must be approved prior to implementation, and what changes may be made and implemented without prior approval.

- By changing the date of incorporation by reference from 2007 to 2016, this provision is proposed to be adopted.
- Revised 71.135 and changed the Compatibility Category for 71.135, as follows:
  - The compatibility category, for those Agreement States that have no users of Type B packages – other than industrial radiography, was changed from Compatibility Category D to C, and for those states which do have users of Type B packages – other than industrial radiography, the Compatibility Category was not changed. The NRC now requires all Agreement States to meet compatibility category C.
  - 71.135 was revised to reference new 71.106, and removed acronyms by spelling out the meaning of the acronyms.
    - Currently, 71.135 is incorporated by reference in section 30373(a). By changing the date of incorporation by reference from 2007 to 2016, this proposal includes the correct reference to new 71.106.
- Revised Appendix A to Part 71 through revision, addition, and redesignation of provisions, all of which NRC has designated as Compatibility Category [B].
  - Currently, Appendix A is incorporated by reference in section 30373(a).
  - By changing the date of incorporation by reference from 2007 to 2016, the revisions to Appendix A are proposed to be adopted.

Subsection (a)(6) is needed to clarify the legal relationship between a Department licensee and an NRC Certificate Holder, as referenced in 10 CFR 71.85. Currently, section 30373(a) incorporates by reference 10 CFR 71.85, which requires a specific licensee to make certain preliminary determinations before first use of the transportation package.

The NRC revised 71.85 to require the certificate holder, as defined in 10 CFR 71.4, instead of the specific licensee, to make these preliminary determinations because only the certificate holder is authorized to design and fabricate packages, and only the certificate holder has a full scope quality assurance program approval. (80 FR 33993 (June 12, 2015).) The NRC is the exclusive authority over a certificate holder and the issuance of a certificate of compliance, as those terms are defined in 10 CFR 71.4, and over the approval of transportation packages under 10 CFR part 71, Subpart D. As indicated by the NRC's designation of 71.85(a) through (c) as Compatibility Category NRC, Agreement States may not adopt an equivalent provision.

Also, to maintain consistency with the DOT's regulations (49 CFR 173.22) that require the person who offers a hazardous material for shipping to make determinations relating to the manufacturing, assembling, and marking of the package or container, the NRC added 10 CFR 71.85(d) to streamline its implementation of part 71 and to better reflect current practice. The NRC designated 10 CFR 71.85(d) as Compatibility Category B, requiring Agreement States to adopt an essentially identical provision.

This proposal, with exception, incorporates 10 CFR 71 (January 1, 2016) by reference. However, incorporation makes the applicability of the provisions of 10 CFR 71.85 unclear because the Department may not adopt an equivalent provision to subdivisions (a) through (c) but instead must adopt an essentially identical provision to subdivision

(d). Taken together, the licensee would not need to ascertain that the certificate holder has made the required determinations. Therefore, subsection (a)(6) is needed to clarify that:

- The licensee, before first use of the transportation package, must ascertain that the NRC certificate holder has made the determinations specified in 71.85(a) through (c). Documentation of ascertainment is specified in 10 CFR 71.91(d), incorporated by reference in section 30373(a); and
- The Department is making no attempt, nor implying or inferring that it is attempting, to regulate or exercise any control over an NRC certificate holder.

The website provided in the second note at the end of section 30373 is no longer valid, due to U.S. Government Printing Office website changes. The note is amended to identify the website where the Code of Federal Regulations may be accessed. This is a change without regulatory effect.

As required by H&S Code section 114820(c) and (d), the Department of the California Highway Patrol (CHP) was consulted in the development of this proposal. (Reference 4.)

## **STATEMENTS OF DETERMINATIONS**

### **SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE**

The Department has determined that the proposed regulatory action would not have a significant adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

### **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.

### **EFFECT ON SMALL BUSINESS**

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.

### **HOUSING COSTS**

The Department has determined that the regulations will not have an impact on housing costs.

### **REPORTING REQUIREMENTS**

The Department has determined that this proposed regulation would require businesses to submit a report and that the report is necessary for the health, safety, and welfare of the people of this state.

### **CONSIDERATION OF REASONABLE ALTERNATIVES**

Alternatives have been considered in those areas not subject to or specifically limited by the adequacy and compatibility criteria made applicable under the State of California's agreement with the United States Atomic Energy Commission, the predecessor to the United States Nuclear Regulatory Commission (H&S Code § 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..." (H&S Code § 115235, art. V).

## **ECONOMIC IMPACT ASSESSMENT**

The Department analyzed whether and to what extent this proposal affects the following:

**A. The creation or elimination of jobs within the State of California.** The proposal will not impact the creation or elimination of jobs because it only addresses compatibility with the NRC through restructuring, clarifying and updating existing regulations, and making a number of nonsubstantial changes.

**B. The creation of new businesses or the elimination of existing businesses within the State of California.** The proposal will not impact the creation or elimination of businesses because it only addresses compatibility with the NRC through restructuring, clarifying and updating existing regulations, and making a number of nonsubstantial changes.

**C. The expansion of businesses currently doing business within the State of California.** The proposal will not impact the expansion of businesses because it only addresses compatibility with the NRC through restructuring, clarifying and updating existing regulations, and making a number of nonsubstantial changes.

**D. The benefits of the regulation to the health and welfare of California residents, worker safety, and the state's environment.** The proposal increases and strengthens the health and welfare of California residents, worker safety, and protection of the State's environment, because it addresses compatibility with the NRC through restructuring, clarifying, and updating existing regulations, as intended by the Legislature, as follows:

- Continues protection of the public health and safety, worker safety, and the environment, as established by the Legislature in the following provisions:
  - H&S Code sections 114705, 114740, 114755, 114965, 114970, 115000, 115230, and 115235.
- Maintains compatibility with the standards and regulatory programs of the NRC, as specified in H&S Code sections 114965(a), 115000(b), and 115235 (article V).
- Maintains consistency with the regulatory programs of other states, as specified in H&S Code section 114965(c).
- Maintains an orderly regulatory pattern within the State, among the States, and between the federal government and the State, as specified in H&S Code section 114965(b).
- Initiates and administers programs of surveillance and control of those activities that could lead to the introduction of radioactive materials into the environment, as specified in H&S Code section 114705.
- Updates and clarifies existing regulations, and deletes unnecessary regulations.

## **ATTACHMENTS**

### **Attachment 1.**

*Order to Implement Increased Controls Over Certain Radioactive Sources*, November 15, 2005, California Department of Health Services.

### **Attachment 2.**

*Order to Implement Fingerprinting and Criminal History Record Checks for Unescorted Access to Radioactive Material in Quantities of Concern*, June 8, 2008, California Department of Public Health.

## **DOCUMENTS RELIED UPON**

### **Reference 1.**

*Adequacy and Compatibility of Agreement State Programs, Management Directive 5.9* as published in Volume 5: Governmental Relations and Public Affairs. <https://scp.nrc.gov/procedures/md0509.pdf>. Accessed on November 7, 2017.

### **Reference 2.**

*Integrated Materials Performance Evaluation Program (IMPEP), Management Directive 5.6* as published in Volume 5: Governmental Relations and Public Affairs. <https://scp.nrc.gov/procedures/md0506.pdf>. Accessed on November 7, 2017.

### **Reference 3.**

NRC Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements – SA – 200*. <https://scp.nrc.gov/procedures/sa200.pdf>. Accessed on November 7, 2017.

### **Reference 3a.**

NRC Procedure SA-201, *Review of State Regulatory Requirements – SA – 201*. <https://scp.nrc.gov/procedures/sa201.pdf>. Accessed on November 7, 2017.

### **Reference 4.**

Summary of November 26, 2012 meeting with CHP staff.