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Director

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



ARNOLD SCHWARZENEGGER
Governor

June 18, 2008

Mr. James G. Luehman, Deputy Director
Division Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs (FSME)
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Luehman:

Enclosed for your review is a copy of the proposed revisions to the California Radiation Control Regulations addressing changes to 10 CFR 71 (Transportation). The date by which the comments are needed is August 2, 2008.

The proposed regulations are identified by line-in/line-out text and correspond to the following equivalent amendments to NRC's regulations:

Rats ID	Title	State Section
2004-1	Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments - Part 71	30373

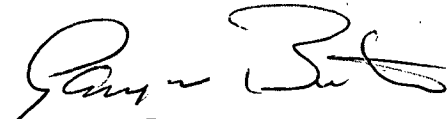
Differences between the proposed regulation and the NRC equivalent regulation are addressed in the document titled Initial Statement of Reasons. Existing regulations referenced in the proposal are attached.

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

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

Sincerely,

A handwritten signature in black ink, appearing to read "Gary W. Butner". The signature is fluid and cursive, with the first name "Gary" and last name "Butner" clearly distinguishable.

Gary W. Butner
Branch Chief
Radiologic Health Branch

Enclosure

cc: Kathleen Schneider
Monica Orendi

Initial Statement of Reasons

The Radiation Control Law (Health & Saf. Code, §§ 114960 – 115273), requires the California Department of Public Health (Department), the successor to the California Department of Health Services pursuant to the California Public Health Act (CPHA) of 2006 (Stats. 2006, c. 241 (Ortiz, SB 162)) as of July 1, 2007, to develop programs for licensing and regulating radioactive materials. (Health & Saf. Code, § 115000, subd. (b).) In 1962, the State of California ratified and approved the State entering into an agreement with the United States Atomic Energy Commission (AEC), the predecessor of the United States Nuclear Regulatory Commission (NRC), by which the federal agency discontinued its regulatory authority over certain radioactive materials. (Health & Saf. Code, § 115230.) By such action California became an "Agreement State."

A provision of the agreement between California and the NRC specifies that the State "will use its best efforts to maintain continuing compatibility between its program and the program of the [United States Atomic Energy] Commission for the regulation of like materials." (Health & Saf. Code, § 115235, art. V.) 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."¹ To determine a state's compatibility, the NRC uses Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs, Handbook 5.9*.² This handbook describes the specific criteria and process that are used to clarify the NRC program elements that should be adopted and implemented by an Agreement State for purposes of compatibility, and those NRC program elements that have a particular health and safety significance. The NRC rates the elements on the degree of compatibility required. Thus, the NRC requires that some be adopted by the states in a form identical to the NRC's while adoption of others need not be identical but are required to meet the essential objective of the program element. (For NRC compatibility definitions, see Attachment 1.) The overall determination of adequacy and compatibility for an Agreement State is made pursuant to Management Directive 5.6, *The Integrated Materials Performance Evaluation Program (IMPEP)*.³ The NRC evaluates Agreement States every three to four

¹ "Adequacy and Compatibility of Agreement State Programs," Management Directive 5.9, page 1. The document is available at the Nuclear Regulatory Commission, Office of State Programs website: <http://www.hsrdo.nrc.gov/nrc/procfm.htm>. (Reference 1.)

² "Adequacy and Compatibility of Agreement State Programs," Management Directive 5.9, Handbook 5.9. The document is available at the Nuclear Regulatory Commission, Office of State Programs website: <http://www.hsrdo.nrc.gov/nrc/procfm.htm>. (Handbook 5.9 is included within Reference 1.)

³ "Integrated Materials Performance Evaluation Program (IMPEP)," Management Directive 5.6. The document is available at the Nuclear Regulatory Commission, Office of State Programs website: <http://www.hsrdo.nrc.gov/nrc/procfm.htm>. (Reference 2.)

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.

Two federal agencies, the Department of Transportation (DOT) and the NRC have established strict requirements for packaging and shipping radioactive material. These requirements are based on the volume, nature and radioactivity of the material. DOT regulates package labeling, shipping papers, personnel training, handling and storage as well as transportation routing and vehicle requirements. The NRC regulates package safety to protect workers and the public. It also establishes regulations for radiation protection and regulates the use of radioactive materials, including the licensing and regulation of shippers and carriers.

Each year, there are approximately 400 million packages of hazardous material shipped in the United States. Radioactive materials account for less than one percent of these shipments. Of these three million packages containing radioactive material, the vast majority are shipments of radiopharmaceuticals and radioisotopes used in medical applications. Transported radioactive materials also include smoke detectors, luminous dials, sources used in non-destructive testing, and waste from industrial and medical facilities contaminated with small amounts of radioactive material.

The proposed changes to the California Code of Regulations are in response to changes made by the NRC regarding the packaging and transportation of radioactive materials found in title 10, Code of Federal Regulations (CFR), Part 71 (10 CFR 71). The NRC amended its regulations on packaging and transporting radioactive materials effective October 1, 2004. This rulemaking made the NRC regulations compatible with the latest version of the International Atomic Energy Agency (IAEA) standards. As international standards are updated, national and state regulations must be amended to maintain consistency and compatibility on all levels including the packaging and transportation of radioactive material across state and national borders.

The IAEA reviews its transportation regulations at intervals of about 10 years recognizing that its international regulations for the safe transportation of radioactive material should be revised periodically to reflect scientific and technical advances and experiences.

The NRC also periodically revises its regulations for the safe transportation of radioactive material to make them compatible with those of the IAEA. On August 5, 1983, the NRC published a revision of 10 CFR 71. That revision, in combination with a parallel revision of the hazardous materials transportation regulations of the Department of Transportation (DOT), brought U.S. domestic

transport regulations into general accord with the 1973 edition of the IAEA transport regulations. Another revision to 10 CFR 71 was published on September 28, 1995 (60 FR 50248) to make part 71 compatible with the 1985 IAEA Safety Series No. 6. The DOT published its corresponding revision to title 49, CFR (49 CFR) on the same date (60 FR 50291).

The last revision to the IAEA Safety Series 6, Safety Standards Series ST-1 was published in December 1996, and revised with minor changes on June 2000, and redesignated as TS-R-1. NRC Staff compared changes made in TS-R-1 and identified affected sections of 10 CFR 71. Based on this comparison, NRC amended 10 CFR 71 (69 FR 3697, January 26, 2004) and implemented those changes effective October 1, 2004.

Historically, the NRC has coordinated its part 71 revisions with the DOT because the DOT is the responsible national authority for transportation of hazardous materials. "Radioactive Materials" is a subset of "Hazardous Materials" in 49 CFR under DOT authority. Currently, DOT and NRC co-regulate transport of nuclear material in the United States.

To ensure compliance with the NRC agreement and compatibility of State regulations including consistency with DOT requirements, this proposal amends existing regulations relating to transportation of radioactive material and addresses those changes made by the NRC as noted in the following Federal Registers regarding transportation:

60 FR 50248 (Sep. 28, 1995)
69 FR 3697 (Jan. 26, 2004)

61 FR 28724 (Jun. 6, 1996)

The statutory authority and reference citation numbers of sections being amended are changed to reflect the numbering system implemented by the 1995 re-codification of the Health and Safety Code and the authority granted CPDH under the California Public Health Act of 2006, resulting in non-substantial change pursuant to title 1, California Code of Regulations, §100.

Alternatives have been considered in those areas not subject to or specifically limited by the adequacy and compatibility criteria under the State of California agreement with the United States Atomic Energy Commission, the predecessor to the United States Nuclear Regulatory Commission (NRC) (Health & Saf. Code, § 115230). NRC categories A and B require that the State be "essentially identical" to the NRC; category C requires that the "essential objectives" are met; category D is not required for purposes of compatibility; and category H & S is not required for purposes of compatibility, but does have health and safety significance and requires adoption of regulations meeting the essential objectives for an adequate program. 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).

The following table identifies the state regulation and its corresponding federal regulation found in 10 CFR 71 as of January 1, 2007, whether the requirements are identical and describes and explains any difference between the two and the reasons for the difference.

State Regulation 17CCR	10 CFR Section	Compatibility Category	Description and Rationale NE=No Equivalent, I=Identical, EI=Essentially Identical
30100(d)			<p>NE. Section 30100(d) is proposed to be amended for consistency with the California Public Health Act of 2006. That act reorganized the California Department of Health Services (DHS) into two departments; namely, California Department of Public Health (CDPH) and Department of Health Care Services (CDHCS).</p> <p>The programs administered under the Radiation Control Law were placed in the administrative control of CDPH. Therefore, §30100(d) is amended to reflect the reorganization of DHS pursuant to CPHA.</p> <p>Therefore, when the term "Department" is used within the regulations found in Title 17, CCR, Division 1, Chapter 5, Subchapter 4.0 it will clearly identify the CDPH as the State entity enforcing those regulations.</p>
30100 (f)			<p>NE. Section 30100(f) is proposed to be amended for consistency with the</p>

State Regulation 17CCR	10 CFR Section	Compatibility Category	Description and Rationale NE=No Equivalent, I=Identical, EI=Essentially Identical
			<p>corresponding DOT definition of "Hazardous radioactive material" found in 49 CFR 173.403 and those changes made by the Legislature in the 2003-2004 Legislative Session (Stats. 2004, ch. 193, § 121).</p> <p>Subsection (f) is amended for consistency with DOT's current definition of "Hazardous radioactive material." The federal register publication date of March 31, 1983 is proposed to be repealed because DOT has amended its regulation pertaining to the transportation of hazardous materials since that time. Because the most current federal DOT regulations are in effect and the Department cannot preempt them, a publication date is not specified. Further, as specified in Health and Safety Code §114820(c), regulations addressing transportation of radioactive material must be compatible with those established by the federal agency or agencies required or permitted by federal law to establish the regulations. Therefore, this proposal removes the reference date to ensure continued consistency with DOT's regulations.</p> <p>Subsection (f) is also amended to change the referenced Health and Safety Code section from §114820(e) to §114820(d)</p>

State Regulation 17CCR	10 CFR Section	Compatibility Category	Description and Rationale NE=No Equivalent, I=Identical, EI=Essentially Identical
			<p>because §114820 was amended through Senate Bill 111 (Stats. 2004, ch. 193, § 121) to repeal expired reporting requirements, which resulted in a redesignation of subdivisions. Thus, subdivision (e) was changed to subdivision (d). Further, subsection (f) is amended to make grammatical changes for consistency with other regulations that reference federal regulations (e.g. 30194.1, 30195.1, 30195.2, & 30253). Therefore, §30100(f) is amended for consistency and clarity with existing law and regulations.</p>
30346.1(c)	39.31(a)(3)	D	<p>EI. Subsection (c) is proposed to be amended to correct an inconsistency and to provide clarity. Currently, subsection (c) requires a licensee conducting well logging as defined in §30345.2(b)(19) to comply with 10 CFR 71 published June 8, 1988. Section 30373 also requires the licensee to comply with 10 CFR 71 published Nov. 30, 1988. Thus, it is unclear which version of 10 CFR 71 must be followed. Therefore, subsection(c) is amended to direct the licensee to §30373 so they can easily determine what regulations apply when transporting radioactive material.</p>

State Regulation 17CCR	10 CFR Section	Compatibility Category	Description and Rationale NE=No Equivalent, I=Identical, EI=Essentially Identical
30373	Part 71		Section 30373 specifies the requirements for transporting radioactive material. The proposed changes address NRC's changes to 10 CFR 71. Compatibility categories for specific Part 71 sections are indicated in the January 26, 2004 publication of the Federal Register (69 Fed.Reg. 3697) and identified in the following discussion.
(a)			EI. Subsection (a) is amended to insert the phrase "on public highways" for consistency with 10 CFR 71.5. This is necessary because of the mobile use of radioactive materials where the "authorized location of use" is a vehicle that can be transported on the public highway system and must be transported safely for the protection of the public. This restriction in language clarifies this requirement in situations such as the above where the public is at risk if transportation of radioactive material is not controlled. This subsection is further amended to change the date of incorporation from November 30, 1988 to Jan. 1, 2007. This is necessary to address NRC's and DOT's changes to federal regulations pertaining to transportation of radioactive material to ensure regulations

State Regulation 17CCR	10 CFR Section	Compatibility Category	Description and Rationale NE=No Equivalent, I=Identical, EI=Essentially Identical
			<p>are consistent and compatible with federal agencies.</p> <p>Subsection (a) is further amended to identify exceptions to the incorporated material. Each item is addressed in the following sections.</p>
(a)(1)	See Description and Rationale	See Description and Rationale	<p>NE. Proposed subsection (a)(1) is needed to identify those sections of 10 CFR 71 that are not incorporated by reference. NRC has designated these sections or subsections as either compatibility category D or category NRC except that, in some instances, other categories are designated as discussed further. Agreement States are not required to adopt category D elements for purposes of compatibility or adequacy. However, Agreement States are not allowed to adopt category NRC elements, as they are reserved to the NRC under the federal AEA. In the order of listing in proposed subsection (a)(1), the compatibility categories for Part 71 sections that are not being adopted are:</p> <ul style="list-style-type: none"> • §§71.0 – 71.3: 71.0 is category [D,] except paragraph C is category [B]; 71.7 & 71.2 are category [D]; and 71.3 is category[B]. §§71.0(c) and 71.3 are addressed in subsection (a)

State Regulation 17CCR	10 CFR Section	Compatibility Category	Description and Rationale NE=No Equivalent, I=Identical, EI=Essentially Identical
			<p>because subsection (a) applies broadly to any person. The term "person" is defined in section 30100(l). If those two provisions were adopted, duplication would occur and clarity lost. Therefore, §§71.0(c) and 71.3 are not incorporated as they are already addressed in subsection (a).</p> <ul style="list-style-type: none"> • §71.6 – 71.13: category [D], except §71.8 is category [C]. Section 71.8 is not incorporated by reference because it is already addressed in 17 CCR 30105 and incorporating through this section would result in duplication. Therefore, §71.8 is excluded from incorporation in this proposal. Section 71.11 is reserved so there is no provision to adopt. • §71.13: category [B]. (This section is already addressed in §30373(b).) • §71.14(b): NRC. • §§71.18, 71.19, 71.24, 71.25, 71.31 – 71.45: category [D] except 71.18, 71.24, & 71.25 are reserved so no provision. • §§71.51 – 71.81: NRC except §71.81 is category [D]. • §§71.91, 71.93, 71.95, 71.99 & 71.100: category [D]. • §71.101(d), (e): NRC; (f):

State Regulation 17CCR	10 CFR Section	Compatibility Category	Description and Rationale NE=No Equivalent, I=Identical, EI=Essentially Identical
			<p>category [D].</p> <ul style="list-style-type: none"> • §71.103 (a): category [C] because the essential objective of this provision is the same as that of §71.101(b), which is proposed to be incorporated. Thus, it is not necessary to adopt this provision again. • §71.103(c) through (f): category[D]. • §71.105(b), (c) & (d): Paragraph (b) is category [C] because the essential objective of this provision is the same as that of §71.103(b), which is proposed to be incorporated. Thus, it is not necessary to adopt this provision again. Paragraphs (c) and (d) are category [D]. • §§71.107 – 71.125: NRC??? • §§71.127 – 71.131: Category [C]-For those states which have licensees that use Type B packages, and have adopted the essential objectives of §71.105, it is not necessary for them to adopt this provision again. Therefore, because California has licensees that use Type B packages and this proposal adopts the essential objectives of §71.105, §§71.127 through 71.131 are not incorporated.

State Regulation 17CCR	10 CFR Section	Compatibility Category	Description and Rationale NE=No Equivalent, I=Identical, EI=Essentially Identical
			<p>Therefore, the following sections in Part 71 not listed in proposed subsection (a)(1) are incorporated by reference. NRC-compatibility category designation is indicated:</p> <ul style="list-style-type: none"> • §§71.4 – 71.5: §71.5 is Category [B]. Regarding §71.4, each term has its own compatibility category as follows: <ul style="list-style-type: none"> ○ A1: Category [B] ○ A2: Category [B] ○ Carrier: Category [B] ○ Certificate holder: Category D--for those States which have no licensees that use Type B packages. Category [B]--for those States which have licensees that use Type B packages. ○ Certificate of compliance. Category [D]--for those States which have no licensees that use Type B packages. Category [B]--for those States which have licensees that use Type B packages. See also discussion regarding proposed subsection (a)(2). ○ Close reflection by water: Category [D]. See also discussion regarding proposed subsection (a)(3). ○ Consignment: Category [B] ○ Containment System: Category D. See also discussion regarding proposed subsection (a)(3). ○ Conveyance: Category [B] ○ Criticality: Category [B]

State Regulation 17CCR	10 CFR Section	Compatibility Category	Description and Rationale NE=No Equivalent, I=Identical, EI=Essentially Identical
			<ul style="list-style-type: none"> ○ Deuterium: Category [B] ○ DOT: Category [D] ○ Exclusive use: Category [B] ○ Fissile material: Category [B] ○ Graphite: Category B ○ Licensed material: [D]. See also discussion regarding proposed subsection (a)(4). ○ Low Specific Activity (LSA) material: Category [B] ○ Low toxicity alpha emitters: [B] ○ Maximum normal operating pressure: Category D. See also discussion regarding proposed subsection (a)(3). ○ Natural thorium: Category [B] ○ Normal form radioactive material: Category [B] ○ Optimum interspersed hydrogenous moderation: Category D. See also discussion regarding proposed subsection (a)(3). ○ Package: Category [B] ○ Fissile material package or Type AF package, Type BF, Type B(U)F package, or Type B(M)F: Category [B] ○ Type A package: Category [B] ○ Type B package: Category [B] ○ Packaging: Category [B] ○ Special form radioactive material: Category [B] ○ Specific activity: Category [B] ○ Spent Nuclear Fuel or Spent Fuel: Category D. See also

State Regulation 17CCR	10 CFR Section	Compatibility Category	Description and Rationale NE=No Equivalent, I=Identical, EI=Essentially Identical
			<p>discussion regarding proposed subsection (a)(3).</p> <ul style="list-style-type: none"> ○ State: Category D. See also discussion regarding proposed subsection (a)(3). ○ Surface Contaminated Object (SCO): Category [B] ○ Transport Index: Category [B] ○ Type A quantity: Category [B] ○ Type B quantity: Category [B] ○ Unirradiated uranium: Category [B] ○ Uranium-- natural, depleted and enriched: Category [B] • §71.14(a): Category [B]. • §71.15: Category [B] • §71.17: Category [B] • §§71.20 – 71.23: Category [B] • §71.47: Category [B] • §71.83: Category [B] • §71.85: Category [B] • §§71.87 – 71.89: Category [B] • §71.97: Category B • §71.101(a), (b), (c)(1), & (g): Paragraphs (a), (b), and (c)(1) are Category C for those States which have users of Type B packages; Paragraph (g) is Category C. • §71.103 (b): Category C. • §71.105(a): Category C. • §71.133: Category C. • §71.135: Category C. • §71.137: Category C. • Appendix A: Category [B].

State Regulation 17CCR	10 CFR Section	Compatibility Category	Description and Rationale NE=No Equivalent, I=Identical, EI=Essentially Identical
(a)(2)	71.4	See Description and Rationale	<p>NE. Proposed subsection (a)(2) is needed to clarify that reference to the NRC within the incorporated regulation text is a reference to the Department with one exception regarding the definition of the term "Certificate of Compliance" (COC) found in 10 CFR 71.4.</p> <p>The exception is necessary to clarify that the Department does not issue the COC but does require licensees to have that document when required by the incorporated material. NRC has designated the term "certificate of compliance" as category B requiring Agreement States to adopt an essentially identical term and definition. Thus, under proposed subsection (a)(1), the term and its definition are incorporated. However, because the definition identifies NRC as the issuer of the COC pursuant to subpart D of 10 CFR 71 and NRC has designated the sections within subpart D (§§71.31 – 71.39) as category NRC, the reference to NRC cannot be modified since the Department, as an agreement state, is disallowed from approving package designs.</p>
(a)(3)	71.4	See Description and Rationale	<p>NE. Proposed subsection (a)(3) is needed to clarify that the following terms, designated as indicated below, are not</p>

State Regulation 17CCR	10 CFR Section	Compatibility Category	Description and Rationale NE=No Equivalent, I=Identical, EI=Essentially Identical
			<p>incorporated by reference:</p> <ul style="list-style-type: none"> • Close reflection by water: Category D • Containment system: Category D • Maximum normal operating pressure: Category D • Optimum interspersed hydrogenous moderation: Category D • Spent nuclear fuel or Spent fuel: Category D. • State: Category D and the content of the definition does not apply in California. <p>Except for the term "State," NRC designated the above terms as Category D because the terms relate to provisions designated as NRC. NRC states that a State may adopt this definition for purposes of clarity or communication. Agreement States can adopt this definition since it in and of itself does not convey any authority whereby a State can regulate in an exclusive NRC jurisdiction. However, if a State chooses to define the term, then the definition should be essentially identical. The department is not incorporating these terms by reference since it does not regulate those activities related to those terms.</p>
(a)(4)	71.4 "Licensed material"	[D]	NE. Proposed subsection (a)(4) is needed to prevent duplication of the term "licensed material" which is included in the

State Regulation 17CCR	10 CFR Section	Compatibility Category	Description and Rationale NE=No Equivalent, I=Identical, EI=Essentially Identical
			regulation text incorporated by reference in §30253. Section 30253 incorporates 10 CFR Part 20 and, as indicated by NRC (69 Fed. Reg. 3772 (Jan. 1, 2004)), for purposes of compatibility, the language of the Part 20 definition should be used.
(a)(5)	71.5	B	EI. Proposed subsection (a)(5) is necessary to clarify that DOT regulations identified in 10 CFR 71.5 are also included in the incorporated material. This proposed regulation incorporates 10 CFR 71.5, which references DOT (49 CFR) regulations. Thus, it is unclear whether 49 CFR regulations are incorporated. Therefore, this proposed subsection clarifies that the DOT's regulations are incorporated.
(b)			NE. No changes are made to subsection (b).
(c)	71.13	[B]	EI. Subsection (c) is proposed to be amended to clarify that physicians who transport radioactive material (RAM) must have a radioactive materials specific license or be identified on such a license as an authorized user. Current requirements are unclear as they could imply that the physician does not need to have a specific license when they are transporting RAM.

State Regulation 17CCR	10 CFR Section	Compatibility Category	Description and Rationale NE=No Equivalent, I=Identical, EI=Essentially Identical
			<p>However, Health and Safety Code §115165, in part, makes it unlawful for any person to receive any source of ionizing radiation, which includes RAM, unless licensed by the Department. 17 CCR 30190(c) requires persons wishing to possess RAM to obtain a specific license. Health and Safety Code §114985(h), in part, defines "specific license" as a license that is issued after application that authorizes the person to use RAM. Therefore, subsection (c) is amended to clarify that the physician is only exempt from transportation requirements under the specified conditions that were already in effect under the authority of statute and other regulation but not clearly specified in the transportation regulations.</p>
Note (2)			<p>NE. The note is amended for clarity to correctly identify from whom and where the adopted material can be obtained.</p>

STATEMENTS OF DETERMINATIONS

ECONOMIC IMPACT

The California Department of Public Health (Department) has determined that the proposed regulatory action 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.

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

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

LOCAL MANDATE DETERMINATION

The Department has determined that the proposed regulations 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 the proposed regulations would effect on small business.

ALTERNATIVES CONSIDERED

The Department has determined that no reasonable alternative considered by the Department or that has been otherwise identified or brought to the attention of the Department would be more effective in carrying out the purpose for which the regulations are proposed or would be as effective and less burdensome to affected private persons than the proposed regulations.

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). 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).

Alternatives have been considered in those areas not subject to or specifically limited by the adequacy and compatibility criteria under the State of California

agreement with the United States Atomic Energy Commission, the predecessor to the United States Nuclear Regulatory Commission (NRC) (Health & Saf. Code, § 115230). NRC categories A and B require that the State be "essentially identical" to the NRC; category C requires that the "essential objectives" are met; category D is not required for purposes of compatibility; and category H&S is not required for purposes of compatibility, but does have health and safety significance and requires adoption of regulations meeting the essential objectives for an adequate program. 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).

EFFECT ON HOUSING COSTS

The Department has made the initial determination that the proposed regulations will have not effect on housing costs.

TITLE 17, CALIFORNIA CODE OF REGULATIONS
DIVISION 1.
CHAPTER 5.
SUBCHAPTER 4.0
GROUP 1. GENERAL
Article 1. Definitions

(1) Amend Section 30100 to read as follows:

§30100. General Definitions.

As used in subchapter 4:

(a) through (c) *No Change to text.*

(d) "Department" means the ~~State~~California Department of Public Health Services.

(e) *No change to text.*

(f) "Hazardous radioactive material", as used in section 33000 of the California Vehicle Code and 114820(ed) of the Health and Safety Code means any "highway route controlled quantity" of radioactive material as such material is defined in ~~The United States~~ title 49, Code of Federal Regulations (CFR), 49 CFR section 173.403(l) as printed in FR 13431, March 31, 1983.

(g) through end *No Change to text.*

Note: Authority cited: Sections ~~400275 and 115000~~ and 131200, Health and Safety Code.

Reference: Sections 114965, 114970, 114985, and 115060, 131050, 131051 and 131052, Health and Safety Code.

GROUP 3. STANDARDS FOR PROTECTION AGAINST RADIATION
Article 7. Radiation Safety Requirements For Well Logging Operations

(2) Amend Section 30346.1 to read as follows:

§ 30346.1. Labels, Security and Transportation.

(a) *No change to text.*

(b) *No change to text.*

(c) ~~The licensee shall not transport radioactive material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set forth in 10 CFR Part 71 (53 FR 21550, Pub. 6/8/88)~~ For transportation of radioactive material, the licensee shall comply with section 30373.

(c) *No change to text.*

(d) *No change to text.*

Note: Authority cited: Sections ~~208 and 25811~~ 115000 and 131200, Health and Safety Code.

Reference: Sections ~~25801, 25802, 25815, 25875 and 25876~~ 114965, 114970, 115060, 115230, 115235, 131050, 131051 and 131052, Health and Safety Code.

GROUP 4. TRANSPORTATION OF RADIOACTIVE MATERIAL
Article 1. Requirements For Transportation Of Radioactive Material

(3) Amend Section 30373 to read as follows:

§ 30373. Transportation Regulations.

(a) No person shall transport any radioactive material outside the confines of that person's facility or other authorized location of use, on public highways, or offer any radioactive material to a carrier for transportation, unless that person complies with, appropriate to the mode of transport, title 10, Code of Federal Regulations, part 71 (10 CFR 71) and Appendix A (January 1, 2007), which is hereby incorporated by reference with the following exceptions~~applicable requirements of the regulations, appropriate to the mode of transport, of the United States Federal Government in 10 CFR, Part 71 (as effective November 30, 1988) insofar as such regulations relate to the packaging of radioactive material, marking and labeling of the packages, loading and storage of packages, placarding of the transportation vehicle, monitoring requirements and accident reporting:~~

(1) 10 CFR 71, sections 71.0 through 71.3, 71.6 through 71.13, 71.14(b), 71.16, 71.18, 71.19, 71.24, 71.25, 71.31 through 71.45, 71.51 through 71.81, 71.91, 71.93, 71.95, 71.99, 71.100, 71.101(c)(2), (d), (e), and (f), 71.103(a), (c) through (f), 71.105(b) through (d), and 71.107 through 71.131 are not incorporated by reference;

(2) Any references to the United States Nuclear Regulatory Commission or any component thereof shall be deemed to be a reference to the "Department"

as defined in section 30100, except for the reference found in the definition of "certificate of compliance" in 10 CFR 71.4;

(3) The terms "Close reflection by water," "Containment system," "Maximum normal operating pressure," "Optimum interspersed hydrogenous moderation," "Spent nuclear fuel or spent fuel," and "State" found in 10 CFR 71.4 are not incorporated by reference;

(4) When the term "licensed material" is used within the material incorporated by this section, it shall mean the same as defined in title 10, Code of Federal Regulations, part 20 section 20.1003 incorporated by reference in section 30253; and

(5) Federal Department of Transportation regulations as of January 1, 2007 referenced in 10 CFR 71.5 are hereby incorporated by reference.

(b) Persons are exempt from this regulation to the extent that they transport any radioactive material or offer any radioactive material to a carrier for transportation where such transportation is subject to the exclusive jurisdiction of the United States Federal Government.

(c) Physicians are exempt from the requirements of this section to the extent that they transport radioactive material for use in the practice of medicine.

However, any physician operating under this exemption shall possess a specific license issued pursuant to section 30195 authorizing human use of radioactive material.

Note: (1) Authority cited: Sections ~~208, 25611, 25651 and 25811,~~ 114765, 114820, 115000 and 131200, Health and Safety Code.

Reference: Sections ~~25606 and 25611~~ 114740, 114765, 131050, 131051 and 131052, Health and Safety Code.

Note: (2) Copies of Title 10, Code of Federal Regulations--Energy, and Title 49, Code of Federal Regulations—Transportation, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Copies can also be obtained at: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1>

Excerpts: Title 17, California Code of Regulations

June 17, 2008

§ 30195. Special Requirements for Issuance of Specific Licenses.

In addition to the requirements set forth in section 30194, specific licenses for certain specialized uses will be issued only if the following conditions are met:

(a) For human use of radioactive material in institutions:

(1) The institution has a formally-constituted and officially-recognized medical radiation safety committee, which should include a representative of the institution's administration and at least three individuals who are knowledgeable in the areas of human use of radioactive material and of radiation safety, and which shall evaluate all proposals for, and maintain surveillance over, all uses of radioactive material within the institution.

(2) The institution has a radiation safety officer, who is a member of the radiation safety committee, and who is qualified by reason of training and experience to oversee the radiation safety aspects of radioactive material use in the institution.

(3) The institution's application includes a detailed statement of qualifications, duties, authority, and responsibility of the radiation safety committee and the radiation safety officer.

(4) The institution had adequate facilities for the clinical care of patients.

(5) Each person to be designated as an individual radioactive material user is a physician and furnishes clear evidence of substantial training and experience in the kinds of uses proposed, including handling and administration of the radioactive material and the appropriate clinical management of patients.

(b) For human use of radioactive material by individuals:

(1) The applicant is a physician and furnishes clear evidence of having substantial training and experience in the kinds of uses proposed, including the handling and administration of the radioactive material and the appropriate clinical management of patients.

(2) The applicant demonstrates access to adequate hospital facilities for the patients, where appropriate.

(c) For use of multiple quantities of types of radioactive material for research and development or for processing for distribution:

(1) The applicant has a radiation safety committee of at least three members which must evaluate all proposals for, and maintain surveillance over, all uses of radioactive material. Committee members shall be knowledgeable and experienced in pertinent kinds of radioactive material use and in radiation safety.

(2) The applicant has a radiation safety officer, who is a member of the radiation safety committee, and who is supported by a staff of a size and degree of competence appropriate to deal with radiation safety problems that might be encountered.

(3) The applicant furnishes a detailed statement of the qualifications, duties, authority, and responsibilities of the radiation safety committee and of the staff radiation safety group.

(d) For distribution of devices to persons generally licensed under sections 30192.1 and 30192.6:

(1) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling, proposed uses and conditions of use, and potential radiation hazards of each device to provide reasonable assurance that:

(A) the radioactive material contained in the device will not be lost;

(B) no individual will receive a radiation dose to the whole body or major portion thereof, head and trunk, lens of the eye, gonads, or active blood-forming organs in excess of 0.5 rem in a year, under ordinary circumstances of use;

(C) the device can be safely operated by individuals not trained in radiation safety; and

(D) the radioactive material within the device would not be accessible to unauthorized individuals.

(2) The applicant submits a sample of the labels to be affixed to the device which include instructions and precautions for safe operation, and indicates the manner in which the labels will be affixed and their location on the device. Each such label shall bear the statement, "Removal of this label is prohibited."

§ 30253. Standards for Protection Against Radiation.

(a) The regulations governing standards for protection against radiation in title 10, Code of Federal Regulations, part 20, (10 CFR 20) sections 20.1001 through 20.2402 and Appendices A through G, (January 1, 2005) are hereby incorporated by reference with the following exceptions:

(1) Title 10, Code of Federal Regulations, sections 20.1001, 20.1002, 20.1006, 20.1007, 20.1008, 20.1009, 20.1401, 20.1402, 20.1403, 20.1404, 20.1405, 20.1406, 20.2106(d), 20.2302, 20.2401, and 20.2402, and Appendix D are not incorporated by reference.

(2) Any references to the United States Nuclear Regulatory Commission (NRC) or any component thereof shall be deemed to be a reference to State Department of Health Services.

(3) The definition of the term "Byproduct material" in 10 CFR 20, section 20.1003 is modified to mean any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to, the process of producing or utilizing special nuclear material.

(4) The definition of the term "License" in 10 CFR 20, section 20.1003 is replaced by the definition of the term "License" as defined in section 30100 of this regulation.

(5) The definition of the term "Licensed material" in 10 CFR 20, section 20.1003 is modified to mean any radioactive material including source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general or specific license issued by the NRC, or by any other Agreement State or by any state that has been either provisionally or finally designated as a Licensing State by the Conference of Radiation Control program Directors, Inc. With respect to dose limits and reporting requirements, the term "Licensed material" is to be construed broadly in context to include any source of ionizing radiation subject to the requirements of this regulation.

(6) The definition of the term "Licensee" as defined in 10 CFR 20, section 20.1003 is replaced by the definition of the term "User" as set forth in section 30100 of this regulation.

(7) The definition of the term "Person" as defined in 10 CFR 20, section 20.1003 is replaced by the definition of the term "Person" as set forth in section 114985(c) of the Health and Safety Code.

(8) The definition of the term "Radiation (ionizing radiation)" as defined in 10 CFR 20, section 20.1003 is replaced by the definition of the term "Ionizing radiation" as set forth in section 114985(b) of the Health and Safety Code.

(9) The definition of the term "Special nuclear materials" as defined in 10 CFR 20, section 20.1003 is replaced by the definition of the term "Special nuclear material" as set forth in section 114985(f) of the Health and Safety Code.

(b) The terms defined in 10 CFR 20, section 20.1003, as incorporated by reference, shall apply to this regulation, except that:

(1) The term "Act" as defined in 10 CFR 20, section 20.1003 is limited to the textual material incorporated by reference in subsection (a) above. The meaning of the term "Act" elsewhere in this regulation, means the "Radiation Control Law," Health and Safety Code, Division 104, Part 9, chapter 8, sections 114960 et seq.

(2) The term "Department" as defined in 10 CFR 20, section 20.1003 is limited to the provisions incorporated by reference in subsection (a). The meaning of the term "Department" elsewhere in this regulation, is as defined in section 114985(j) of the Health and Safety Code.