



MARK B HORTON, MD, MSPH
Director

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



ARNOLD SCHWARZENEGGER
Governor

December 15, 2010

Mr. Terrence Reis
Deputy Director
Division of Materials Safety and State Agreements
U.S. Nuclear Regulatory Commission
11545 Rockville Pike
Rockville, MD 20852

Dear Mr. Reis:

Enclosed for your review is a copy of the final adopted revisions to the California Radiation Control Regulations addressing changes to 10 CFR 20 (Standards for Protection Against Radiation).

Your letter dated July 7, 2010 (ML101520162) contained 20 comments, none of which applied to 10 CFR 20. As noted in your letter, section number “30293” should read “30253” as section “30293” was not amended or submitted for review.

The adopted version did not change substantially from the proposed version. The Radiologic Health Branch believes that the final adopted regulations satisfy the compatibility and health and safety criteria in STP Procedure SA-200 for the regulatory changes identified in the State Regulation Status data sheet. The final adopted regulations include:

Rats ID	Title	State Section
2006-1	Minor Amendments, Parts 20, 30, 32, 35, 40 and 70	
2006-3	National Source Tracking System, Part 20	
2007-3	Requirements for Expanded Definition of Byproduct Material, Parts 20, 30, 31, 32, 33, 35, 61, 150	30253
2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent, Parts 19, 20	

Mr. Terrence Reis
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If you have any questions, please feel free to contact me at (916) 440-7942 or by e-mail at gary.butner@cdph.ca.gov or Phillip Scott at (916) 440-7978 or by e-mail at phillip.scott@cdph.ca.gov.

Sincerely,

Gary W. Butner, Chief
Radiologic Health Branch

Enclosure

cc: Kathleen Schneider, Sr. Project Manager
Division of Materials Safety and State Agreements
U.S. Nuclear Regulatory Commission
11545 Rockville Pike
Rockville, MD 20852

Monica Orendi
Division of Materials Safety and State Agreements
U.S. Nuclear Regulatory Commission
11545 Rockville Pike
Rockville, MD 20852

TITLE 17, CALIFORNIA CODE OF REGULATIONS
DIVISION 1, CHAPTER 5, SUBCHAPTER 4.0
Group 3. Standards for Protection Against Radiation

(1) Amend Section 30253 to read:

§ 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~~2008) 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, 20.1905(g), 20.2106(d), 20.2203(c), 20.2206, 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 the California Department of Public Health ~~Services~~.

(3) The definition of the term “Byproduct material” in 10 CFR 20, section 20.1003 is replaced by the definition of the term “radioactive material” as defined in section 30100 of this regulation~~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 ~~p~~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.

(10) Reports of transactions and inventories required in 10 CFR 20, section 20.2207 shall be submitted to the National Source Tracking System maintained by NRC as specified in section 20.2207. Methods of reporting specified in section 20.2207(f) are identified on NRC's form, referenced in section 20.2207(f)(4).

(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, is as defined in section 30100 of 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 30100 of this regulation~~114985(j) of the Health and Safety Code.~~

Note: Authority cited: Sections ~~400275-114975, and 115000, 131051, 131052, 131055, and 131200~~, Health and Safety Code. Reference: Sections 114960, 114965, 114970, 114985, 114990, 115060, 115105, 115110, 115120, 115165, 115230 and 115235, Health and Safety Code.

(2) Amend Section 30255 to read as follows:

§ 30255. Notices, Instructions, and Reports to Personnel.

(a) *No change to text*

(b) Each user shall:

(b)(1) through (b)(5) No change to text

(6) Provide reports to any individual of ~~his~~their radiation exposure data and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of that individual as specified in this section. The information reported shall include data and results obtained pursuant to Department regulations, orders, or license conditions, as shown in records maintained by the user pursuant to Department regulations. Each notification and report shall: be in writing; include appropriate identifying data such as the name of the user, the name of the individual, the individual's Social Security number; include the individual's exposure information; and contain the following statement:

"This report is furnished to you under the provisions of the California State Department of ~~Public Health Services~~ Regulations: Standards for Protection Against Radiation. You should preserve this report for future reference."

These reports shall be provided as follows:

(A) ~~At the request of any individual, each~~ Each user shall advise each worker such individual annually of his ~~exposure~~ the worker's dose to radiation or radioactive material as shown in records maintained by the licensee or registrant ~~user~~ pursuant to ~~United States, title 10, Code of Federal Regulations, part 20, (10 CFR 20), section 20.2106 subpart M~~ as incorporated by reference in section 30253, ~~including the results of any calculations and analyses of radioactive material deposited in the body of the individual.~~ The user shall provide an annual report to each monitored individual pursuant to section 20.1502, incorporated by reference in section 30253, of the dose received in that monitoring year if:

1. The individual's occupational dose exceeds 100 mrem total effective dose equivalent or 100 mrem to any individual organ or tissue; or
2. The individual requests his or her annual dose report.

(B) ~~At the request of an individual a worker~~ formerly engaged in work controlled by the user, the user shall furnish to the ~~individual~~ worker a report of his ~~the worker's~~ exposure to radiation or radioactive material as shown in records maintained by the user pursuant to 10 CFR 20, section 20.2106 that has been incorporated by reference in section 30253, for each year the worker was required to be monitored pursuant to section 20.1502 and for each year the worker was required to be monitored under the monitoring requirements in effect prior to March 3, 1994. Such report shall be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the user, whichever is later; ~~shall cover, within the period of time specified in the request, each calendar quarter in which the individual's activities involved exposure to radiation from radioactive materials licensed by, or radiation machines registered with the Department; and shall include the dates and locations of work under the license or registration in which the individual participated during this period.~~ This report shall cover the period of time that the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation machines registered with, the Department and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

(C) When a user is required pursuant to ~~United States, title 10, Code of Federal Regulations, part 20, subpart M~~ 10 CFR 20, sections 20.2202, 20.2203, or 20.2204, as incorporated by reference in section 30253, to report to the Department any exposure of an individual to radiation or radioactive material, the user shall also provide the individual a report on his exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Department.

(D) ~~At the request of an individual who is terminating employment or assignment to work involving radiation exposure in the user's facility in a given calendar quarter, the user shall furnish to the individual a written report of the individual's exposure to radiation or radioactive material received during that specifically identified calendar quarter. Such report shall contain an estimate of exposures if the final reports are not available at the time of termination. Estimated exposures shall be clearly indicated as such.~~ At the request of a worker who is terminating employment with the user that involved exposure to radiation or radioactive materials, during the current calendar

quarter or the current year, each user shall provide at termination to each worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the user during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose must be provided together with a clear indication that this is an estimate.

Note: Authority cited: Sections ~~208 and 25811~~114975, 115000, 131051, 131052, 131055, and 131200, Health and Safety Code. Reference: Sections ~~25801, 25802, 25811, 25815, 25826, 25875 and 25876~~,114965, 114940, 115000, 115060, 115110, 115230 and 115235, Health and Safety Code.

(3) Amend Section 30256 to read as follows:

§ 30256. Vacating Installations: Records and Notice.

(a) *No change to text.*

(b) Each person granted a specific license pursuant to Group 2 of this Subchapter shall, no less than 30 days before vacating any installation which may have been contaminated with radioactive material as a result of ~~his~~the licensee's activities, notify the department in writing of intent to vacate. This notice shall be submitted on form ~~RHB 314 (12/95)~~CDPH 5314 (06/09), entitled "Certificate of Disposition of Materials," which is incorporated by reference herein, and shall address all requirements specified in ~~§~~subsection (c).

(c) If a licensee does not submit an application for license renewal under section 30194, the licensee shall on or before the expiration date specified in the license:

(1) through (3) *No change to text.*

(4) Submit a completed form ~~RHB 314 (12/95)~~CDPH 5314 (06/09), which certifies information concerning the disposition of materials; and

(5) *No change to text.*

(d) through (g) *No change to text.*

(h) Upon approval of the decommissioning plan by the Department, the licensee shall complete decommissioning in accordance with the approved plan. As a final step in decommissioning, the licensee shall again submit the information required in ~~§~~subsection (c)(5) and shall certify the disposition of accumulated wastes from decommissioning by completing form ~~RHB 314 (12/95)~~CDPH 5314 (06/09).

(i) through (k) *No change to text.*

Note: Authority cited: Sections ~~400275~~114975, 115000, 131051, 131052, 131055, and 131200, Health and Safety Code. Reference: Sections 114965, 114970, 115060, 115230 and 115235, Health and Safety Code.

FINAL STATEMENT OF REASONS

The information contained in the Initial Statement of Reasons (ISR) at the time of Public Notice remains unchanged with the exception of the following modifications.

Section 30253(a)(1): Currently, title 10, Code of Federal Regulations (10 CFR), section 20.2203 is incorporated. However, it was noted that section 20.2203(c) is compatibility category NRC meaning that it is reserved to the federal government and should not be adopted. Therefore, subsection (a)(1) is amended to list 20.2203(c) as not being incorporated by reference. Section 20.2203(c) applies to nuclear power plants, which are subject to federal jurisdiction. This is a nonsubstantial change.

Also, under 10 CFR 20.2206, certain licensees must submit an annual report. However, it was noted that the information required under section 20.2206 is reviewed by California Department of Public Health (CDPH) inspectors during inspections that occur every year or every other year. Requiring submittal of the already reviewed information is burdensome, costly, and duplicative. The Nuclear Regulatory Commission's (NRC) compatibility category for section 20.2206 is Category NRC (subsections (a)(1), (3), (4) & (5)) and Category D (subsections (a)(2), (a)(6), (a)(7), (b) & (c)). Regulations designated as Category NRC cannot be adopted by a state and regulations designated as Category D are not required to be adopted for purposes of compatibility. Therefore, language is amended to clarify that section 20.2206 is not being incorporated by reference resulting in repealing the annual reporting requirement of section 20.2206. A non-substantive change is made correcting a typographical error in the name of the California Department of Public Health.

Section 30255(b)(6): Reviewing NRC's equivalent regulation, 10 CFR 19.13, many inconsistencies were noted indicating that the current regulation text, including the proposed text, did not meet NRC's compatibility category; namely, Category C, requiring the state to adopt a regulation that meets the essential objective of the NRC regulation. Therefore, language is amended to ensure consistency with 10 CFR 19.13 and the word "worker," as defined in section 30100 of Department regulations, is used for consistency with other Department and NRC regulations. Acronyms are created to reduce the physical length of phrases and are nonsubstantial. Other nonsubstantial grammatical and structural changes are made.

Regarding the date of March 3, 1994 specified in section 30255(b)(6)(B), in 1994, the Department adopted emergency regulations to address major NRC regulatory changes that took effect January 1, 1994. The Department's emergency regulations took effect March 3, 1994 and the regulations became permanent after properly filing a certificate of compliance. Therefore, language is amended to ensure a user understands that the particular report must also include exposure data prior to March 3, 1994, as applicable.

Section 30256 & Form CDPH 5314: It was noted that the ISR, proposed text, and Form CDPH 5314 contained inconsistencies. Thus, the following nonsubstantial changes are proposed:

- Proposed Text, subsections (b) & (h): a capitalization change to the word "Subsection" is made.

- Proposed Text, subsections (b), (c)(4), & (h): “RH” is changed to “CDPH” to reflect the actual acronym used in Department controlled forms.
- Form CDPH 5314:
 - Internet address is changed to reflect a shorter address.
 - Regarding the sentence found in section “A. Materials Data” that is underlined, ISR, page 9, states that it is being reformatted to be in bold and italic font. However, the sentence on the form is underlined and not bolded or in italic font. Therefore, the form is amended to be consistent with the ISR statement.
 - The form number publication date on the bottom left of the form is changed from “(01/09)” to “(06/09)” to reflect the actual publication date.

Initial Statement of Reasons (ISR), page 9: The sentence “The form number is changed from RHB 314 (12/95) to RH 5314 (06/09)” found in the first bulleted paragraph regarding section 30256 is deleted and replaced with the sentence “The form number is changed from RHB 314 (12/95) to CDPH 5314 (06/09).”

ISR, page 7: Regarding the discussion of the proposed changes to subsection (a)(1), the paragraph is replaced with the following:

Subsection (a)(1) is proposed to be amended to clarify that 10 CFR 20.1905(g) and 20.2203(c) are not incorporated by reference; 10 CFR 20.1905(g) and 20.2203(c) pertain to exemptions from labeling at power reactors and to reports, respectively, and are not adopted because both provisions are an NRC program element that addresses a regulation that cannot be relinquished to Agreement States. Program elements designated compatibility category NRC should not be adopted by Agreement States. (72 Fed.Reg. 68043 (Dec. 4, 2007).)

Incorporation by Reference: The form CDPH 5314 incorporated by reference in section 30256(b), (c), and (h), though short in length and the content of which could be specified in regulation text, is incorporated for workflow uniformity and efficiency. Requiring use of the form ensures all licensees use the same format so as to reduce staff review time by standardizing submitted content and increases visual recognition by staff of the requested action allowing for efficient processing. Further, the documents are readily available at the website indicated on the form.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE INITIAL

NOTICE PERIOD OF APRIL 2, 2010 THROUGH MAY 20, 2010.

This regulation (DPH-08-008) was made available to the public from April 2, 2010, and ended at 5:00 pm on May 20, 2010. A request for a public hearing was not received and, thus, no public hearing was held. The written proceeding produced comments from the below individuals:

1. Stanley E. Skubic, Ph.D, Radiation Safety Officer (RSO), Radiological Associates of Sacramento (RAS).
2. Richard Myers, MD, RSO, RAS.
3. Thomas Pounds, MD, RSO, RAS.
4. Benjamin Franc, MD, RSO, RAS.
5. Frederic Conte, MD, RSO, RAS.

Comments & Response

Comments from commenters one through five are duplicative and are addressed in whole.

Commenters one through five object to the provision (section 30255(b)(6)(A)1) requiring annual written notification of individuals exceeding an arbitrary preset limit. Commenters recommend that if such notification must be mandated, then the limit should be set to the ALARA¹ limit and at least raised to 500 mrem in a year.

Response: CDPH rejects the recommendation for the following reasons:

- The limit of 100 mrem is not arbitrary. The ISR, page 8, clearly identifies that the limit being used is the public dose limit specified in 10 CFR 20.1301, which is incorporated by reference in section 30253. Further, the ISR specifies how the value was obtained and the basis for that value. Lastly, as it pertains to radioactive material use, the same provision is being applied in all 50 States and territories by the NRC.
- Regarding raising the value to 500 mrem as it pertains to the use of X-ray producing machines, current requirements as to when personnel monitoring is required are specified in 10 CFR 20.1201 as incorporated by reference in section 30253. Monitoring is required if the worker's occupational dose is likely to exceed 10 percent of the annual limit. This equates to a total effective dose equivalent (TEDE) of 500 mrem. Thus, the commenter's recommendation is essentially inherent in the provision. Reporting needs only to occur if required to monitor and the monitored value is greater than 100 mrem. Thus, the provision reduces reporting burdens on some users while ensuring workers can obtain their dose report.
- As indicated in the ISR, page 8, NRC's compatibility category for 10 CFR 19.13 is C, requiring agreement states to adopt a regulation that meets the essential objective of the provision. California could not adopt a less restrictive requirement and be compatible. The recommendation would

¹ ALARA means As Low As Reasonably Achievable.

create a less restrictive provision as compared to NRC. Therefore, the recommendation is rejected.

- The commenter states that the provision would pose a substantial administrative burden without concomitant reduction in radiation dose. It should be noted that nuclear medicine technologists, radiologists, radiologic technologists, and X-ray technicians often, with or without their current employer being aware, work for other facilities in which they receive an occupational dose. Occupational dose limits are limits set on how much exposure an individual receives not on how much one can receive at one facility. That equates to allowing a person who works in two or more facilities to receive two or more maximum exposures. Thus, an individual who receives radiation doses from multiple users is limited to the individual exposure limit. Current requirements, 10 CFR 20.1201(f), incorporated by reference in section 30253, requires the user to reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. Also, 10 CFR 20.2104 applies and addresses this issue. Though this provision will reduce administrative burdens on some users and increase it for others, it ensures that the individual who is occupationally exposed to radiation is provided with their dose records and the individual can also take any additional actions they determine will help reduce their exposure.

COMMENTS RECEIVED DURING THE PERIOD THE MODIFIED TEXT WAS AVAILABLE TO THE PUBLIC.

CDPH has complied with the requirements of section 44 of Title 1 of the California Code of Regulations. The date upon which the notice and text were mailed was August 12, 2010. The public availability period began August 12, 2010, and ended August 30, 2010. CDPH did not receive any comments on the modified text during the availability period.

ALTERNATIVES DETERMINATION

CDPH has determined that, because the radiation control program must maintain compatibility with the regulations of the United States Atomic Energy Commission, the predecessor to NRC (Health & Saf. Code, § 115230), and according to the agreement, the state is to use its "best efforts to maintain continuing compatibility between its program and the program of the [United States Atomic Energy] Commission for the regulation of like materials..." (Health & Saf. Code, § 115235, art. V) no alternative considered by CDPH would be more effective in carrying out the purpose for which the regulation is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

IMPOSITION OF LOCAL MANDATE

The proposed regulations do not impose a mandate on local agencies or school districts.