



MARK B HORTON, MD, MSPH
Director

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



ARNOLD SCHWARZENEGGER
Governor

October 27, 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 35 (Medical Use.)

Your letter dated July 7, 2010 (ML101520162) contained 20 comments, none of which applied to 10 CFR 35. As noted in your letter, section number “30293” should read “30253” as section “30293” was not amended or submitted for review.

The final adopted version did not change substantially from the proposed version so 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 RATS ID number:

Rats ID	Title	State Section
1992-1	Quality Management Program and Misadministration	30195
1995-7	Medical Administration of Radiation and Radioactive Materials, Parts 20 & 35	
1997-3	Criteria for the Release of Individuals Administered Radioactive Material	
1998-5	Minor Corrections, Clarifying Changes, and a Minor Policy Change, Parts 20, 35, 36	
2002-2	Medical Use of Byproduct Material, Parts 20, 32, 35	
2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards, Part 35	

2006-1	Minor Amendments, Parts 20, 30, 32, 35, 40 and 70	
2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications, Parts 32 and 35	
2007-3	Requirements for Expanded Definition of Byproduct Material, Parts 20, 30, 31, 32, 33, 35, 61, 150	

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,

Gary W. Butner, Chief
Radiologic Health Branch
(916) 440-7942

Enclosure

cc: Kathleen Schneider
Steven Poy

TITLE 17, California Code of Regulations
Division 1, Chapter 5, Subchapter 4.0, Group 1, Article 1.

(1) Amend Section 30100 to read as follows:

§ 30100. General Definitions.

As used in subchapter 4:

(a) "Act" means the "Radiation Control Law," Health and Safety Code, Division 104, Part 9, chapter 8, sections 114960 et seq.

(b) "Agreement State" means any state with which the United States Atomic Energy Commission or Nuclear Regulatory Commission has entered into an effective agreement under section 274b of the Atomic Energy Act of 1954, Title 42, United States Code, section 2021(b) (formerly section 274(b)).

(c) "Decommission" means to remove safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the license.

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

(e) "Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

(f) "Hazardous radioactive material," as used in section 33000 of the California Vehicle Code and 114820(d) of the Health and Safety Code, means any "highway route controlled quantity" of radioactive material as such material is defined in title 49, Code of Federal Regulations, section 173.403.

(g) "Human use" means the internal or external administration of radiation or radioactive materials to human beings.

(h) "Installation" means the location where one or more reportable sources of radiation are possessed.

(i) "License," except where otherwise specified, means a license issued pursuant to group 2, Licensing of Radioactive Material.

~~(j) "Misadministration" means the administration of:~~

~~(1) A radiopharmaceutical or radiation from a sealed source other than the one intended;~~

~~(2) A radiopharmaceutical or radiation to the wrong patient;~~

~~(3) A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician;~~

~~(4) A diagnostic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 50 percent;~~

~~(5) A therapeutic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 10 percent; or~~

~~(6) A therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent.~~

(kj) "Other official agency specifically designated by the Department" means an agency with which the Department has entered into an agreement pursuant to section 114990 of the Health and Safety Code.

(lk) "Person" means 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.

(ml) "Personnel monitoring equipment" means devices designed to be worn or carried by an individual for the purpose of measuring the dose received by that individual (e.g., film badges, pocket chambers, pocket dosimeters, film rings, etc.).

(pm) "Possess" means to receive, possess, use, transfer or dispose of radioactive material pursuant to this regulation.

(pn) "Possessing a reportable source of radiation" means having physical possession of, or otherwise having control of, a reportable source of radiation in the State of California.

(po) "Radiation" (ionizing radiation) means gamma rays and X-rays; alpha and beta particles, high-speed electrons, neutrons, protons, and other nuclear particles; but not sound or radio waves, or visible, infrared, or ultraviolet light.

(qp) "Radiation machine" means any device capable of producing radiation when the associated control devices are operated, but excluding devices which produce radiation only by the use of radioactive material.

(rq) "Radioactive material" means any material which emits radiation spontaneously.

(sr) "Registrant" means any person who is registering or who has registered with the Department pursuant to group 1.5, Registration of Sources of Radiation.

(ts) "Reportable sources of radiation" means either of the following:

(1) Radiation machines, when installed in such manner as to be capable of producing radiation.

(2) Radioactive material contained in devices ~~designed and manufactured for the purpose of detecting, measuring, gauging, controlling thickness, density, level, interface location, radiation, leakage or qualitative or quantitative chemical composition, for producing light or an ionized atmosphere,~~ possessed pursuant to a general license under provisions of sections 30192.1 and 30192.6 of group 2 of this subchapter (Licensing of Radioactive Materials).

(ut) "Research and development" means theoretical analysis, exploration, experimentation or the extension of investigative findings and scientific or technical theories into practical application for experimental or demonstration purposes, including the experimental production and testing of models, prototype devices, materials and processes; but shall not include human use.

(vu) "Sealed source" means any radioactive material that is permanently encapsulated in such manner that the radioactive material will not be released under the most severe conditions likely to be encountered by the source.

(wv) "Source of radiation" means a discrete or separate quantity of radioactive material or a single radiation machine.

(xw) "Special nuclear material" means:

(1) Plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Department declares by rule to be special nuclear material after the United States Nuclear Regulatory Commission, or any successor thereto, has determined the material to be such, but does not include source material; or

(2) Any material artificially enriched by any of the foregoing, but does not include source material.

(yx) "Specific license" means a license or the equivalent document issued to a named person by the Department or by the Nuclear Regulatory Commission or by any other Agreement State.

(zy) "This regulation" means: California Code of Regulations, Title 17, Division 1, Chapter 5, Subchapter 4.

(~~aa~~) "User" means any person who is licensed to possess radioactive material or who has registered as possessing a reportable source of radiation pursuant to groups 1.5 and 2 of this subchapter, or who otherwise possesses a source of radiation which is subject to such licensure or registration.

(~~aba~~) "Worker" means any individual engaged in activities subject to this regulation ~~title 17, California Code of Regulations, chapter 5, subchapter 4,~~ and controlled by a user, but does not include the user.

Note: Authority cited: Sections 114975, 115000 and 131200, Health and Safety Code.
Reference: Sections 114965, 114970, 114985 and 115060, 131050, 131051 and 131052, Health and Safety Code.

GROUP 2. LICENSING OF RADIOACTIVE MATERIALS
Article 4. Licenses

(2) Amend Section 30195 to read as follows:

§ 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.~~

(a) For human use of radioactive material limited to medical purposes, the applicant submits documentation demonstrating that they are capable of complying with the regulations governing the medical use of radioactive material in title 10, Code of Federal Regulations, Part 35 (10 CFR 35) (January 1, 2008), which is hereby incorporated by reference with the exceptions listed at subsections (a)(1) through (a)(15) below, and upon issuance of a license maintains compliance with said regulations:

(1) Title 10, Code of Federal Regulations, sections 35.1, 35.5, 35.7, 35.8, 35.10, 35.11(c), 35.12, 35.13, 35.14, 35.15, 35.18, 35.19, 35.26, 35.65, 35.4001, and 35.4002 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 "Department" as defined in section 30100 of this regulation.

(3) Any reference to 10 CFR 35, section 35.5 shall be deemed to be a reference to section 30293 of this regulation.

(4) Any reference to “Person” in 10 CFR 35 shall be deemed to be a reference to the term “Person” as defined in section 114985(c) of the Health and Safety Code.

(5) Any reference to “Licensee” in 10 CFR 35 shall be deemed to be a reference to the term “User” as defined in section 30100 of this regulation.

(6) Any reference to “Byproduct material” in 10 CFR 35 is replaced by the term “Radioactive Material” as defined in section 30100 of this regulation.

(7) The definition of the term “Agreement State” in 10 CFR 35, section 35.2 is replaced by the definition of the term “Agreement State” as defined in section 30100 of this regulation.

(8) The definition of the term “Sealed source” in 10 CFR 35, section 35.2 is replaced by the definition of the term “Sealed source” as defined in section 30100 of this regulation.

(9) The definition of the term “Dentist” in 10 CFR 35, section 35.2 is modified to mean an individual possessing a current and valid license to practice as a dentist pursuant to the California Dental Practice Act specified in Business and Professions Code Section 1600 et seq.

(10) The definition of the term “Pharmacist” in 10 CFR 35, section 35.2 is modified to mean an individual possessing a current and valid license to practice as a pharmacist pursuant to the California Pharmacy Law specified in Business and Professions Code Section 4000 et seq.

(11) The definition of the term “Podiatrist” in 10 CFR 35, section 35.2 is modified to mean an individual possessing a current and valid license to practice as a podiatrist pursuant to California Business and Professions Code sections 2460 et seq.

(12) The definition of the term “Physician” in 10 CFR 35, section 35.2 is modified to mean an individual possessing a current and valid license to practice as a physician and surgeon or as an osteopathic physician and surgeon pursuant to the California Medical Practice Act specified in Business and Professions Code Section 2000 et seq.

(13) The reference to section 19.12 found in 10 CFR 35, section 35.27(b)(1) shall be deemed to be a reference to section 30255 of this regulation.

(14) The date January 1, 2011 is substituted for the date October 24, 2002 found in 10 CFR 35, section 35.57(a)(1) and (b)(1). Subdivisions (a)(2) and (b)(2) of 10 CFR 35, section 35.57 are substituted with the following:

(A) “An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist, or an authorized medical physicist, or an authorized nuclear pharmacist, and physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license or an NRC or Agreement State license or a permit issued by a Department, NRC or Agreement State broad scope licensee or NRC master material license permit or by an NRC master material license permittee of broad scope before January 1, 2011 need not comply with the training requirements of 10 CFR 35, sections 35.50, 35.51, or 35.55, and subparts D through H of 10 CFR 35, respectively.”

(15) Nothing in this incorporation by reference shall be construed to authorize the Department to approve of specialty boards or medical specialty boards for meeting training requirements specified in 10 CFR 35.

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

(1) through (3) *No Change to Text.*

(ec) For distribution of devices to persons generally licensed under Sections 30192.1 and 30192.6:

(1) through (2) *No Change to Text.*

Note: Authority cited: Sections ~~208 and 25814~~114975, 115000 and 131200, Health and Safety Code. Reference: Sections ~~25801, 25802, 25815, 25855 and 25876~~ 114965, 114970, 115060, 115165, 115235, 131050, 131051 and 131052, Health and Safety Code.

GROUP 3. STANDARDS FOR PROTECTION AGAINST RADIATION

Article 5. Special Requirements for the Use of Radioactive Material in the Healing Arts

(3) Repeal Section 30321 as follows:

§ 30321. Accountability, Storage, and Transit.

~~(a) In each hospital and clinic possessing sealed sources, there shall be a custodian of such sources. The custodian or his specified alternate shall keep a permanent record of the issue and return of all such sources.~~

~~(b) When not in use, sources and applicators containing sealed sources shall be kept in a protective enclosure of such material and wall thickness as may be necessary to assure compliance with the United States, title 10, Code of Federal Regulations, part 20, subparts C and D as incorporated by reference in section 30253.~~

Note: Authority cited: Sections 208 and 25811, Health and Safety Code. Reference: Sections 25801, 25802, 25811, 25815, 25875 and 25876, Health and Safety Code.

(4) Repeal Section 30321.1 as follows:

§ 30321.1. Confirming Removal of Implants.

~~The custodian or his specified alternate shall assure that patients treated with removable radioactive source implants remain hospitalized until a source count and a radiation survey of the patient confirm that all implants have been removed.~~

Note: Authority cited: Sections 208 and 25811, Health and Safety Code. Reference: Sections 25801, 25802, 25811, 25815, 25875 and 25876, Health and Safety Code; and 10 CFR 35.15(b) (vi) and (vii) (39 FR 26143 and 43 FR 553467).

(5) Repeal Section 30322 as follows:

§ 30322. Records and Reports of Misadministration.

~~(a) When a misadministration involves a therapy procedure, the licensee shall notify the Department. The licensee shall also notify the referring physician of the affected patient and the patient or the responsible relative or guardian, unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative or guardian would be harmful to one or the other, respectively. These notifications shall be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of this.~~

~~(b) Within 15 days after the initial therapy misadministration report to the Department, the licensee shall report, in writing, to the Department and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative or guardian if either was previously notified by the licensee, as required by Subsection 30322(a). The written report shall include the licensee's name; the referring physician's name; a brief description of the event; the effect on the patient; the action taken to prevent recurrence; whether the licensee informed the patient or the patient's responsible relative or guardian, and if not, why not. The report shall not include the patient's name or other information that could lead to identification of the patient.~~

~~(c) When a misadministration involves a diagnostic procedure, the radiation safety officer shall promptly investigate its cause, make a record for agency review, and retain the record as directed by Subsection 30322(d). The licensee shall also notify the referring physician and the Department, in writing on Department Form DHS 8453 (11/89) (Diagnostic Misadministration Report) within 15 days, if the misadministration involved use of radioactive material not intended for medical use, administration of dosage five-fold different from the intended dosage, or administration of radioactive material such that the patient is likely to receive an organ dose greater than 2 Rem or a whole body dose of greater than 500 millirem (mRem). Licensees shall use the best available dosimetry data, correcting only for amount of radioactivity administered, to determine whether a report is required. Reports and records required pursuant to this section shall include reference to the source for dosimetry data used to determine whether a report is required.~~

~~(d) Each licensee shall retain a record of each misadministration for 10 years. The record shall contain the names of all individuals involved in the event, including the physician, allied health personnel, the patient and the patient's referring physician, the patient's social security number or identification number if one has been assigned, a brief description of the event, the effect on the patient, and the action taken, if any, to prevent recurrence.~~

~~(e) Aside from the notification requirement, nothing in Subsections 30322(a) through (d) shall affect any rights or duties of licensees and physicians in relation to each other, patients, or responsible relatives or guardians.~~

Note: Authority cited: Sections 208 and 25811, Health and Safety Code. Reference: Sections 25801, 25802, 25815, 25875 and 25876, Health and Safety Code.