

DEPARTMENT OF HEALTH SERVICES

RADIOLOGIC HEALTH BRANCH

P.O. BOX 942732, MS-178

SACRAMENTO, CA 94234-7320

(916) 445-0931



August 22, 2000

Paul H. Lohaus
Deputy Director
Office of State and Tribal Programs
U.S. NRC
Mailstop 03C10
Washington, D.C. 20555

Dear Deputy Director:

REVIEW OF AGREEMENT STATE REGULATIONS

As requested in the Office of State and Tribal Programs (STP) Procedure SA-201, *Review of State Regulations*, the enclosed proposed regulations (R-31-98) are submitted for your review. Please respond by October 16, 2000 as this is the end of the public comment period.

The purpose of the proposed regulation is to establish compatibility with the amendments of 10 C.F.R. Part 20 as noted in the following publications of the Federal Register:

| | |
|------------------------------------|------------------------------------|
| 58 Fed.Reg. 67659 (Dec. 22, 1993), | 58 Fed.Reg. 69219 (Dec. 30, 1993), |
| 60 Fed.Reg. 7900 (Feb. 10, 1995), | 60 Fed.Reg. 15649 (Mar. 27, 1995), |
| 60 Fed.Reg. 20183 (Apr. 25, 1995), | 60 Fed.Reg. 25983 (May 16, 1995), |
| 60 Fed.Reg. 36038 (Jul. 13, 1995), | 61 Fed.Reg. 65120 (Dec. 10, 1996), |
| 61 Fed.Reg. 24669 (May 16, 1996), | 62 Fed.Reg. 4120 (Jan. 29, 1997), |
| 62 Fed.Reg. 39058 (Jul. 21, 1997), | 63 Fed.Reg. 39477 (Jul. 23, 1998), |
| 63 Fed.Reg. 45393 (Aug. 26, 1998), | 63 Fed.Reg. 50128 (Sep. 21, 1998). |

We believe that the proposed regulation satisfies the compatibility and health and safety component criteria in Handbook 5.9 and the assigned designations set out in STP Procedure, SA-200.

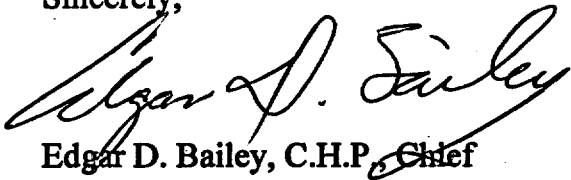
We believe that differences noted in a review of California's proposed regulations and the NRC's regulations are not significant. This is based on Appendix B of STP Procedure SA-201.

5408

Deputy Director
Page 2
August 22, 2000

If you have any questions regarding the proposed regulations, please contact me or Phillip L. Scott, Associate Health Physicist at (916) 324-3727.

Sincerely,

A handwritten signature in cursive script, appearing to read "Edgar D. Bailey".

Edgar D. Bailey, C.H.P., Chief

cc: Phillip L. Scott, Associate Health Physicist
Radiologic Health Branch
P.O. Box 942732 MS 178
Sacramento, CA 94234-7320

TITLE 17. PUBLIC HEALTH

GROUP 2. LICENSING OF RADIOACTIVE MATERIALS

ARTICLE 7. RECIPROCAL RECOGNITION OF LICENSES

§ 30225. Persons Licensed by Other Agencies.

(a) Any person who holds a specific license issued by the United States Nuclear Regulatory Commission, 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., other than this State, may conduct activities of the kind therein authorized within this State for a period not in excess of 180 days in any calendar year without obtaining a specific license from the department, provided that the following conditions are satisfied:

(1) The person maintains an office for directing the licensed activity, and at which radiation safety records are normally maintained, in a location under jurisdiction of the agency which issued the specific license.

(2) The license does not limit the authorized activity to specified installations or locations.

(3) The person provides written notice ~~such as to reach~~ the department at least 3 days prior to engaging in such activity. Such notice shall indicate the location, specific time period, and type of proposed possession and use within this ~~S~~state, and shall be accompanied by a copy of the pertinent license. If, for a specific case, the 3-day period would impose an undue hardship on the person, the person may make application to the department to proceed sooner.

(4) The person complies with all applicable regulations of the department and with all the terms and conditions of his the license, except ~~any~~ such terms and conditions which may be inconsistent with said regulations.

(5) The person supplies such other information as the department may request.

(6) The person pays a fee in accordance with §section 30230(d) to the Department prior to the engagement of activities within the §state.

(b) Any person who holds a specific license issued by the United States Nuclear Regulatory Commission, 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., other than this State, authorizing the holder to install or service a device described in §section 30192.1(a) shall be issued a general license to install or service such device in this State, provided that the following conditions are satisfied:

(1) The person files a report with the department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State identifying each device recipient by name and address, the type of device transferred or installed, and the quantity and type of radioactive material contained in each device.

(2) The device has been manufactured and labeled and is installed and serviced in accordance with applicable provisions of the specific license.

(3) The person assures that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device are affixed and bear a statement that "Removal of this label is prohibited."

(4) The person furnishes to each device recipient in this State to whom he or she transfers such a device or on whose premises he or she installs the device, a copy of Group 1.5 of this subchapter, of §section 30192.1(a) and (b) of this regulation, and of §sections 30253, 30254, 30293(a)(2), ~~30294~~, and 30295 and 30297 of Group 3 of this subchapter.

(c) The department may withdraw, limit, or qualify its acceptance of any license specified in §sections 30225(a) or (b) upon determining that such action is necessary to protect health or to minimize danger to life or property.

R-31-98
10-27-99

Note: Authority cited: Sections ~~208~~ 100275, ~~25811~~ 115000 and ~~25816~~ 115060, Health and Safety Code.

Reference: Sections ~~25801~~ 114965, ~~25802~~ 114970, ~~25811~~ 114985, 114990, ~~25815~~ 115060, ~~25816~~ 115065, 115090, 115093, 115105, 115110, 115120, ~~25855~~ 115165, ~~25875~~ 115230 and ~~25876~~ 115235, Health and Safety Code.

GROUP 3. STANDARDS FOR PROTECTION AGAINST RADIATION

ARTICLE 1. GENERAL

§ 30253. Standards for Protecting Against Radiation.

(a) The regulations governing standards for protection against radiation in ~~the United States~~, title 10, Code of Federal Regulations, part 20, sections 20.1001 through 20.2402 and Appendices A through EG, (~~revised January 1, 1993~~) are hereby incorporated by reference with the following exceptions:

(1) ~~The following sections of Title 10, Code of Federal Regulations, sections 20.1001, 20.1002, 20.1006, 20.1007, 20.1008, 20.1009, 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 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 title 10, Code of Federal Regulations, 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 title 10, Code of Federal Regulations, section 20.1003 is replaced by the definition of the term "License" as defined in title 17, California Code of Regulations, section 30100.

(5) The definition of the term "Licensed material" in title 10, Code of Federal Regulations, 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 Nuclear Regulatory Commission, 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 title 17, California Code of Regulations, ~~D~~division 1, ~~C~~chapter 5, subchapter 4.

(6) The definition of the term "Licensee" as defined in title 10, Code of Federal Regulations, section 20.1003 is replaced by the definition of the term "User" as set forth in title 17, California Code of Regulations, section 30100.

(7) The definition of the term "Person" as defined in title 10, Code of Federal Regulations, section 20.1003 is replaced by the definition of the term "Person" as set forth in ~~title 17, California Code of Regulations, section 30100,~~ section 114985(c) of the Health and Safety Code.

(8) The definition of the term "Radiation (ionizing radiation)" as defined in title 10, Code of Federal Regulations, section 20.1003 is replaced by the definition of the term "~~Radiation~~ (~~ionizing radiation~~)" as set forth in ~~title 17, California Code of Regulations, section 30100~~ section 114985(b) of the Health and Safety Code.

(9) The definition of the term "Special nuclear materials" as defined in title 10, Code of Federal Regulations, section 20.1003 is replaced by the definition of the term "Special nuclear material" as set forth in ~~title 17, California Code of Regulations, section 30100~~ section 114985(f) of the Health and Safety Code.

(10) The phrase "Upon the receipt of an LTP or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to Secs. 20.1403 or 20.1404, or whenever the Commission deems such notice to be in the public interest, the Commission shall" in title 10, Code of Federal Regulations, section 20.1405 is replaced with the phrase "Upon the receipt of an LTP, decommissioning plan from the licensee, or proposal for release of a site pursuant to Secs. 20.1403 or 20.1404, and upon a determination by the Commission that deems

such notice is in the public interest, the Commission may".

(11) The word "and" found in title 10, Code of Federal Regulations, section 20.1405 between subdivision (a)(1) and (a)(2) is replaced with the word "and/or".

(12) The phrase "in the Federal Register and in a forum" in title 10, Code of Federal Regulations, section 20.1405(b) is replaced with the phrase "in a forum".

(b) The terms defined in title 10, Code of Federal Regulations, section 20.1003, as incorporated by reference, shall apply to title 17, California Code of Regulations, Division 1, Chapter 5, Subchapter 4, except that:

(1) The term "Act" as defined in title 10, Code of Federal Regulations, section 20.1003 is limited to the textual material incorporated by reference in subdivision (a) above. The meaning of the term "Act" elsewhere in title 17, California Code of Regulations, Division 1, Chapter 5, Subchapter 4, ~~is the same as the term "Act" as defined in title 17, California Code of Regulations, section 30100~~ means the "Radiation Control Law," Health and Safety Code, Part 9, chapter 8, sections 114960 et seq.

(2) The term "Department" as defined in title 10, Code of Federal Regulations, section 20.1003 is limited to the provisions incorporated by reference in ~~paragraph~~ subdivision (a) of this section. The meaning of the term "Department" elsewhere in title 17, California Code of Regulations, division 1, Chapter 5, Subchapter 4, is as defined in ~~title 17, California Code of Regulations, section 30100~~ section 114985(j) of the Health and Safety Code.

~~(c) Users possessing sources of radiation registered or licensed on or before January 1, 1994 may continue to utilize such sources subject to the following conditions;~~

~~(1) The exposure to any member of the public shall not exceed .5 Rem in a year.~~

~~(2) The user shall file with the Department Form RH 500 (1/94) entitled "Certification Dose to Members of Public," incorporated herein by reference, making the showings required therein no later than January 1, 1995.~~

Note: Authority cited: Sections ~~208~~ 100275 and ~~25811~~ 115000, Health and Safety Code.
Reference: Section ~~25801~~ 114960, 114965, 25802 114970, 114985, 114990, 115060, 115105,
115110, 115120, 25811 115165, 25875 115230 and 25876-115235, Health and Safety Code.

§ 30350. Security.

(a) A logging supervisor shall be physically present at a temporary jobsite whenever radioactive materials or particle accelerators are being handled or are not stored and locked in a vehicle or storage place. The logging supervisor may leave the jobsite in order to obtain assistance if a source becomes lodged in a well.

(b) During well logging, except when radiation sources are below ground or in shipping or storage containers, the logging supervisor or other individual designated by the logging supervisor shall maintain direct surveillance of the operation to prevent unauthorized entry into a "controlled area", as defined in Section 30100 of this chapter, title 10, Code of Federal Regulations, section 20.1003, as incorporated by reference by section 30253.

Note: Authority cited. Sections ~~208 and 25811~~ 100275 and 115000, Health and Safety Code.
Reference: Sections ~~25801, 25802, 25815, 25875 and 25876~~ 114965, 114970, 115060, 115230 and 115235, Health and Safety Code.

INITIAL STATEMENT OF REASONS

In the Radiation Control Law, the Department of Health Services (Department) is directed 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, 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 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, pg. 13.) 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 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.

In May 1991, the NRC amended title 10, Code of Federal Regulations, part 20 (10 C.F.R., § 20.1001, et. seq.), which was the first major revision of the federal radiation protection standards in more than 30 years. California incorporated by reference part 20 as published on January 1, 1993. However, NRC has since amended part 20 numerous

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.hsrn.gov/nrc/procfm.htm>

² Ibid.

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.hsrn.gov/nrc/procfm.htm>

times but California has failed to adopt those amendments. California's agreement state status, thus, is in jeopardy.

This proposed regulation amendment implements the revised federal radiation protection standards in place as of the publication of that volume of the Code of Federal Regulations in 1999 and maintains compatibility with the NRC as required by law. (See Health & Saf. Code, § 115235.) Also, this proposed regulation grants reciprocal recognition to states that are provisionally or finally designated as a Licensing State (as opposed to an Agreement State) by the Conference of Radiation Control Program Directors (CRCPD). Such recognition is being proposed because California's regulations apply to all regulated sources of radiation including sources not covered by California's agreement with the NRC. This proposal is consistent with the Department's legislative mandate to maintain regulations compatible with other states. (Health & Saf. Code, §§114965(c) and 114970.)

In addition to the specific authority granted to the Department to regulate sources of ionizing radiation, the Department has general authority to promulgate regulations (Health & Saf. Code, § 100275).

The regulations that implement, interpret and make specific the provisions of the Radiation Control Law are in title 17, California Code of Regulations, sections 30100 through 30373.

The revision of existing state radiation control regulations in Division 1, title 17, California Code of Regulations improves radiation protection standards for California. These revised standards achieve compatibility with the revised NRC regulatory framework.

The statutory authority and reference citation numbers of sections being amended are changed to reflect the numbering system implemented by the 1995 recodification of the Health and Safety Code resulting in a nonsubstantial change pursuant to title 1, California Code of Regulations, section 100.

The changes to existing state regulations are explained as follows:

1. **Section 30225. Persons Licensed by Other Agencies.** The amendment of section 30225 is necessary to clarify that individuals who hold a specific license issued by a Licensing State may receive reciprocal recognition. Some states are licensing states and not agreement states, while others are only agreement states, and some are both licensing and agreement states. A "Licensing State" is any state which has been provisionally or finally so designated by the CRCPD. Because California regulates some radioactive materials that are not regulated by NRC, California wants to grant reciprocity to licensing states.

The CRCPD consists of the program directors who oversee radiation control in each state and issues radioactive material licenses, recognized by the NRC and other state programs for operations that use radioactive material. Designation as a licensing state

requires that the state have equivalent CRCPD requirements, a licensing program for the regulatory control of radioactive material, and final or provisional designation by the CRCPD. Those states that have received such designation are called Licensing States. The CRCPD licensing state concept is a peer and state acknowledgement that a state is able to protect the citizenry from exposure to naturally occurring or accelerator-produced radiation. Licensing states include: Arizona, Colorado, Florida, Georgia, Illinois, Louisiana, Maryland, Mississippi, North Dakota, Oregon, Rhode Island, Tennessee, Texas, Utah, and Washington.

This amendment will benefit California businesses because it will permit them to receive reciprocal licenses from other states. Many state programs will grant reciprocal recognition to licensed individuals or entities which are from a licensing state but require those individuals or entities, which are from a non-licensing state, to obtain a radioactive materials license issued by that state. Because California does not grant reciprocal recognition to individuals or entities from licensing states, some CRCPD licensing states refuse to grant California businesses the reciprocal recognition which would allow them to sell products or operate in those states. Also, some states that are both agreement states and licensing states will not grant reciprocity to California because California does not grant reciprocity to licensing states and some states that are only licensing states will not grant reciprocity to California businesses. This forces California businesses to obtain a separate license from that state, increasing operational costs for California businesses wishing to work in a licensing state. Thus, by recognizing the CRCPD licensing state designation, California businesses will be able to compete in more states than they presently do.

The amendment also further implements the Legislative Policy in section 114970 subsection (b) of the Health & Safety Code, which directs the State to provide programs that, "Promote an orderly regulatory pattern within the State, among the states, ...and facilitate intergovernmental co-operation with respect to use and regulation of sources of ionizing radiation...."

In addition, gender specific terminology in this section is modified to include both genders. Errors in capitalization have been corrected. Repealed sections are deleted for clarity.

2. **Section 30253. Standards for Protection Against Radiation.** The amendment of section 30253 is necessary to achieve compatibility with the revised NRC radiation protection standards. Section 30253(a) is amended to incorporate by reference those changes that were made to title 10, Code of Federal Regulations, sections 20.1001 et seq. and Appendices A through G from January 1, 1993 to January 1, 1999. By changing the date, the incorporated material will include the changes made by the NRC in the following Federal Register Notices, which are available at the federal website "http://www.access.gpo.gov/su_docs/aces/aces140.html":

58 Fed.Reg. 67659 (Dec. 22, 1993),
60 Fed.Reg. 7900 (Feb. 10, 1995),
60 Fed.Reg. 20183 (Apr. 25, 1995),

58 Fed.Reg. 69219 (Dec. 30, 1993),
60 Fed.Reg. 15649 (Mar. 27, 1995),
60 Fed.Reg. 25983 (May 16, 1995),

60 Fed.Reg. 36038 (Jul. 13, 1995),
61 Fed.Reg. 24669 (May 16, 1996),
62 Fed.Reg. 39058 (Jul. 21, 1997),
63 Fed.Reg. 45393 (Aug. 26, 1998),

61 Fed.Reg. 65120 (Dec. 10, 1996),
62 Fed.Reg. 4120 (Jan. 29, 1997),
63 Fed.Reg. 39477 (Jul. 23, 1998),
63 Fed.Reg. 50128 (Sep. 21, 1998).

This amendment will also serve to correct an error found in the existing incorporated material. Appendix C to part 20 provides a list of quantities of licensed material requiring labeling. The January 1, 1993 version of the incorporated regulations incorrectly lists the quantity of material requiring labeling for carbon-14 as 1,000 microcuries while it should be 100. (60 Fed.Reg. 20183 (April 25, 1995).) Currently, there is a regulatory conflict between California and the federal government. This impedes California's ability to abide by its duty as an Agreement State to use "...its best efforts to maintain continuing compatibility between its program and the program of the Commission for the regulation of like materials." (Health & Saf. Code, §115235, art. V.) A comparison of the 1993 and 1999 version of part 20 is attached. (Attachment 1.)

Subpart E of title 10, Code of Federal Regulations, Part 20 is a new subpart that provides radiological criteria for license termination. The criteria identify an annual dose limit of 25 millirem per year. This dose limit is different from the U.S. Environmental Protection Agency (EPA) limit. Thus, the NRC and EPA do not completely agree on decommissioning dose limits. This disagreement manifests in those interest groups and individuals that adhere to EPA's assessment of the dose limit and those who adhere to NRC's dose limit. Further, the NRC has detailed these differences in the July 21, 1997 publication of the Federal Register. (62 Fed.Reg. 39075 (Jul. 21, 1997).)

Because California is an agreement state, the state must use "its best efforts to maintain continuing compatibility between its program and the program of the Commission." (Health & Saf. Code, § 115235, art. V.) Therefore, it is incumbent on the state to adhere to the agreement and use the decommissioning criteria specified by NRC. It is not anticipated that this discrepancy will adversely impact the state.

Therefore, the Department is proposing additional exceptions to the incorporation of title 10, Code of Federal Regulations, part 20 as published on January 1, 1999. However, any exception to the incorporated material must be consistent with the compatibility category stated by the NRC in its rulemaking. The compatibility category of subpart E of 10 CFR 20 is level C. (62 Fed.Reg. 39075 (Jul. 21, 1997).) Category C requires that the program element meet the essential objective.⁴ Subsection (a)(10) is proposed to clarify when the Department would publish a notice to the public regarding termination of a license. This is because the incorporated language found in title 10, Code of Federal Regulations, section 20.1405 is unclear.

⁴ "Adequacy and Compatibility of Agreement State Programs," Management Directive 5.9. The document is available at the Nuclear Regulatory Commission, Office of State Programs website:
<http://www.hsr.dornl.gov/nrc/procfm.htm>

Subsection (a)(11) is proposed to clarify that subdivision (a)(1) of section 20.1405 may occur independent of subdivision (a)(2) of section 20.1405 or that both subdivisions may occur. This is because subdivision (a)(2) of section 20.1405 does not occur in all instances of decommissioning.

Subsection (a)(12) is proposed to clarify that any published notice would be noticed in publications most likely read by Californians.

Subsection (a)(1) is amended to correct a typographical error resulting in a nonsubstantial change. Subsection (a)(5) is amended to include "licensing state" for the reasons stated regarding section 30225.

Subsections (a)(7), (a)(9) and (b)(2) are amended to refer to terms defined by the Radiation Control Law. Subsection (b)(1) is modified to provide the meaning of the word "Act." Subsection (c) is deleted to remove provisions, which expired January 1, 1995.

3. **Section 30350. Security.** The amendment of section 30350 corrects and clarifies an incorrect reference to section 30100. The term "controlled area" referred to in subsection (b) of section 30350 was previously defined in section 30100. (Cal. Code Regs., tit. 17, Register 85, No. 48 (Nov. 25, 1985).) However, the term "controlled area" was removed from section 30100 when federal regulations were incorporated. (Cal. Code Regs., tit. 17, § 30100, Register 94, No. 9 (Mar. 3, 1994).) The term "controlled area" is defined in title 10, Code of Federal Regulations, section 20.1003, which is incorporated by reference in section 30253. Therefore, it is necessary to correct the reference to the definition of "controlled area."