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EDMUND G. BROWN JR.
Governor

November 1, 2018

Ms. Sabrina Attack, Acting Deputy Director
Division of Material Safety, State, Tribal, and Rulemaking Programs
Office of Nuclear Material Safety and Safeguards (NMSS)
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Ms. Attack:

Enclosed for your review is a copy of the proposed revisions to the California Radiation Control Regulations addressing changes made in response to comments provided in your letter dated April 19, 2018. Because California law requires us to submit our final adoption file by February 23, 2019 to the California Office of Administrative Law, we are requesting an expedited review of our proposed changes so we can ensure the proposal meets NRC's requirements and we can complete our adoption within state statutory deadlines. We request a response by November 26, 2018.

Responses to the NRC's April 19, 2018 (ML18087A957) comments are enclosed, as cited references. We believe these additional revisions would satisfy the compatibility and health and safety categories established in the NMSS Procedure SA-200. Existing regulations referenced in the proposal are enclosed.

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,

Signature on File.

Gonzalo L. Perez,
Branch Chief
Radiologic Health Branch

Attachments

cc: Michelle Beardsley



Attachment List

1. Responses to April 19, 2018 letter.
2. Email dated April 26, 2018, forwarded to Phillip Scott, from Michelle Beardsley, Health Physicist/State Regulation Review Coordinator, Agreement States Program Branch, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission (NRC).
3. Excerpts from California Health and Safety Code.
4. Excerpts from Title 17, California Code of Regulations.
5. Proposed Regulation Text for DPH-13-001.
6. Second Supplemental Statement of Reasons for DPH-13-001.

Responses to the NRC's April 19, 2018 comments.

Comment 1:

- The proposal is amended to identify the location of provisions addressing:
 - 10 CFR 71.8. New subsection 30373(a)(7) is added to cite to 17 CCR 30105¹ previously approved on March 9, 2006 by NRC for purposes of RATS ID 1998-1 (ML060670437) addressing the Deliberate Misconduct rule. Section 30105 is provided in this document.
 - 10 CFR 71.13. New subsection 30373(a)(8) is added to cite to subsection 30373(c).
- Reference to 71.103(a) is already proposed to be deleted from those provisions listed in 30373(a)(1) not being adopted. Thus, 10 CFR 71.103(a) is proposed to be adopted under 30373(a).
- The comment misidentifies the compatibility category of 10 CFR 71.127, 71.129 & 71.131 as C. The correct category is [C] and, if 10 CFR 71.105 is adopted, then those three provisions need not be adopted. (Reference 6.) This proposal adopts 71.105. Thus, adoption of those three provisions are not adopted.

Comment 2:

- Because the proposal adopts the 2016 edition of 10 CFR 71, and that 71.20 does not exist within the adopted edition, 71.20 is effectively removed and the comment addressed.

Comment 3:

- The initially proposed text for section 30373 identified some existing provisions not being amended by use of the phrase “no change to text.” The proposal now fully presents those existing provisions for review.
- Section 30373(a)(2) is amended to add two subparagraphs addressing the comment as follows:
 - For provisions referencing “certificate of compliance (CoC), certificate holder or applicant for a CoC,” the following provisions indicated in the comment are either included or not included for the indicated reason:
 - 10 CFR 71.5(b) is included in 30373(a)(2)(B) as recommended;
 - 10 CFR 71.10 is not included since it is compatibility category D, is not required to be adopted, and is not being adopted;
 - 10 CFR 71.17(c)(3) & (e) are included 30373(a)(2)(B) as recommended;
 - 10 CFR 71.85(c) is not included but is listed in 30373(a)(1) as not being adopted because it is compatibility category NRC, may not be adopted, and is not being adopted;
 - 10 CFR 71.88(a)(4) is included in 30373(a)(2)(B) as recommended;

¹ The citation format “17 CCR 30192.5” means Title 17, California Code of Regulations, section 30192.5. This short format for any given State regulation will be used throughout this document for brevity.

- 10 CFR 71.93(c) & 71.95 are not included since both are compatibility category D, are not required to be adopted, and are not being adopted; and
- 10 CFR 71.91(c), (c)(3)(iii) & (f) are included in 30373(a)(2)(B) as recommended.

Comment 4:

- The proposal is revised to include section 30293(a)(2) as indicated. Currently, the existing provision applies to users, as defined in 17 CCR 30100(z), of both radiation machines and radioactive materials. Because the NRC does not regulate radiation machines, section 30293(a)(2) is revised for consistency with 10 CFR 40.61(a)(2) by providing an exception specific to source material, a subset of radioactive material as defined in 17 CCR 30100(q). NRC has designated 10 CFR 40.61(a)(2) as compatibility category C, requiring agreement states to adopt the essential objectives. Additionally, because the existing provision applies to all users of radioactive materials, 10 CFR 30.51(a)(2) was reviewed, and the existing provision deemed equivalent, to ensure the proposal did not change the regulatory effect for radioactive material users not possessing source material.
- However, this proposal excludes reference to “byproduct material,” as defined in 10 CFR 40.4, found within 10 CFR 40.61(a)(2) because California has no licensees possessing that defined material. Under NRC’s policy, a State need not adopt a specific regulation if the State has no licensees that would be subject to the regulation.

Comment 5:

- Section 30220(a)(2) is revised so that the term “fingerprint orders” is adopted by reference in subsection (a). The term “government agency,” incorrectly identified in the comment as compatibility category C, is designated by NRC as compatibility category D as indicated in 78 FR 17002 (Mar. 19, 2013), remains, as initially proposed, to not be adopted.
- Because of this revision, proposed subsection 30220(a)(4) is revised to clarify references to NRC in the cited provisions, and subsections 30220(a)(7) through (a)(9) are deleted as unnecessary.

Comment 6:

- This comment was accepted and addressed during the first 15-day comment period. No additional changes are proposed.

Comments 7, 8 & 9:

- The initially proposed text for section 30373 identified some existing provisions not being amended by use of the phrase “no change to text.” The proposal now fully presents those existing provisions for review.
- Section 30373(a)(2) is revised to clarify when references to NRC should remain as a reference to NRC, or be to the Department. Regarding the reference to NRC in 10 CFR 71.101(c)(1), it appears the comment intended 71.101(c)(2), not 71.101(c)(1) since 71.101(c)(1) does not contain terms applicable only to NRC. Because

71.101(c)(2) is designated as compatibility category NRC, agreement states may not adopt that provision. Thus, the reference to NRC in 71.101(c)(1) is replaced with "Department" as recommended.

Editorial Comment 1:

- Because the document incorporated by reference in 17 CCR 30332(a)(1) is a published document, designated and titled by the issuing organization using the word "Standard" in the singular form, no change to the proposal is made.

Excerpts from California Health and Safety Code
(Existing law referenced in proposal or in response to comments)

§ 114985.

As used in this chapter:

- (a) "Secretary" means the Secretary of the Resources Agency.
- (b) "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.
- (c) "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.
- (d) "Byproduct material" means 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.
- (e) "Source material" means (1) uranium, thorium, or any other material which the department declares by rule to be source material after the United States Nuclear Regulatory Commission, or any successor thereto, has determined the material to be such; or (2) ores containing one or more of the foregoing materials, in such concentration as the department declares by rule to be source material after the United States Nuclear Regulatory Commission, or any successor thereto, has determined the material in such concentration to be source material.
- (f) "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.
- (g) "General license" means a license, pursuant to regulations promulgated by the department, effective without the filing of an application, to transfer, acquire, own, possess or use quantities of, or devices or equipment utilizing, byproduct, source, or special nuclear materials or other radioactive material occurring naturally or produced artificially.
- (h) "Specific license" means a license, issued after application, to use, manufacture, produce, transfer, receive, acquire, own, or possess quantities of, or devices or equipment utilizing, byproduct, source, or special nuclear materials or other radioactive material occurring naturally or produced artificially.
- (i) "Registration" means the reporting of possession of a source of radiation and the furnishing of information with respect thereto, in accordance with subdivision (b) of Section 115060.

(j) "Department" means the State Department of Health Services.

(k) "Director" means the State Director of Health Services.

(l) "Federal research and development activity" means any activity of the Secretary of Energy conducted at any research facility owned or operated by the United States Department of Energy.

(m) "Low-level waste" means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or the byproduct material defined in Section 11(e)(2) of the Atomic Energy Act of 1954 (42 U.S.C. Sec. 2014 (e)(2)). For purposes of this subdivision, the following definitions shall apply:

(1) "High-level radioactive waste" means either of the following:

(A) The highly radioactive material resulting from the reprocessing of spent nuclear fuel, including liquid waste produced directly in reprocessing and any solid material derived from this liquid waste that contains fission products in sufficient concentrations.

(B) Other highly radioactive material that the Nuclear Regulatory Commission, consistent with existing law, determines by rule requires permanent isolation.

(2) "Spent nuclear fuel" means fuel that has been withdrawn from a nuclear reactor following irradiation, the constituent elements of which have not been separated by reprocessing.

(3) "Transuranic waste" means any waste containing more than 100 nanocuries of alpha emitting transuranic nuclides with half-life greater than five years per gram of waste material.

(n) "Mammogram" means an X-ray image of the human breast.

(o) "Mammography" means the procedure for creating a mammogram.

(p) "Mammography quality assurance" means the detection of a change in X-ray and ancillary equipment that adversely affects the quality of films and the glandular radiation dose, and the correction of this change.

(q) "Mammogram certification" means a certification, issued by the department after registration, that the equipment dedicated to or used for mammography meets the standards prescribed pursuant to this chapter.

Excerpts from Title 17, California Code of Regulations
(Existing regulations referenced in proposal or in response to comments)

§ 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) "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.

(k) "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.

(l) "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.).

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

(n) "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.

(o) "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.

(p) "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.

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

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

(s) "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 possessed pursuant to a general license under provisions of sections 30192.1 and 30192.6.

(t) "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.

(u) "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.

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

(w) "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.

(x) "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.

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

(z) "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.

(aa) "Worker" means any individual engaged in activities subject to this regulation 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, 115060, 131050, 131051 and 131052, Health and Safety Code.

§ 30105. Deliberate Misconduct.

(a) A user, applicant for a license or registration, employee of a user or applicant, or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any user or applicant for a license or registration, who knowingly provides to any user, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a user's or applicant's activities subject to this regulation, shall not:

(1) Engage in deliberate misconduct, as defined in subsection (c), that causes or would have caused, if not detected, a user or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Department; or

(2) Deliberately submit to the Department, a user, an applicant, or a user's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Department.

(b) A person who violates subsection (a) shall be subject to enforcement action in accordance with the Act.

(c) For the purposes of subsection (a), deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a user or applicant to be in violation of any rule, regulation, or order, or any term, condition, or limitation, or any license or registration issued by the Department; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a user, applicant, contractor, or subcontractor.

Note: Authority cited: Sections 100170, 100275, 115000, 115230 and 115235, Health and Safety Code. Reference: Sections 114965, 114970, 115000, 115215, 115230 and 115235, Health and Safety Code.

§ 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, 2013) 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.

(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.

(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.

(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).

(11) Sections 30.35(g), 40.36(f), and 70.25(g), as cited in 10 CFR 20.1501(b), shall be deemed to reference section 30256(a); sections 50.75(g) and 72.30(d), as cited in 10 CFR 20.1501(b), are not incorporated by reference.

(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.

(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.

Note: Authority cited: Sections 114975, 115000 and 131200, Health and Safety Code.
Reference: Sections 114960, 114965, 114970, 114985, 114990, 115060, 115105, 115110, 115120, 115165, 115230, 115235, 131050, 131051 and 131052, Health and Safety Code.

§ 30254. Inspection.

(a) Each user shall afford to the Department or other official agency specifically designated by the Department, at all reasonable times, opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these regulations.

(b) During an inspection, inspectors may consult privately with workers as specified below. The user may accompany inspectors during other phases of an inspection.

(1) Inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Department regulations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(2) During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violation of the Radiation Control Law, these regulations, or license condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material or a registered radiation machine under the user's control. Any such notice in writing shall comply with the requirements of subsection (h) hereof.

(3) The provision of paragraph (b)(2) of this section shall not be interpreted as authorization to disregard instructions pursuant to Section 30255(b)(1).

(c) If, at the time of inspection, an individual has been authorized by the workers to represent them during inspections, the user shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(d) Each worker's representative shall be routinely engaged in work under control of the user and shall have received instructions as specified in Section 30255(b)(1).

(e) Different representatives of users and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(f) With the approval of the user and the workers' representative, an individual who is not routinely engaged in work under control of the user, for example, a consultant to the user or to the workers' representative, shall be afforded the opportunity to accompany inspectors during the inspection of physical working conditions.

(g) Notwithstanding the other provisions of this section, inspectors are authorized to refuse to permit accompaniment by an individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the user to enter that area.

(h) Any worker or representative of workers who believes that a violation of the Radiation Control Law, these regulations or license conditions exists, or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Department or other official agency specifically designated by the Department. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the user by the Department no later than at the time of inspection except that, upon the request of the worker giving such notice, his name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Department except for good cause shown.

(i) If, upon receipt of such notice, the Chief, Radiologic Health Branch, of the Department, determines that the complaint meets the requirements set forth in subsection (h) hereof, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he shall cause an inspection to be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this section need not be limited to matters referred to in the complaint.

(j) No user shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these regulations or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by this section.

(k) If the Chief, Radiologic Health Branch, of the Department, determines with respect to a complaint under subsection (h) hereof that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the complainant shall be notified in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position to the Director of the Department, who will provide the user with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The user may submit an opposing written statement of position with the Director of the Department who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the Director of the Department, or his designee, may hold an informal conference in which the complainant and the user may orally present their views. An informal conference may also be held at the request of the user, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written or oral views presented, the Director of the Department shall affirm, modify, or reverse the determination of the Chief, Radiologic Health Branch, of the Department, and furnish the complainant and the user a written notification of his decision and the reason therefor.

(l) If the Department determines that an inspection is not warranted because the requirements of subsection (h) hereof have not been met, it shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of subsection (h) hereof.

Note: Authority cited: Sections 114975, 115000 and 131200, Health and Safety Code.
Reference: Sections 114965, 114970, 115000, 115060, 115165, 115230, 115235, 131050, 131051 and 131052, Health and Safety Code.

§ 30293. Records.

(EDITORIAL NOTE: This section is being amended in this proposal in response to NRC's comment 4.)

(a) Each user shall keep records showing the receipt, transfer, and disposal of each source of radiation which is subject to licensure or registration pursuant to groups 1.5 and 2 of this subchapter as follows:

(1) The user shall retain each record of receipt of a source of radiation as long as the source of radiation is possessed and for three years following transfer or disposal of the source of radiation.

(2) The user who transferred the source of radiation shall retain each record of transfer for three years after each transfer unless a specific requirement in another part of the regulations in this subchapter dictates otherwise.

(3) The user who disposed of the radioactive material shall retain each record of disposal of the radioactive material until the Department terminates each license that authorizes disposal of the radioactive material.

(b) The user shall retain each record that is required by the regulations in this subchapter or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record shall be retained until the Department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(c) Records which shall be maintained pursuant to this subchapter may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by department regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, shall include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(d) If there is a conflict between the Department's regulations in this subchapter, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this subchapter for such records shall apply unless the Department, pursuant to 30104, has granted a specific exemption from the record retention requirements specified in the regulations in this subchapter.

(e) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall, if requested by the Department, forward the following records to the Department:

(1) Records of disposal of licensed material made under Title 10, Code of Federal Regulations, sections 20.2002, 20.2003, 20.2004, 20.2005, incorporated by reference in section 30253; and

(2) Records required by Title 10, Code of Federal Regulations section 20.2103(b)(4), incorporated by reference in section 30253.

(f) If licensed activities are transferred or assigned in accordance with section 30194(c), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material made under Title 10, Code of Federal Regulations, sections 20.2002, 20.2003, 20.2004, 20.2005, incorporated by reference in section 30253; and

(2) Records required by Title 10, Code of Federal Regulations, section 20.2103(b)(4), incorporated by reference in section 30243.

(g) Prior to license termination, each licensee shall, if requested by the Department, forward the records required by section 30256(a) to the Department.

Note: Authority cited: Sections 100275 and 115000, Health and Safety Code.

Reference: Sections 114965, 114970, 115105, 115110, and 115235, Health and Safety Code.

§ 30332. Performance Requirements for Radiographic Exposure Devices, Storage Containers, and Source Changers.

(a) All radiographic exposure devices and associated equipment shall comply with the following:

(1) Except as provided in subsection (b), each radiographic exposure device, source assembly or sealed source and all associated equipment shall meet the requirements specified in American National Standard N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," published as NBS Handbook 136, issued January 1981 (ANSI N432)*;

(2) Each radiographic exposure device shall have attached to it a durable, legible, clearly visible label bearing the:

(A) Chemical symbol and mass number of the radionuclide in the device;

(B) Activity and date on which this activity was last measured;

(C) Model number and serial number of the sealed source;

(D) Manufacturer of the sealed source; and

(E) Licensee's name, address and telephone number;

(3) Radiographic exposure devices intended for use as Type B transport containers shall meet the applicable requirements of section 30373;

(4) Modification of radiographic exposure devices, source changers, source assemblies and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the safety design features of the system;

(5) For radiographic exposure devices and associated equipment that allow the source to be moved out of the device for routine operation:

(A) The coupling between the source assembly and the control cable shall be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling shall be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions;

(B) The device shall automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device;

(C) The outlet fittings, lock box, and control cable fittings on each radiographic exposure device shall be equipped with safety plugs or covers which shall be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter;

(D) Each sealed source or source assembly shall have attached to it or engraved in it, a durable, legible, visible label with the words "Danger -Radioactive." The label shall not interfere with the safe operation of the exposure device or associated equipment;

(E) The guide tube shall have passed the crushing tests for the control tube as specified in ANSI N432 and a kinking resistance test that closely approximates the kinking forces likely to be encountered during use;

(F) Guide tubes shall be used when moving the source out of the device.

(G) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube shall be attached to the outermost end of the guide tube during radiographic operations;

(H) The guide tube exposure head connection shall be able to withstand the tensile test for control units specified in ANSI N432; and

(I) Source changers shall provide a system for assuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the control cable to or from a source assembly.

(b) Equipment used in radiographic operations need not comply with section 8.9.2(c) of the Endurance Test in ANSI N432, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the industrial radiography equipment can realistically exert on the lever or crankshaft of the control mechanism.

(c) Storage containers and source changers shall not exceed a radiation exposure rate of 200 millirems per hour (mrem/hr) at any exterior surface and 10 mrem/hr at one meter from any exterior surface with the sealed source in the shielded position.

*Copies of American National Standard N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography" (published as NBS Handbook

136, issued January 1981) may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 and from the American National Standards Institute, Inc., 25 West 43rd Street, New York, New York 10036 or from IHS Standards Store at "<http://global.ihs.com>" using the title as the search parameter.

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