TITLE 17. PUBLIC HEALTH

Division 1. State Department of Health Services

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Chapter 5. Sanitation (Environmental)

Chapter 5. Sanitation (Environmental)

Subchapter 4. Radiation

Subchapter 4. Radiation

Group 1. General

Group 1.5. Registration of Sources of Radiation

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Group 1. General

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Article 1. Definitions

30100. General Definitions.

Section

30100. General Definitions.

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, Section 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


HISTORY

1. Repealer of group 1 and new group 1 (Section 30100 through 30146) filed 11-29-65; effective thirtieth day thereafter (Register 65, No. 23). For prior histories, see Registers 62, No. 1 and 62, No. 8.

2. Repealer and new section filed 11-25-85; effective thirtieth day thereafter (Register 85, No. 48).
3. Change without regulatory effect of subsection (ad)(2) (Register 88, No. 6).

4. Amendment of subsection (j), relettering of former subsections (p)-(ap) to subsections (q)-(aq), and new subsection (p) filed 9-5-89; operative 10-5-89 (Register 89, No. 36).

5. New subsection (k) and redesignation of former sections (k) through (aq) to subsections (l) through (ar) filed 4-19-91; operative 5-19-91 (Register 91, No. 20).

6. Editorial correction of printing error in subsections (q)-(ar) (Register 91, No. 30).

7. Change without regulatory effect amending subsection (an) filed 11-1-91 pursuant to Section 100, title 1, California Code of Regulations (Register 92, No. 5).

8. Amendment of section and Note filed 3-3-94 as an emergency; operative 3-3-94 (Register 94, No. 9). A Certificate of Compliance must be transmitted to OAL by 7-1-94 or emergency language will be repealed by operation of law on the following day.

9. Certificate of Compliance as to 3-3-94 order transmitted to OAL 6-7-94 and filed 7-14-94 (Register 94, No. 28).

10. Amendment of subsection (a), new subsection (c) and subsection relettering filed 10-16-95 as an emergency; operative 10-16-95 (Register 95, No. 42). A Certificate of Compliance must be transmitted to OAL by 2-13-96 or emergency language will be repealed by operation of law on the following day.

11. Certificate of Compliance as to 10-16-95 order, including amendment of subsections (a), (f) and (k) and of Note, transmitted to OAL 2-9-96 and filed 3-25-96 (Register 96, No. 13).

12. Amendment of subsection (q) and NOTE filed 6-22-2005 as an emergency; operative 6-22-2005 (Register 2005, No. 25). A Certificate of Compliance must be transmitted to OAL by 10-20-2005 or emergency language will be repealed by operation of law on the following day.


14. Amendment of subsection (a) filed 7-20-2006; operative 8-19-2006 (Register 2006, No. 29).

15. Amendment of subsections (d) and (f) and Note filed 4-24-2009; operative 5-24-2009 (Register 2009, No. 17).

16. Repealer of subsections (j)-(j)(6), subsection relettering, amendment of newly designated subsections (k), (s)(2), (y) and (aa) and amendment of Note filed 10-13-2010; operative 1-1-2011 (Register 2010, No. 42).

Article 2. Exemptions and Enforcement

30104. Exemptions.

Section

30104. Exemptions.

(a) The Department may, upon application by any user, or upon its own initiative, grant such exemptions from the requirements of this regulation as it determines are authorized by law and will not result in undue hazard to health, life or property. Applications for exemptions shall specify why such exemption is necessary.

(b) Before granting an exemption, the Department shall determine that there is reasonable and adequate assurance that:
(1) the doses to any individual in any controlled area will not exceed those specified in Section 30265;

(2) the dose to the whole body of any individual in an uncontrolled area will not exceed 0.5 rem in a year;

(3) The deposition of radioactive material in the body of any individual will not likely result in a greater risk to the individual than would be expected from the dose specified in Section 30104 (b)(1) or (2), as appropriate, based on guidance from such bodies as the International Commission on Radiological Protection, and the National Council on Radiation Protection and Measurements; and

(4) there is no significant hazard to life or property.

NOTE


HISTORY

1. Renumbering and amendment of former Section 30345 to article 2 (Section 30104) filed 11-25-85; effective thirtieth day thereafter (Register 85, No. 48).

2. Change without regulatory effect of subsection (b)(3) (Register 87, No. 4).

3. Change without regulatory effect amending subsections (b) and (b)(3) filed 11-1-91 pursuant to Section 100, title 1, California Code of Regulations (Register 92, No. 5).

Group 1.5. Registration of Sources of Radiation

Article 1. Registration Procedure

Article 2. Exclusions from Registration

Article 4. Fees

Article 1. Registration Procedure

30108. Registration Requirement.

30108.1. Registration and General Provisions for Persons Possessing Devices Under Sections 30192.1 and 30192.6.

30110. Initial Registration.

30111. Renewal of Registration.


30108. Registration Requirement.

Every person possessing a reportable source of radiation shall register with the Department in accordance with the provisions of this Group.
30108.1. Registration and General Provisions for Persons Possessing Devices Under Sections 30192.1 and 30192.6.

(a) A person required to register pursuant to Section 30192.1(d)(1) or 30192.6(b)(1) shall, within 30 calendar days of taking possession of a device or product, submit to the Department the following:

(1) Legal name, mailing address, and telephone number of the registering person. If renewing registration, the registration number previously issued to the registrant shall also be included;

(2) For each device subject to Section 30192.1:

(A) The manufacturers name, serial number, model number, the radioisotope, and the radioisotopes activity (as indicated on the devices label). For devices used in a fixed location, the physical address of each location where a device is used and the total number of devices at each location shall be submitted. For portable devices, the physical address of each primary place of storage and the total number of devices stored at each location shall be submitted. If renewing registration and there has been no change in the previously indicated devices, indicate that no change has occurred;

(B) Name, title, and telephone number, if different than the number specified in subsection (a)(1), of the individual appointed pursuant to Section 30192.1(d)(15);

(C) Name and license number of the distributor from whom the device was obtained; and

(D) Signature and date of signature of the individual identified in subsection (a)(2)(B), attesting to the following statement:

I [insert name as it appears in response to subsection (a)(2)(B)] attest that I am aware of the requirements of the general license specified in Section 30192.1 of title 17, California Code of Regulations, and that the information provided concerning the device or product has been verified through a physical inventory and checking of label information.

(3) For persons possessing devices subject to Section 30192.6:

(A) A statement that the registrant has, pursuant to Section 30192.6(b)(3), developed, implemented, and will continue to maintain procedures designed to establish physical control over the depleted uranium described in Section 30192.6(a), and designed also so as to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(B) Name, title, and telephone number, if different than the number specified in subsection (a)(1), of the individual appointed pursuant to Section 30192.6(b)(4);
(4) Except for persons possessing devices pursuant to Section 30192.6, the registration fee specified in Section 30145.

(b) Each person shall renew registration annually on or before the current registrations expiration date, by submitting to the Department all required items in subsection (a).

(c) In lieu of the requirements in Section 30115, within 30 calendar days of the occurrence of the event, each person registered pursuant to this section shall notify the Department of any change in the information submitted in response to subsection (a), including discontinuance of use of a device or product.

NOTE

HISTORY
1. New section filed 6-8-2011; operative 7-8-2011 (Register 2011, No. 23).

30110. Initial Registration.

(a) Every person not already registered who acquires a reportable source of radiation shall register with and pay the fee as specified in Section 30145 to the Department within 30 days of the date of acquisition.

(b) Every person who intends to acquire a radiation machine capable of operating at a potential in excess of 500 kVp shall notify the Department at least 60 days prior to his/her possession of the machine or at least 60 days prior to the commencement of construction or reconstruction of the room which will house the machine, whichever occurs first. This equipment shall not be used to treat patients until written approval of provisions for radiation safety has been obtained by the user from the Department.

(c) Every person who registers or renews a registration shall complete a separate registration form furnished by the Department for each separate installation.

NOTE

HISTORY
1. Amendment filed 6-24-80; effective thirtieth day thereafter (Register 80, No. 26).
2. Amendment filed 11-25-85; effective thirtieth day thereafter (Register 85, No. 48).
3. Amendment of subsection (a) filed 11-1-93 as an emergency; operative 11-1-93 (Register 93, No. 45). A Certificate of Compliance must be transmitted to OAL by 3-1-94 or emergency language will be repealed by operation of law on the following day.
4. Certificate of Compliance as to 11-1-93 order transmitted to OAL 2-24-94; disapproved by OAL 4-7-94 (Register 94, No. 27).
5. Amendment of subsection (a) refiled 7-6-94 as an emergency; operative 7-6-94 (Register 94, No. 27). A Certificate of Compliance must be transmitted to OAL by 11-3-94 or emergency language will be repealed by operation of law on the following day.
6. Certificate of Compliance as to 7-6-94 order transmitted to OAL 6-30-94 and filed 7-20-94 (Register 94, No. 29).

**30111. Renewal of Registration.**

Every person already registered pursuant to 30110 shall renew such registration annually and pay the fee as specified in Section 30145 to the Department on or before the registration renewal date.

**NOTE**


**HISTORY**

1. Amendment filed 11-25-85; effective thirtieth day thereafter (Register 85, No. 48).
2. Repealer and new section and amendment of Note filed 1-20-99; operative 2-19-99 (Register 99, No. 4).

**30115. Report of Change.**

Except for persons subject to Section 30108.1, the registrant shall report in writing to the Department, within 30 days, any change in: registrants name, registrants address, location of the installation, or receipt, sale, transfer, disposal, or discontinuance of use of any reportable source of radiation.

**NOTE**


**HISTORY**

1. Amendment filed 6-24-80; effective thirtieth day thereafter (Register 80, No. 26).
2. Amendment filed 11-25-85; effective thirtieth day thereafter (Register 85, No. 48).
3. Amendment of section and Note filed 6-8-2011; operative 7-8-2011 (Register 2011, No. 23).

**Article 2. Exclusions from Registration**

**30125. Excluded Material and Devices.**

**30126. Exempt Possessors.**

Section

30125. Excluded Material and Devices.

30126. Exempt Possessors.

**30125. Excluded Material and Devices.**

The following devices and materials do not require registration:

(a) Electrical equipment that produces radiation incidental to its operation for other purposes, but which does not produce radiation in any area accessible to individuals such that there is a
reasonable likelihood that any individual will receive a radiation dose to the whole body, head and trunk, gonads, or lens of the eye or active blood-forming organs in excess of 0.5 rem in a year.

(b) All radioactive materials except as specified in Sections 30192.1 and 30192.6.

NOTE


HISTORY

1. New NOTE filed 7-12-84 (Register 84, No. 28).
2. Editorial renumbering of former article 5 to article 2 (Register 85, No. 48).
3. Change without regulatory effect amending subsection (b) filed 11-1-91 pursuant to Section 100, title 1, California Code of Regulations (Register 92, No. 5).
4. Amendment of section and Note filed 6-8-2011; operative 7-8-2011 (Register 2011, No. 23).

30126. Exempt Possessors.

Common and contract carriers are exempt from the requirement to register to the extent that they transport or store reportable sources of radiation in the regular course of their carriage for another or storage incident thereto.

NOTE


HISTORY

1. Amendment filed 11-25-85; effective thirtieth day thereafter (Register 85, No. 48).

Article 4. Fees

30145. Registration Fees.

30146. Payment of Fee.

30145. Registration Fees.

(a) Each radiation machine that is a reportable source of radiation as defined in Section 30100(t), is classified as one of the following:

(1) High priority radiation machine, a radiation machine, which has high potential for exposing humans by means of heavy use, high radiation exposure, specialized use for radiosensitive areas of the human body, or misadjustment or malfunction of radiation safety features. A high priority radiation machine is further defined as one of the following machine types, or a machine that is used by any of the following categories of users:

(A) Orthopedist.

(B) Radiologist or roentgenologoist.
(C) Chiropractor.
(D) Hospital.
(E) Medical clinic.
(F) Portable X-ray service (human use).
(G) Fluoroscope used on humans.
(H) Chest photofluorography (minifilm unit).
(I) Non-human use particle accelerator with maximum energy capable of equaling or exceeding 10 MeV.
(J) Non-human use radiation machine used in field radiography, as defined in Section 30336(c).
(2) Medium priority radiation machine, a radiation machine not covered by subsections (a)(1), (a)(3) or (a)(4).
(3) Dental priority radiation machine, a radiation machine used exclusively in dental radiography of human beings.
(4) Special priority radiation machine, a radiation machine used for mammography.

(b) When a radiation machine is equipped with two or more tubes that can be used separately, each tube shall be considered as a single radiation machine.

(c) For registration or renewal of registration as a general licensee pursuant to Section 30192.1, the fee shall be $70.00 for each device in possession, except that persons possessing such devices under a specific license shall be exempt from this fee.

(d) Except as provided in subsection (e), initial registration shall be valid for a period of one year.

(e) The initial registration period for a reportable source of radiation being registered by a person who has a reportable source of radiation already registered with the Department shall be coterminous with the existing registration.

(f) Any fees collected for a radiation machine or a device for any registration period shall be transferred to any replacement radiation machine or device for the remainder of the registration period.

(g) For initial registration or renewal of registration, the fees shall be $214.00 annually for each high priority radiation machine, $172.00 annually for each medium priority radiation machine, $79.00 annually for each dental priority radiation machine and, except as provided in Section 30145.1, $475.00 annually for each special priority radiation machine. Where the initial registration period is less than one year pursuant to subsection (e), the initial registration fee shall be prorated, based on the priority classification and number of full months in the initial registration period in accordance with the following formula:

\[
\text{Initial Registration Fee} = A \times \left( \frac{B}{12 \text{ Months}} \right)
\]

Where:
A = Annual fee as specified above, dollars per year
B = Number of full months remaining in coterminous period

(h) The total registration fee paid by a registrant for high priority, medium priority, special priority, and dental priority radiation machines, which are at the same installation, shall not exceed $6,000.00 per year.

(i) A late fee of 25% of the annual fee shall be charged for any registration fee which is 30 days past due.

(j) Fees required by this section shall be nonrefundable.

NOTE
Authority cited: Section 114975, 115000, 115060, 115065, 115080, 115085 and 131200, Health and Safety Code.
Reference: Section 114980, 115065, 115080, 115085, 115165, 131050, 131051 and 131052, Health and Safety Code.

HISTORY
1. Amendment of subsection (a) filed 7-1-75; effective thirtieth day thereafter (Register 75, No. 27).
2. Amendment filed 4-30-76; effective thirtieth day thereafter (Register 76, No. 18).
3. Amendment filed 7-3-79 as an emergency; effective upon filing (Register 79, No. 27).
5. Amendment filed 11-25-85; effective thirtieth day thereafter (Register 85, No. 48).
6. Change without regulatory effect of subsections (a) and (a)(1)(k) (Register 88, No. 6).
7. Amendment of subsection (a) filed 4-19-91; operative 5-19-91 (Register 91, No. 20).
8. Amendment of subsection (a) and Note, and adoption of subsections (d)-(f) filed 11-1-93 as an emergency; operative 11-1-93 (Register 93, No. 45). A Certificate of Compliance must be transmitted to OAL by 3-1-94 or emergency language will be repealed by operation of law on the following day.
9. Certificate of Compliance as to 11-1-93 order transmitted to OAL 2-24-94; disapproved by OAL 4-7-94 (Register 94, No. 27).
10. Amendment of subsection (a) and Note and new subsections (d)-(f) refiled 7-6-94 as an emergency; operative 7-6-94 (Register 94, No. 27). A Certificate of Compliance must be transmitted to OAL by 11-3-94 or emergency language will be repealed by operation of law on the following day.
11. Certificate of Compliance as to 7-6-94 order transmitted to OAL 6-30-94 and filed 7-20-94 (Register 94, No. 29).
12. Amendment of section and Note filed 1-20-99; operative 2-19-99 (Register 99, No. 4).
13. Amendment of section heading, section and NOTE filed 6-22-2005 as an emergency; operative 6-22-2005 (Register 2005, No. 25). A Certificate of Compliance must be transmitted to OAL by 10-20-2005 or emergency language will be repealed by operation of law on the following day.
15. New subsection (c), subsection relettering, amendment of newly designated subsections (d), (f) and (g) and amendment of Note filed 6-8-2011; operative 7-8-2011 (Register 2011, No. 23).

30146. Payment of Fee.
Each registration or registration renewal which reports possession of a radiation machine, and each report of change reporting the receipt of an additional radiation machine, shall be accompanied by an amount to pay the fee for the period to the next regularly scheduled registration renewal date.

NOTE


HISTORY

1. Amendment filed 7-1-75; effective thirtieth day thereafter (Register 75, No. 27).
2. Amendment filed 4-30-76; effective thirtieth day thereafter (Register 76, No. 18).
3. New NOTE filed 7-12-84 (Register 84, No. 28).

Group 2. Licensing of Radioactive Materials

Article 4. Licenses

Article 6. Enforcement

Article 7. Reciprocal Recognition of Licenses

Article 4. Licenses

30195. Special Requirements for Issuance of Specific Licenses.

30205. Modification, Suspension, Revocation and Termination of Licenses.

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 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, Section 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 reference 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, Section 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.
(b) For use of multiple quantities of types of radioactive material for research and development or for processing for distribution:

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

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

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

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

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

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

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

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

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

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

 NOTE


HISTORY

1. Repealer and new subsection (e) filed 10-12-72; effective thirtieth day thereafter (Register 72, No. 42).

2. Repealer of subsection (e) filed 7-7-86; effective thirtieth day thereafter (Register 86, No. 28).

3. Change without regulatory effect amending subsection (d) filed 11-1-91 pursuant to Section 100, title 1, California Code of Regulations (Register 92, No. 5).


5. Editorial correction of subsection (a)(14) (Register 2010, No. 45).

30205. Modification, Suspension, Revocation and Termination of Licenses.
(a) All licenses shall be subject to modification, suspension, or revocation by regulations or orders issued by the department.

(b) Any license may be modified, suspended, or revoked by the department:
   (1) for any material false statement in the application or in any required report;
   (2) because of conditions revealed by any means which would warrant refusal to grant such a license on an original application; or
   (3) for violation of any terms and conditions of the Act, of the license, or of any relevant regulation or order of the department, including non-payment of license fee pursuant to Section 30230-30232 of this regulation.

(c) Prior to the institution of proceedings to modify, suspend, or revoke a license, facts or conduct which may warrant such action shall be called to the attention of the licensee in writing and the licensee shall be accorded reasonable opportunity to demonstrate or achieve compliance, except in cases of willful violation or those in which the public health or safety requires otherwise.

(d) A specific license may be terminated by mutual consent between the licensee and the department.

NOTE


HISTORY
1. Amendment of subsection (b)(3) filed 10-12-72; effective thirtieth day thereafter (Register 72, No. 42).
2. New NOTE filed 8-22-84 (Register 84, No. 34).

Article 6. Enforcement

30220. Violations.

30220. Violations.

NOTE


HISTORY
1. Repealer of Article 6 (Section 30215 through 30217) and new Article 6 (Section 30220) filed 11-29-65; effective thirtieth day thereafter (Register 65, No. 23). For prior history, see Register 62, No. 21.
2. Repealer filed 7-8-87; operative 8-7-87 (Register 87, No. 29).

Article 7. Reciprocal Recognition of Licenses

30225. Persons Specifically Licensed by Other Agencies.
30226. Persons Generally Licensed by Other Agencies.

30225. Persons Specifically Licensed by Other Agencies.

(a) Any person who holds a specific license issued by the United States Nuclear Regulatory Commission (NRC), 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. (CRCPD), 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:

1) The person maintains an office for directing the licensed activity, 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 to the Department at least three 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 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 the license, except such terms and conditions as may be inconsistent with said regulations;

5) The person supplies such other information as the Department may request; and

6) The person pays a fee in accordance with Section 30230(f) to the Department, prior to the engagement of activities within the state.

(b) Any person who holds a specific license issued by the NRC, by any other Agreement State or by any state that has been either provisionally or finally designated as a Licensing State by the CRCPD, other than this State, authorizing the holder to manufacture, install or service a device described in Section 30192.1(a), is hereby issued a general license to install or service such device in this State, provided that:

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, identifying the type of device transferred or installed, and identifying 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; and

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 the regulations contained
in Group 1.5 of this subchapter and Section 30192.1, 30254, 30257, 30293(a)(2) and 30295 of Group 3 of this subchapter, and Sections 20.2201 and 20.2202 of title 10, Code of Federal Regulations, Part 20, incorporated by reference in Section 30253.

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

(d) Authorization granted pursuant to this section does not authorize a person to conduct activities in areas within this State that are under exclusive federal jurisdiction.

NOTE

HISTORY
1. Repealer of article 7 (Section 30220) and new article 7 (Section 30225) filed 11-29-65; effective thirtieth day thereafter (Register 65, No. 23). For prior history, see Register 62, No. 21.
2. Amendment of subsection (a) filed 7-22-71; effective thirtieth day thereafter (Register 71, No. 30).
3. Amendment of subsection (a) filed 10-12-72; effective thirtieth day thereafter (Register 72, No. 42).
4. New NOTE filed 8-22-84 (Register 84, No. 34).
5. Amendment filed 7-7-86; effective thirtieth day thereafter (Register 86, No. 28).
6. New subsection (a)(6) and amendment of Note filed 10-23-91; operative 11-22-91 (Register 92, No. 5).
8. Amendment of subsection (a)(6) filed 6-22-2005 as an emergency; operative 6-22-2005 (Register 2005, No. 25). A Certificate of Compliance must be transmitted to OAL by 10-20-2005 or emergency language will be repealed by operation of law on the following day.
10. Amendment of section heading, section and Note filed 6-8-2011; operative 7-8-2011 (Register 2011, No. 23).

30226. Persons Generally Licensed by Other Agencies.

(a) A person generally licensed by the United States Nuclear Regulatory Commission (NRC), or an Agreement State other than this State, is not subject to the registration requirements specified in Section 30192.1(d)(1) if the device is used in areas subject to the Departments jurisdiction for a period less than 180 days in any calendar year.

(b) Authorization granted pursuant to this section shall not authorize a person to conduct activities in areas within this State that are under exclusive federal jurisdiction within this State.

NOTE

HISTORY
1. New section filed 6-8-2011; operative 7-8-2011 (Register 2011, No. 23).
Group 3. Standards for Protection Against Radiation

Article 2. Notices, Instructions, and Reports to Workers; Inspections and Investigations

Article 3.1. Records and Notification

Article 4. Special Requirements for the Use of X-Ray in the Healing Arts

Article 2. Notices, Instructions, and Reports to Workers; Inspections and Investigations

30254. Inspection.

30255. Notices, Instructions, and Reports to Personnel.

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 users 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 workers representative shall be routinely engaged in work under control of the user and shall have received instructions as specified in Section 30280(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.
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.

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.

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.

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.

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 proceedings or because of the exercise by such worker on behalf of himself or others of any option afforded by this section.

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.

(1) 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


HISTORY

1. Repealer and new section filed 8-19-75 as an emergency; effective upon filing (Register 75, No. 34). Approved by CAL/OSHA Standards Board 12-16-75.

2. Certificate of Compliance filed 11-28-75 (Register 75, No. 48).

3. Amendment of subsections (b)(3) and (d) filed 8-23-76; effective thirtieth day thereafter (Register 76, No. 35).

4. Amendment of subsections (h), (i) and (k) filed 6-18-87; operative 7-18-87 (Register 87, No. 28).

5. New article 2 heading and amendment of subsection (b)(3) filed 3-3-94 as an emergency; operative 3-3-94 (Register 94, No. 9). A Certificate of Compliance must be transmitted to OAL by 7-1-94 or emergency language will be repealed by operation of law on the following day.

6. Certificate of Compliance as to 3-3-94 order transmitted to OAL 6-7-94 and filed 7-14-94 (Register 94, No. 28).

30255. Notices, Instructions, and Reports to Personnel.

(a) This section establishes requirements for notices, instructions, and reports by users to individuals engaged in work under a license or registration; and options available to such individuals in connection with Department inspections of licensees or registrants to ascertain compliance with the provisions of the Radiation Control Law and regulations, orders, and licenses issued thereunder regarding radiological working conditions. The requirements in this section apply to all persons who receive, possess, use, own or transfer material licensed by or registered with the Department.

(b) Each user shall:

(1) Inform all individuals working in or frequenting any portion of a controlled area of the storage, transfer, or use of radioactive materials or of radiation in such portions of the controlled area; instruct such individuals in the health protection problems associated with exposure to such radioactive materials or radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed; instruct such individuals in, and instruct them to observe, to the extent within their control, the applicable provisions of Department regulations and license conditions for the protection of personnel from exposures to radiation or radioactive materials occurring in such areas; instruct such individuals of their responsibility to report promptly to the licensee or registrant any condition which may lead to or cause a violation of department regulations or license conditions or unnecessary exposure to radiation or radioactive material, and of the inspection provisions of Section 30254; instruct such individuals in the appropriate response to warnings made in the event of any unusual occurrence or
malfunction that may involve exposure to radiation or radioactive materials; and advise such
individuals as to the radiation exposure reports which they may request pursuant to this section.
The extent of these instructions shall be commensurate with potential radiological health
protection problems in the controlled area.

(2) Conspicuously post a current copy of this regulation, a copy of applicable licenses for
radioactive material, and a copy of operating and emergency procedures applicable to work with
sources of radiation. If posting of documents specified in this paragraph is not practicable the
user may post a notice which describes the document and states where it may be examined.

(3) Conspicuously post a current copy of Department Form RH-2364 (Notice to Employees) in
a sufficient number of places to permit individuals working in or frequenting any portion of a
controlled area to observe a copy on the way to or from such area.

(4) Conspicuously post any notice of violation involving radiological working conditions or
any order issued pursuant to the Radiation Control Law and any required response from the user.
Department documents posted pursuant to this paragraph shall be posted within two working
days after receipt of the documents from the Department; the users response, if any, shall be
posted within two working days after dispatch by the user. Such documents shall remain posted
for a minimum of five working days or until action correcting the violation has been completed,
whichever is later.

(5) Assure that documents, notices, or forms posted pursuant to this section shall appear in a
sufficient number of places to permit individuals engaged in work under the license or
registration to observe them on the way to or from any particular work location to which the
document applies, shall be conspicuous, and shall be replaced if defaced or altered.

(6) Provide reports to any individual of 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 title 10, Code of Federal Regulations, part 20, (10 CFR 20),
Section 20.2106 as incorporated by reference in Section 30253. 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 individuals 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 a worker formerly engaged in work controlled by the user, the user shall furnish to the worker a report of the workers 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. This report shall cover the period of time that the workers 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 10 CFR 20, Section 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 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 workers 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


HISTORY

1. Renumbering and amendment of former Section 30280 to Section 30255 filed 3-3-94 as an emergency; operative 3-3-94 (Register 94, No. 9). A Certificate of Compliance must be transmitted to OAL by 7-1-94 or emergency language will be repealed by operation of law on the following day.

2. Certificate of Compliance as to 3-3-94 order transmitted to OAL 6-7-94 and filed 7-14-94 (Register 94, No. 28).

3. Amendment of subsections (a)(6)-(a)(6)(D) and amendment of Note filed 11-9-2010; operative 12-9-2010 (Register 2010, No. 46).

Article 3.1. Records and Notification

30293. Records.
30295. Notification of Incidents.

30293. Records.
(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 Departments 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:


(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:


(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


HISTORY

1. New article 3.1 (Sections 30293 and 30295) and section filed 9-9-97; operative 10-9-97 (Register 97, No. 37).
For prior history, see Register 94, No. 28.

30295. Notification of Incidents.

(a) Each user shall notify the Department as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits.

(b) Each user shall notify the Department within 24 hours after the discovery of any of the following events involving radiation or radioactive materials:

(1) An unplanned contamination event involving licensed radioactive material that:

(A) Requires access to the contaminated area by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(B) Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of Title 10, Code of Federal Regulations, part 20, incorporated by reference in Section 30253 for the material; and

(C) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(2) An event in which equipment is disabled or fails to function as designed when:

(A) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(B) The equipment is required to be available and operable when it is disabled or fails to function; and

(C) No redundant equipment is available and operable to perform the required safety function.

(3) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(4) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:
(A) The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of Title 10, Code of Federal Regulations, part 20, incorporated by reference in Section 30253 for the material; and

(B) The damage affects the integrity of the licensed material or its container.

(C) Reports made by users in response to the requirements of this section shall be made as follows:

Each user shall make reports required by subsections (a) and (b) by telephone to the Department. To the extent that the information is available at the time of notification, the information provided in these reports shall include:

(1) The callers name and call back telephone number;

(2) A description of the event, including date and time;

(3) The exact location of the event;

(4) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(5) Any personnel radiation exposure data available.

(d) Each user who makes a report required by this section shall submit a written follow-up report within 30 days of the initial report. These written reports shall be sent to the Department and include:

(1) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(2) The exact location of the event;

(3) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(4) Date and time of the event;

(5) Corrective actions taken or planned and the results of any evaluation or assessment; and

(6) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

NOTE

HISTORY
1. New section filed 9-9-97; operative 10-9-97 (Register 97, No. 37). For prior history, see Register 94, No. 28.
2. Amendment of section and Note filed 4-11-2008; operative 5-11-2008 (Register 2008, No. 15).

Article 4. Special Requirements for the Use of X-Ray in the Healing Arts


30306. Definitions.

30307. Fluoroscopic Installations

30308.1. Quality Assurance for Radiographic Installations (Other Than Mammography, Dental, and Veterinary Medicine)

30309. Special Requirements for Mobile Radiographic Equipment.

30311.1. Quality Assurance for Dental Radiography.

30312. Therapeutic X-Ray Installations.

30313. Special Requirements for X-Ray Therapy Equipment Operated at Potentials of 50 kV and Below.

30314. Veterinary Medicine Radiographic Installations.


(a)(1) This article pertains to use of X-rays in medicine, dentistry, osteopathy, chiropractic, podiatry, and veterinary medicine. The provisions of this article are in addition to, and not in substitution for, other applicable provisions of this regulation and of Group 1 of this subchapter.

(2) Any existing machine or installation need not be replaced or substantially modified to conform to the requirements of this regulation provided that the user demonstrates to the Departments satisfaction achievement of equivalent protection through other means.

(3) No person shall make, sell, lease, transfer, lend, or install X-ray or fluoroscopic equipment or the supplies used in connection with such equipment unless such supplies and equipment, when properly placed in operation or properly used, will meet the requirements of this regulation. This includes responsibility for the delivery of cones or collimators, filters, adequate timers and fluoroscopic shutters (where applicable).

(4) For X-ray equipment manufactured after July 31, 1974, the user shall provide sufficient maintenance to keep the equipment in compliance with all applicable radiation protection sections of the Code of Federal Regulations, Title 21, Chapter 1, Subchapter J, Part 1020, Section 1020.30, 1020.31, and 1020.32.

(5) Each installation shall be provided with such primary barriers and/or secondary barriers as are necessary to ensure compliance with Sections 30265 and 30268. Special requirements are contained in Title 24, California Code of Regulations, Section 2-9102 through 2-9105.

(b) Use.

(1) The user shall assure that all X-ray equipment under his jurisdiction is operated only by persons adequately instructed in safe operating procedures and competent in safe use of the equipment.

(2) The user shall provide safety rules to each individual operating X-ray equipment under his control, including any restrictions of the operating technique required for the safe operation of
the particular X-ray apparatus, and require that the operator demonstrate familiarity with these rules.

(3) No user shall operate or permit the operation of X-ray equipment unless the equipment and installation meet the applicable requirements of these regulations and are appropriate for the procedures to be performed.

(4) Deliberate exposure of an individual to the useful beam for training or demonstration purposes shall not be permitted unless there is also a medical or dental indication for the exposure and the exposure is prescribed by a physician or dentist.

(c) Areas or rooms that contain permanently installed X-ray machines as the only source of radiation shall be posted with a sign or signs

CAUTION
X-RAY

in lieu of other signs required by the United States, title 10, Code of Federal Regulations, part 20, Section 20.1902 as incorporated by reference in Section 30253.

(d) High radiation areas caused by radiographic and fluoroscopic machines used solely in the healing arts and which are in compliance with the access control and signal requirements of title 24, California Code of Regulations, Section 9102 through 9105 shall be exempt from the access control and signal requirements of the United States, title 10, Code of Federal Regulations, part 20, Section 20.1601 as incorporated by reference in Section 30253.

NOTE

HISTORY

1. Amendment filed 3-5-71; effective thirtieth day thereafter. Approved by State Building Standards Commission 2-26-71. (Register 71, No. 10).

2. Renumbering and amendment filed 9-4-73 as an emergency; effective upon filing (Register 73, No. 36). Approved by State Building Standards Commission 11-30-73.

3. Certificate of Compliance filed 12-28-73 (Register 73, No. 52).

4. Amendment filed 6-24-80; effective thirtieth day thereafter (Register 80, No. 26).

5. New subsection (a)(5) and repealer of subsection (c) filed 6-18-87; operative 7-18-87 (Register 87, No. 28).

6. Amendment of article heading and new subsections (c) and (d) filed 3-3-94 as an emergency; operative 3-3-94 (Register 94, No. 9). A Certificate of Compliance must be transmitted to OAL by 7-1-94 or emergency language will be repealed by operation of law on the following day.

7. Certificate of Compliance as to 3-3-94 order transmitted to OAL 6-7-94 and filed 7-14-94 (Register 94, No. 28).


(a) Each user subject to this article, as specified in Section 30305(a)(1), who performs radiography shall assure that:
(1) Radiographic films are stored, handled, and processed in accordance with manufacturers' recommendations. Expired film may not be used for clinical purposes.

(2) Intensifying screens, grids, viewers, film processing equipment, chemicals, and solutions are stored, used, and maintained in accordance with manufacturers' recommendations.

(3) For each X-ray machine, a technique chart is provided which establishes for each view commonly performed:

(A) Patient size versus selectable exposure factors;
(B) Source-to-Image distance (if not fixed);
(C) Grid data;
(D) Film/Screen combination; and
(E) Patient shielding (if appropriate).

NOTE:

HISTORY:
1. New section filed 9-4-2012; operative 10-4-2012 (Register 2012, No. 36).

30306. Definitions.

(a) Automatic exposure control means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation.

(b) Cineradiography means the making of a motion picture record of the successive images appearing on a fluorescent screen.

(c) Contact therapy means irradiation of accessible lesions usually employing a very short source-skin distance and potentials of 40-50 KV.

(d) Dead-man switch means a switch so constructed that a circuit-closing contact can only be maintained by continuous pressure by the operator.

(e) Diagnostic-type tube housing means an X-ray tube housing so constructed that the leakage radiation measured at a distance of 1 meter from the source cannot exceed 100 milliroentgens in 1 hour when the tube is operated at its maximum continuous rate of current for the maximum rated tube potential.

(f) Filter means material placed in the useful beam to absorb preferentially the less penetrating radiations.

(g) Interlock means a device for precluding access to an area of radiation hazard either by preventing entry or by automatically removing the hazard.

(h) Leakage radiation means all radiation coming from within the tube housing except the useful beam.

(i) Protective barrier means a barrier of attenuating materials used to reduce radiation exposure.
(j) Primary protective barrier means a barrier sufficient to attenuate the useful beam to the required degree.

(k) Scattered radiation means radiation that, during passage through matter, has been deviated in direction.

(l) Secondary protective barrier means a barrier sufficient to attenuate stray radiation to the required degree.

(m) Shutter means a device, generally of lead, fixed to an X-ray tube housing to intercept the useful beam.

(n) Stray radiation means radiation not serving any useful purpose. It includes leakage and scattered radiation.

(o) Therapeutic-type tube housing means,

(1) For X-ray therapy equipment not capable of operating at 500 kVp or above, an X-ray tube housing so constructed that the leakage radiation at a distance of 1 meter from the source does not exceed 1 roentgen in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential.

(2) For X-ray therapy equipment capable of operating at 500 kVp or above, an X-ray tube housing so constructed that the leakage radiation at a distance of 1 meter from the source does not exceed either 1 roentgen in an hour or 0.1 percent of the useful beam dose rate at 1 meter from the source, whichever is greater, when the machine is operated at its maximum rated continuous current for the maximum rated accelerating potential.

(3) In either case, small areas of reduced protection are acceptable provided the average reading over any 100 square centimeters area at 1 meter distance from the source does not exceed the values given above.

(p) Useful beam means that part of the radiation which passes through the window, aperture, cone, or other collimating device of the tube housing. (T17-30306-T24).

NOTE


HISTORY

1. Renumbering and amendment filed 9-4-73 as an emergency; effective upon filing (Register 73, No. 36). Approved by State Building Standards Commission 11-30-73.

2. Certificate of Compliance filed 12-28-73 (Register 73, No. 52).

3. Amendment of subsection (e) filed 6-18-87; operative 7-18-87 (Register 87, No. 28).

30307. Fluoroscopic Installations

(a) Equipment.

(1) The tube housing shall be of diagnostic type.
(2) The target-to-panel or target-to-table top distance should not be less than 18 inches and shall not be less than 12 inches.

(3) The total filtration permanently in the useful beam shall not be less than 2.5 millimeters aluminum equivalent. This requirement may be assumed to have been met if the half-value layer is not less than 2.5 millimeters aluminum at normal operating voltages.

(4) The equipment shall be so constructed that the entire cross-section of the useful beam is attenuated by a primary barrier. This barrier is usually the viewing device, either a conventional fluoroscopic screen or an image intensification mechanism.

(A) The lead equivalent of the barrier of conventional fluoroscopes shall be at least 1.5 millimeters for equipment capable of operating up to 100 kVp, at least 1.8 millimeters for equipment whose maximum operating potential is greater than 100 kVp and less than 125 kVp, and at least 2.0 millimeters for equipment whose maximum operating potential is 125 kVp or greater. Special attention must be paid to the shielding of image intensifiers so that neither the useful beam nor scattered radiation from the intensifier can produce a radiation hazard to the operator or personnel. With the fluorescent screen 14 inches (35 cm) from the panel or table top, the exposure rate 2 inches (5 cm) beyond the viewing surface of the screen shall not exceed 30 mR/hr for each R per minute at the table top with the screen in the useful beam without a patient and with the fluoroscope operating at the highest potential employed.

(B) Collimators shall be provided to restrict the size of the useful beam to less than the area of the barrier. For conventional fluoroscopes this requirement is met if, when the adjustable diaphragm is opened to its fullest extent, an unilluminated margin is left at all edges of the fluorescent screen with the screen centered in the beam at a distance of 35 cm (14 inches) from the panel or table top.

For image intensified fluoroscopy, shutters shall be provided which can be adjusted to restrict the X-ray field to the visible portion of the image receptor during fluoroscopy. For systems employing rectangular X-ray fields and circular image receptors, this requirement is met if the collimated beam forms a square which circumscribes, and is tangent to, the circular margin of the image receptor.

(C) The tube mounting and the carrier shall be so linked together that the carrier always intercepts the entire useful beam. The X-ray exposure shall automatically terminate when the carrier is removed from the useful beam.

(D) Collimators and adjustable diaphragms or shutters to restrict the size of the useful beam shall provide the same degree of protection as is required of the tube housing.

(5) The exposure switch shall be of the dead-man type.

(6) Each fluoroscopic unit shall be equipped with a manual-reset cumulative timing device, activated by the exposure switch, which will either indicate elapsed exposure time by a signal audible to the fluorocopist or turn off the apparatus when the total exposure exceeds a predetermined limit not exceeding five minutes in one or a series of exposures.

(7) Useful beam exposure rate.

(A) All fluoroscopic equipment. For routine fluoroscopy, the exposure rate measured at the point where the center of the useful beam enters a typical patient shall be as low as is practicable
and shall not exceed 5 roentgens per minute under the conditions specified herein. This limit shall not apply during magnification procedures or the recording of fluoroscopic images where higher exposure rates are required. Compliance with this paragraph shall be determined using the measuring specifications of Section 30307(a)(7)(D), plus the following procedures when the automatic exposure rate control is used:

1. The useful beam exposure rate shall be measured with a phantom equivalent to 9 inches of water or 7 7/8 inches of lucite, intercepting the entire useful beam.

2. If the X-ray source is below the table, the X-ray exposure rate shall be measured with the nearest part of the imaging assembly located at 14 inches above the table top.

3. The field size at the point of exposure rate measurement shall be at least 6 square inches in area in the plane perpendicular to the central ray.

(B) Fluoroscopic equipment manufactured after August 1, 1974, and equipped with automatic exposure rate controls. Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 roentgens per minute at the point where the center of the useful beam enters the patient, except during recording of fluoroscopic images, or when an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(C) Fluoroscopic equipment manufactured after August 1, 1974, without automatic exposure rate controls. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient, except during recording of fluoroscopic images, or when an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(D) Measuring useful beam exposure rate compliance.

1. If the X-ray tube is below the table, the exposure rate shall be measured 1 centimeter above the tabletop or cradle.

2. If the X-ray tube is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

3. In a C-arm type of fluoroscope, the exposure rate shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly.
(8) Mobile fluoroscopic equipment shall meet the requirements of this section where applicable, except that:

(A) Inherent provisions shall be made so that the machine is not operated at a source-skin distance of less than 30 cm (12 inches).

(B) Image intensification shall always be provided. Conventional fluoroscopic screens shall not be used.

(C) It shall be impossible to operate a machine when the collimating cone or diaphragm is not in place.

(D) It shall be impossible to energize the useful beam of a mobile fluoroscope unless the entire useful beam is intercepted by the image receptor.

(9) Devices which indicate the X-ray tube potential and current shall be provided, and should be located in such a manner that the operator may monitor the tube potential and current during fluoroscopy.

(10) A shielding device of at least 0.25 millimeters lead equivalent shall be provided for covering the bucky-slot during fluoroscopy.

(11) Whenever practicable, protective drapes, or hinged or sliding panels, of at least 0.25 millimeters lead equivalent shall be provided between the patient and the fluoroscopist to intercept scattered radiation which would otherwise reach the fluoroscopist and others near the machine. Such devices shall not substitute for wearing of a protective apron.

(b) Operating Procedures.

(1) Protective aprons of at least 0.25 mm lead equivalent shall be worn in the fluoroscopy room by each person, except the patient, whose body is likely to be exposed to 5 mR/hr or more.

(2) On fluoroscopes with automatic exposure controls the operator shall monitor the tube current and potential at least once each week to ascertain that they are in their usual ranges for a given set of operating parameters. This requirement may be met by adjusting the controls to usual settings for fluoroscopying an average patient, and using a phantom of any suitable material with attenuation roughly equivalent to six to ten inches of water. Whenever the monitored tube current or potential vary in a way which could increase the patient X-ray exposure rate by more than 25% over the latest exposure rate measurement required by Section 30307(b)(3), the cause(s) for the change shall be determined promptly and the patient exposure rate shall be remeasured. On fluoroscopes with manual exposure control only, the operator shall monitor the tube current and potential at least once each day during use to ascertain that they are within the normal ranges used by the facility. A written log shall be kept of all monitored readings and shall include at least the tube current and potential, the date, identification of the fluoroscope, and name of the person who did the monitoring. Records of all monitored readings shall be preserved at the facility for at least three years.

(3) Measurements of the table top or patient exposure rate shall be made at least once each year for units with automatic exposure control, and at least once each 3 years for units without automatic exposure control, and immediately following alteration or replacement of a major component, such as the X-ray tube, the exposure controls, the imaging assembly, and the power source.
(4) On cineradiography equipment, the exposure rates to which patients are normally subjected shall be determined at least once each year, and immediately following alterations or replacement of a major component, such as the X-ray tube, the exposure controls, the imaging assembly, and the power source.

NOTE


HISTORY

1. Renumbering and amendment filed 9-4-73 as an emergency; effective upon filing (Register 73, No. 36). Approved by State Building Standards Commission 11-30-73.

2. Certificate of Compliance filed 12-28-73 (Register 73, No. 52).

3. Amendment filed 6-24-80; effective thirtieth day thereafter (Register 80, No. 26).

4. Amendment filed 6-18-87; operative 7-18-87 (Register 87, No. 28).

30308.1. Quality Assurance for Radiographic Installations (Other Than Mammography, Dental, and Veterinary Medicine)

(a) Each user subject to this article, as specified in Section 30305(a)(1), who develops clinical radiographs for diagnostic purposes with automatic film processors for other than mammographic, dental, or veterinary use, shall assure all of the following:

(1) Each processor used to develop clinical radiographs is adjusted and maintained to meet the manufacturer's processing specifications for the highest speed radiographic film used clinically.

(2) Measurements are performed each day before clinical radiographs are processed, so as to determine that the processor is operating within the following limits:

(A) The base-plus-fog density is within plus 0.05 of the operating level established with the highest speed radiographic film used clinically;

(B) The mid-density is within plus or minus 0.15 of the operating level established with the highest speed radiographic film used clinically; and

(C) The density-difference is within plus or minus 0.15 of the operating level established with the highest speed radiographic film used clinically.

(3) Tests are performed at intervals not to exceed three months to determine that the residual fixer level retained in clinical radiographic films is not more than 5.0 micrograms per square centimeter.

(4) Tests are performed at intervals not to exceed six months to determine that the optical density attributable to darkroom fog is not more than 0.05 when the highest speed of each type radiographic film used clinically, which has a mid-density of no less than 1.20 optical density, is exposed on the counter top for one minute under typical darkroom conditions with the safelight on.

(5) For any test result falling outside the criteria specified in this section, the problem is identified and corrective action is taken before clinical radiographs are processed.
(6) Records of the tests specified in this section, including the problems detected, corrective actions taken, and the effectiveness of those corrective actions, are maintained for at least one year from the date the test was performed.

NOTE:

HISTORY:
1. New section filed 9-4-2012; operative 10-4-2012 (Register 2012, No. 36).

30309. Special Requirements for Mobile Radiographic Equipment.

(a) Equipment.
(1) All requirements of Section 30308(a) apply except 30308(a)(5) and 30308(a)(9).
(2) The exposure control switch shall be of the dead-man type and shall be so arranged that the operator can stand at least 6 feet from the patient and well away from the useful beam.
(3) Inherent provisions shall be made so that the equipment is not operated at source-skin distances of less than 12 inches.

(b) Operating Procedures.
(1) All provisions of Section 30308(b) apply except 30308(b)(5).
(2) The target-to-skin distance shall be not less than 12 inches.
(3) Personnel monitoring shall be required for all individuals operating mobile X-ray equipment.

NOTE

HISTORY
1. Amendment filed 3-5-71; effective thirtieth day thereafter. Approved by State Building Standards Commission 2-26-71. (Register 71, No. 10).
2. Renumbering and amendment filed 9-4-73 as an emergency; effective upon filing (Register 73, No. 36). Approved by State Building Standards Commission 11-30-73.
3. Certificate of Compliance filed 12-28-73 (Register 73, No. 52).
4. Amendment of subsection (b)(1) filed 6-18-87; operative 7-18-87 (Register 87, No. 28).

30311.1. Quality Assurance for Dental Radiography.

(a) Each user subject to this article, as specified in Section 30305(a)(1), using intra-oral film for dental radiography of human beings shall assure all of the following:
(1) A reference film meeting the interpreting dentists' criteria for image density, contrast, sharpness and overall quality is selected for use in daily comparisons of dental radiographs.
(2) For each day dental radiographs are processed, clinical radiographs are compared to the selected reference film for density, contrast, sharpness, and overall image quality.

(3) Corrective action is taken when observable changes occur in clinical radiographic image density, contrast, sharpness and overall quality.

(4) Records of the corrective actions taken, and the effectiveness of those corrective actions, are maintained for a minimum of one year from the date the corrective action was taken.

(5) Corrective action, as directed by the Department, is taken if the entrance exposure to an adult patient for a routine intraoral bitewing exam is found by the Department to be outside the ranges specified in the following table.

<table>
<thead>
<tr>
<th>Tube Potential (kVp)</th>
<th>D Speed Film (mR)</th>
<th>E or F Speed Film (mR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 425-575</td>
<td>220-320</td>
<td></td>
</tr>
<tr>
<td>55 350-500</td>
<td>190-270</td>
<td></td>
</tr>
<tr>
<td>60 310-440</td>
<td>165-230</td>
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</tr>
<tr>
<td>65 270-400</td>
<td>140-200</td>
<td></td>
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<tr>
<td>70 240-350</td>
<td>120-170</td>
<td></td>
</tr>
<tr>
<td>75 170-260</td>
<td>100-140</td>
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<tr>
<td>80 150-230</td>
<td>90-120</td>
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<td>85 130-200</td>
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<td>90 120-180</td>
<td>70-90</td>
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<tr>
<td>95 110-160</td>
<td>60-80</td>
<td></td>
</tr>
<tr>
<td>100 100-140</td>
<td>50-70</td>
<td></td>
</tr>
</tbody>
</table>

1 Linear extrapolation or interpolation shall be used for an x-ray tube potential (kVp) not listed in the table.

2 The kVp shall be measured to determine the correct exposure limit to be applied.

3 Exposures values are specified as free-in-air exposures without backscatter.

NOTE:


HISTORY:

1. New section filed 9-4-2012; operative 10-4-2012 (Register 2012, No. 36).

30312. Therapeutic X-Ray Installations.
(a) Equipment.

(1) The tube housing shall be of therapeutic type.

(2) For equipment installed on or before August 1, 1979, permanent diaphragms or cones used for collimating the useful beam shall afford the same degree of protection as the housing. Adjustable or removable beam-defining diaphragms or cones shall transmit not more than 5 percent of the useful beam obtained at the maximum kilovoltage and with maximum treatment filter.

(3) For equipment installed after August 1, 1979, permanent beam-defining devices or diaphragms shall afford the same degree of protection as the housing. Adjustable or interchangeable beam-defining devices shall transmit no more than 2 percent of the useful beam for the portion of the useful beam which is to be attenuated by the beam limiting device. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the normal treatment distance.

(4) Filters shall be secured in place to prevent them from dropping out during treatment. A filter indication system shall be used on all therapy machines using interchangeable filters. It shall indicate, from the control panel, or from the control station, the presence or absence of any filter except compensating filters, and it shall be designed to permit easy identification of the filter in place. The filter slot shall be so constructed that the radiation escaping through it does not exceed 1 roentgen per hour at 1 meter, or, if the patient is likely to be exposed to radiation escaping from the slot, 30 roentgens per hour at 5 centimeters from the external opening. Each interchangeable filter shall be marked with its thickness and material.

(5) The X-ray tube shall be so mounted that it cannot turn or slide with respect to the aperture.

(6) Means shall be provided to immobilize the tube housing during stationary portal treatment.

(7) A suitable exposure control device such as an automatic timer, exposure meter, or dose meter shall be provided to terminate the exposure after a preset time interval or preset exposure or dose limit. A timer shall be provided to terminate the exposure after a preset time regardless of what other exposure limiting devices are present. Means shall be provided for the operator to terminate the exposure at any time.

(8) Equipment utilizing shutters to control the useful beam shall have a shutter position indicator on the control.

(9) An easily discernible indicator which shows whether or not X-rays are being produced shall be on the control panel.

(10) Mechanical and/or electrical stops shall be provided on X-ray machines capable of operating at 150 kVp or above to insure that the useful beam is oriented only toward primary barriers.

(11) When the relationship between the beam interceptor (when present) and the useful beam is not permanently fixed, mechanical or electrical stops shall be provided to insure that the beam is oriented only toward primary barriers.

(b) Operating Procedures.
(1) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

(2) No patient other than the one being treated shall be in the treatment room during exposure.

(3) No person other than the patient shall be in the treatment room when the tube is operated at potentials exceeding 150 kVp. At operating potentials of 150 kVp or below, persons other than the patient and operator may be in the treatment room for good reason but only if they are adequately protected and their radiation exposure is appropriately monitored.

(4) A calibration of the output of each radiation therapy system shall be performed before the system is first used for irradiation of a patient, and thereafter at intervals not to exceed 24 months. Therapy equipment shall not be used for any therapy treatments except at those combinations of effective energy, field size, and treatment distance for which the equipment has been calibrated. The calibration shall be performed by or under the direct supervision of a person who has been determined by the Department to have adequate training, experience and knowledge in radiation therapy physics, and who shall be present at the facility during such calibration. After any change which might significantly alter the output, spatial distribution, or other characteristics of the therapy beam, the parameters which might be affected shall be measured.

(A) For therapy systems operating at potentials above 500 kVp, the determinations included in the calibration shall be provided in sufficient detail so that the absorbed dose in tissue in the useful beam may be calculated to within 5 percent. The calibration shall include, but shall not be limited to, the following determinations:

1. Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the side light and back-pointer alignment with the isocenter when these specifications are known and applicable, variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at specified depths.

2. The relative dose at various depths in a tissue equivalent phantom for each effective energy and the ranges of field sizes and treatment distances used for radiation therapy.

3. The congruence between the radiation field and the field indicated by the localizing device.

4. The uniformity of the radiation field and its dependency upon the direction of the useful beam.

5. The absolute dose per unit time and dose per monitor setting.

(B) For therapy systems operating at potentials between 150 kVp and 500 kVp inclusive, the calibration shall include, but shall not be limited to, the following determinations:

1. The exposure rates and/or dose rates for each combination of field size, technique factors, filter, and treatment distance used.

2. The degree of congruence between the radiation field and the field indicated by the localizing device if such device is present.

3. An evaluation of the uniformity of the radiation field symmetry for the field sizes used, and any dependence upon tube housing assembly orientation.
(5) All new installations and existing installations not previously surveyed shall have a radiation protection survey performed by or under the direction of a person determined by the Department to have adequate knowledge and training to advise regarding radiation protection needs, to measure ionizing radiation and to evaluate safety techniques. If the survey shows that supplementary shielding is required a resurvey shall be performed after its installation. In addition, a resurvey shall be made after every change which might decrease radiation protection significantly. The surveyor shall report his findings in writing to the user. The report shall indicate whether or not the installation is in compliance with all applicable radiation protection requirements of this section. The user shall report the findings of the survey in writing to the Department within 15 days of his receipt of the survey report.

(6) The exposure rate or dose rate of the useful beam and the size and shape of the useful beam shall be known with reasonable certainty at all times during operation of the radiation therapy apparatus for medical purposes.

(7) Spot checks shall be performed at least once each week for therapy systems operating at potentials above 500 kVp, and at least once each month for therapy systems operating at 500 kVp or below.

(A) The measurements taken during spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the system or the radiation delivered to a patient during a therapy procedure.

(B) For systems in which the calibrating person believes beam quality can vary significantly, spot checks shall include beam quality checks.

(C) The spot check procedures shall be in writing and shall have been developed or approved by the individual who made the most recent calibration of the system pursuant to Section 30312(b)(4). The written spot check procedures shall specify when measurements and determinations indicate an inconsistency or potential change in radiation output. When more than the minimum frequency of spot checking is necessary, the spot check procedures shall specify the frequency at which spot checks are to be performed.

(D) When spot check results are erratic or inconsistent with calibration data, the person who designed the spot check procedures, or a person of equivalent competence, shall be consulted immediately and the reason(s) for the inconsistency corrected before the system is used for patient irradiation.

(8) Calibration of the therapy beam shall be performed with a measurement instrument which has been calibrated within the preceding two years directly, or through no more than one exchange, at the National Institute of Standards and Technology, or facility determined acceptable by the Department. In addition, indirect spot checks or intercomparisons of measurement instruments with secondary standards shall be made at least each six months.

(9) Reports of each radiation safety survey spot check and calibration performed pursuant to this section shall be maintained at the facility for at least three years. A copy of the treatment data developed from the latest calibration shall be available for use by the operator at the treatment control station.

NOTE
30313. Special Requirements for X-Ray Therapy Equipment Operated at Potentials of 50 kV and Below.

(a) Equipment.

(1) All provisions of Section 30312(a) apply.

(2) A therapeutic-type protective tube housing shall be used. Contact therapy machines shall meet the additional requirement that the leakage radiation at 2 inches from the surface of the housing not exceed 0.1 R/hr.

(3) Automatic timers shall be provided which will permit accurate presetting and determination of exposures as short as one second.

(b) Operating Procedures.

(1) All provisions of Section 30312(b) apply except 30312(b)(1) and 30312(b)(7).

(2) In the therapeutic application of apparatus constructed with beryllium or other low-filtration windows adequate shielding shall be required to protect against unnecessary exposure from the useful beam, and special safeguards are essential to avoid accidental exposures to the useful beam. There shall be on the control panel some easily discernible device which will give positive information as to whether or not the tube is energized.

(3) Machines having an output of more than 1,000 roentgens per minute at any accessible place shall not be left unattended without the power being shut off at the primary disconnecting source.

(4) If the X-ray tube of a contact therapy machine is hand-held during irradiation, the operator shall wear protective gloves and apron.

NOTE


HISTORY

1. Amendment filed 3-5-71; effective thirtieth day thereafter. Approved by State Building Standards Commission 2-26-71 (Register 71, No. 10).
2. Renumbering and amendment filed 9-4-73 as an emergency; effective upon filing (Register 73, No. 36). Approved by State Building Standards Commission 11-30-73.

3. Certificate of Compliance filed 12-28-73 (Register 73, No. 52).

4. Amendment of subsections (a)(1), (b)(1) and (b)(4) filed 6-18-87; operative 7-18-87 (Register 87, No. 28).

5. Change without regulatory effect amending subsection (b)(3) filed 11-1-91 pursuant to Section 100, title 1, California Code of Regulations (Register 92, No. 5).

6. Amendment of section heading filed 3-3-94 as an emergency; operative 3-3-94 (Register 94, No. 9). A Certificate of Compliance must be transmitted to OAL by 7-1-94 or emergency language will be repealed by operation of law on the following day.

7. Certificate of Compliance as to 3-3-94 order transmitted to OAL 6-7-94 and filed 7-14-94 (Register 94, No. 28).

30314. Veterinary Medicine Radiographic Installations.

(a) Equipment.

(1) The tube housing shall be of diagnostic type.

(2) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

(3) The total filtration permanently in the useful beam shall not be less than 1.5 millimeters aluminum-equivalent for equipment operating up to 70 kvp and 2.0 millimeters aluminum-equivalent for machines operated in excess of 70 kvp.

(4) A device shall be provided to terminate the exposure after a pre-set time or exposure.

(5) A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length so that the operator can stand out of the useful beam and at least 6 feet from the animal during all X-ray exposures.

(b) Operating Procedures.

(1) The operator shall stand well away from the tube housing and the animal during radiographic exposures. The operator shall not stand in the useful beam. If film must be held, it shall be held by individuals not occupationally exposed to radiation. Hand-held fluoroscopic screens shall not be used. The tube housing shall not be held by the operator. No individuals other than the operator shall be in the X-ray room while exposures are being made unless such persons assistance is required.

(2) In any application in which the operator is not located behind a protective barrier, clothing consisting of a protective apron having a lead-equivalent of not less than 0.25 millimeter shall be worn by the operator and any other individuals in the room during exposures.

(3) No individual shall be regularly employed to hold or support animals during radiation exposures. Operating personnel shall not perform this service except very infrequently and then only in cases in which no other method is available. Any individual holding or supporting an animal during radiation exposure shall wear protective gloves and apron having a lead-equivalent of not less than 0.25 millimeter.

NOTE

HISTORY

1. Amendment filed 3-5-71; effective thirtieth day thereafter. Approved by State Building Standards Commission 2-26-71. (Register 71, No. 10).

2. Renumbering filed 9-4-73 as an emergency; effective upon filing (Register 73, No. 36). Approved by State Building Standards Commission 11-30-73.

3. Certificate of Compliance filed 12-28-73 (Register 73, No. 52).

4. Amendment filed 6-18-87; operative 7-18-87 (Register 87, No. 28).