California Department of Public Health CDPH

Division of Food, Drug and Radiation Safety
Radiologic Health Branch

Summary of Regulatory Changes Rule Number DPH-05-018: Adoption of 10 CFR Part 35

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Agenda

- **Welcome and Introductions**
  - *9:00 am/1:00 pm* *Ira Schneider*
- **Summary of Regulatory Changes and Information Notices**
  - *9:05 am/1:05 pm* *Ira Schneider*
- **Break**
  - *9:45 am/1:45 pm*
- **Qualifying Training and Experience, Preceptors and New Forms**
  - *10:00 am/2:00 pm* *Rob Custodio and Jennifer Cho*
- **Break**
  - *11:00 am/3:00 pm*
- **Written Directives, Reformatting Licenses and Contents of an Amendment Request**
  - *11:15 am/3:15pm* *Jennifer Granger*
- **Questions and Answers**

History

- **Examination of issues surrounding medical use regulation**
  - 1993 NRC internal senior management review
  - 1996 National Academy of Sciences, Institute of Medicine
  - NRC Strategic Assessment and Rebaselining Initiative (SARI)

- **NRC Commissioners supported a continuation of medical use regulation and directed restructuring of 10 CFR Part 35**

- **Revised Part 35 implemented by NRC October 2002**
  - risk-informed and more performance-based
  - focus on radiation safety aspects of medical procedures that pose the highest risk
  - reduce prescriptivesness of requirements in low risk activities

History

- **CA as NRC Agreement State**
  - Incorporation of applicable sections of 10 CFR Part 35 to maintain compatibility with Federal regulations and reciprocity with other NRC AS
  - Rule Number DPH-05-018, Medical Use of Radioactive Material

- **Why adopt Part 35 by reference???**
  - Easier to adopt regulations by reference under Administrative Procedures Act standards of:
    - Authority
    - Reference
    - Consistency
    - Clarity
    - Non-duplication
    - Necessity
  - Less cumbersome than to create our own regulation from scratch

History

Rule Number DPH-05-018

- Adoption of 10 CFR Part 35 (2008)
- Sections Affected: California Code of Regulations Title 17 Sections 30100, 30195, 30321, 30321.1 & 30322
- Notice of Proposed Rulemaking published April 2, 2010
- California Regulatory Notice Register 2010, No. 14-Z
- Public Comment Period closed May 20, 2010
- Filed with Office of Administrative Law on August 30, 2010
- Proposed implementation on January 1, 2011

Adopting NRC 2008 version with exceptions

- 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, 35.4002
- Examples include: Purpose and scope, maintenance of records, license amendments, notifications, exemptions, violations, criminal penalties

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Errata

- **10 CFR 35.24 Authority and Responsibilities for the radiation protection program.**
  - **(a)** In addition to the radiation protection program requirements of §20.1101 of this chapter, a licensee's management shall approve in writing–
    (3) Radiation protection program changes that do not require a license amendment and are permitted under §35.26;
    - *§35.26 not incorporated by reference in DPH-05-018*

- **10 CFR 35.2026 Records of radiation protection program changes.**
  - A licensee shall retain a record of each radiation protection program change made in accordance with §35.26(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.
    - *§35.26(a) not incorporated by reference in DPH-05-018*

- **Licensees will be bound by the commitments and conditions of their license.**

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

(1) Amend Section 30100 to read as follows:

§ 30100. General Definitions.

As used in subchapter 4:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(~~i~~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.

(~~m~~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.).

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

(~~o~~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.

(~~p~~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.

(~~q~~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.

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

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(~~s~~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.

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

(~~u~~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.

(~~v~~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.

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

(~~x~~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.

(~~y~~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.

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

(~~aa~~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.

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

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

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GROUP 2. LICENSING OF RADIOACTIVE MATERIALS
Article 4. Licenses

(2) Amend Section 30195 to read as follows:

§ 30195. Special Requirements for Issuance of Specific Licenses.

In addition to the requirements set forth in Section 30194, specific licenses for certain specialized uses will be issued only if the following conditions are met:

~~(a) For human use of radioactive material in institutions:~~
~~(1) The institution has a formally constituted and officially recognized medical radiation safety committee, which should include a representative of the institution's administration and at least three individuals who are knowledgeable in the areas of human use of radioactive material and of radiation safety, and which shall evaluate all proposals for, and maintain surveillance over, all uses of radioactive material within the institution.~~
~~(2) The institution has a radiation safety officer, who is a member of the radiation safety committee, and who is qualified by reason of training and experience to oversee the radiation safety aspects of radioactive material use in the institution.~~
~~(3) The institution's application includes a detailed statement of qualifications, duties, authority, and responsibility of the radiation safety committee and the radiation safety officer.~~
~~(4) The institution had adequate facilities for the clinical care of patients.~~
~~(5) Each person to be designated as an individual radioactive material user is a physician and furnishes clear evidence of substantial training and experience in the kinds of uses proposed, including handling and administration of the radioactive material and the appropriate clinical management of patients.~~

~~(b) For human use of radioactive material by individuals:~~
~~(1) The applicant is a physician and furnishes clear evidence of having substantial training and experience in the kinds of uses proposed, including the handling and administration of the radioactive material and the appropriate clinical management of patients.~~
~~(2) The applicant demonstrates access to adequate hospital facilities for the patients, where appropriate.~~

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

(1) Title 10, Code of Federal Regulations, sections 35.1, 35.5, 35.7, 35.8, 35.10, 35.11(c), 35.12, 35.13, 35.14, 35.15, 35.18, 35.19, 35.26, 35.65, 35.4001, and 35.4002 are not incorporated by reference.

(2) Any references to the United States Nuclear Regulatory Commission (NRC) or any component thereof shall be deemed to be a reference to the "Department" as defined in section 30100 of this regulation.

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

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

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

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

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

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

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(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 [effective date of regulation to be inserted by Office of Administrative Law] is substituted for the dates October 24, 2002 and April 29, 2005 found in 10 CFR 35, section 35.57.

(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.

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

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

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

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

Note: Authority cited: Sections ~~208 and 25811~~114975, 115000 and 131200, Health and Safety Code. Reference: Sections ~~25801, 25802, 25815, 25855 and 25876~~114965, 114970, 115060, 115165, 115235, 131050, 131051 and 131052, Health and Safety Code.

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GROUP 3. STANDARDS FOR PROTECTION AGAINST RADIATION
Article 5. Special Requirements for the Use of Radioactive Material in the Healing Arts

(3) Repeal Section 30321 as follows:

§ 30321. Accountability, Storage, and Transit.

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

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

Note: Authority cited: Sections 208 and 25811, Health and Safety Code. Reference: Sections 25801, 25802, 25811, 25815, 25875 and 25876, Health and Safety Code.
(4) Repeal Section 30321.1 as follows:

§ 30321.1. Confirming Removal of Implants.

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

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

(5) Repeal Section 30322 as follows:

§ 30322. Records and Reports of Misadministration.

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

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

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

~~(d) Each licensee shall retain a record of each misadministration for 10 years. The record shall contain the names of all individuals involved in the event, including the physician, allied health personnel, the patient and the patient's referring physician, the patient's social security number or identification number if~~

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~~one has been assigned, a brief description of the event, the effect on the patient, and the action taken, if any, to prevent recurrence.~~

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

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

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10 CFR 35 10 CFR 35 Subpart A – General Information

- 35.1 Purpose and scope.
- 35.2 Definitions.
- 35.5 Maintenance of records.
- 35.6 Provisions for the protection of human research subjects.
- 35.7 FDA, other Federal, and State requirements.
- 35.8 Information collection requirements: OMB approval.
- 35.10 Implementation.
- 35.11 License required, (a) and (b)
- 35.11 License required (c)
- 35.12 Application for license, amendment, or renewal.
- 35.13 License amendments.
- 35.14 Notifications.
- 35.15 Exemptions regarding Type A specific licenses of broad scope.
- 35.18 License issuance.
- 35.19 Specific exemptions.

Not incorporated by reference

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10 CFR 35 Subpart B – General Administrative Requirements

- 35.24 Authority and responsibilities for the radiation protection program.
- 35.26 Radiation protection program changes.
- 35.27 Supervision.
- 35.40 Written directives.
- 35.41 Procedures for administrations requiring a written directive.
- 35.49 Suppliers for sealed sources or devices for medical use.
- 35.50 Training for Radiation Safety Officer.
- 35.51 Training for an authorized medical physicist.
- 35.55 Training for an authorized nuclear pharmacist.
- 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.
- 35.59 Recentness of training.

Not incorporated by reference

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- 35.24 Authority and responsibilities for the radiation protection program.

(c) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer, under §§ 35.50 and 35.59, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in paragraph (g) of this section, if the licensee takes the actions required in paragraphs (b), (e), (g), and (h) of this section and notifies the Commission in accordance with § 35.14(b).

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- 35.24 Authority and responsibilities for the radiation protection program.

(f) Licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of this part, or two or more types of units under Subpart H of this part, shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

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10 CFR 35 Subpart C – General Technical Requirements

- 35.60 Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material.
- 35.61 Calibration of survey instruments.
- 35.63 Determination of dosages of unsealed byproduct material for medical use.
- 35.65 Authorization for calibration, transmission, and reference sources.
- 35.67 Requirements for possession of sealed sources and brachytherapy sources.
- 35.69 Labeling of vials and syringes.
- 35.70 Surveys of ambient radiation exposure rate.
- 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.
- 35.80 Provision of mobile medical service.
- 35.92 Decay-in-storage.

Not incorporated by reference

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- 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.

(a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).1

(b) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include--

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, if any, of failure to follow the guidance.

(c) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with § 35.2075(a).

(d) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with § 35.2075(b).

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10 CFR 35 Subpart D – Unsealed Byproduct Material, Written Directive Not Required

- 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.
- 35.190 Training for uptake, dilution, and excretion studies.
- 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.
- 35.204 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.
- 35.290 Training for imaging and localization studies.

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10 CFR 35 Subpart E – Unsealed Byproduct Material, Written Directive Required

- 35.300 Use of unsealed by product material for which a written directive is required.
- 35.310 Safety instruction.
- 35.315 Safety precautions.
- 35.390 Training for use of unsealed byproduct material for which a written directive is required.
- 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).
- 35.394 Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).
- 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.

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10 CFR 35 Subpart F – Manual Brachytherapy

- 35.400 Use of sources for manual brachytherapy.
- 35.404 Surveys after source implant and removal.
- 35.406 Brachytherapy sources accountability.
- 35.410 Safety instruction.
- 35.415 Safety precautions.
- 35.432 Calibration measurements of brachytherapy sources.
- 35.433 Decay of strontium-90 sources for ophthalmic treatments.
- 35.457 Therapy-related computer systems.
- 35.490 Training for use of manual brachytherapy sources.
- 35.491 Training for ophthalmic use of strontium-90.

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10 CFR 35 Subpart G – Sealed Sources for Diagnosis

- 35.500 Use of sealed sources for diagnosis.
- 35.590 Training for use of sealed sources for diagnosis.

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10 CFR 35 Subpart H – Photon Emitting Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units

- 35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.
- 35.604 Surveys of patients and human research subjects treated with a remote afterloader unit.
- 35.605 Installation, maintenance, adjustment, and repair.
- 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
- 35.615 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
- 35.630 Dosimetry equipment.

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10 CFR 35 Subpart H – Photon Emitting Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units (continued)

- 35.632 Full calibration measurements on teletherapy units.
- 35.633 Full calibration measurements on remote afterloader units.
- 35.635 Full calibration measurements on gamma stereotactic radiosurgery units.
- 35.642 Periodic spot-checks for teletherapy units.
- 35.643 Periodic spot-checks for remote afterloader units.
- 35.645 Periodic spot-checks for gamma stereotactic radiosurgery units.
- 35.647 Additional technical requirements for mobile remote afterloader units.

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10 CFR 35 Subpart H – Photon Emitting Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units (continued)

- 35.652 Radiation surveys.
- 35.655 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.
- 35.657 Therapy-related computer systems.
- 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

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10 CFR 35 Subpart I – [Reserved]

10 CFR 35 Subpart J – [Reserved]

10 CFR 35 Subpart K – Other Medical Uses of Byproduct Material or Radiation from Byproduct Material

- 35.1000 Other medical uses of byproduct material or radiation from byproduct material.

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10 CFR 35 Subpart L – Records

- 35.2024 Records of authority and responsibilities for radiation protection programs.
- 35.2026 Records of radiation protection program changes.
- 35.2040 Records of written directives.
- 35.2041 Records for procedures for administrations requiring a written directive.
- 35.2060 Records of calibrations of instruments used to measure the activity of unsealed byproduct materials.
- 35.2061 Records of radiation survey instrument calibrations.
- 35.2063 Records of dosages of unsealed byproduct material for medical use.
- 35.2067 Records of leaks tests and inventory of sealed sources and brachytherapy sources.

Package DPH-05-018

10 CFR 35 Subpart L – Records (continued)

- 35.2070 Records of surveys for ambient radiation exposure rate.
- 35.2075 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.
- 35.2080 Records of mobile medical services.
- 35.2092 Records of decay-in-storage.
- 35.2204 Records of molybdenum-99, strontium-82, and strontium-85 concentrations.
- 35.2310 Records of safety instruction.
- 35.2404 Records of surveys after source implant and removal.
- 35.2406 Records of brachytherapy source accountability.
- 35.2432 Records of calibration measurements of brachytherapy sources.

Package DPH-05-018

10 CFR 35 Subpart L – Records (continued)

- 35.2433 Records of decay of strontium-90 sources for ophthalmic treatments.
- 35.2605 Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
- 35.2610 Records of safety procedures.
- 35.2630 Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
- 35.2632 Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.
- 35.2642 Records of periodic spot-checks for teletherapy units.
- 35.2643 Records of periodic spot-checks for remote afterloader units.
- 35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units.

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10 CFR 35 Subpart L – Records (continued)

- 35.2647 Records of additional technical requirements for mobile remote afterloader units.
- 35.2652 Records of surveys of therapeutic treatment units.
- 35.2655 Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

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Package DPH-05-018

10 CFR 35 Subpart M – Reports

- 35.3045 Report and notification of a medical event.
- 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child.
- 35.3067 Report of a leaking source.

10 CFR 35 Subpart N – Enforcement

- 35.4001 Violations.
- 35.4002 Criminal penalties.

Not incorporated by reference

California Department of Public Health CDPH

Division of Food, Drug and Radiation Safety
Radiologic Health Branch

Information Notice (1)

To maintain compatibility with the US Nuclear Regulatory Commission (NRC) and other Agreement States that have adopted 10 CFR 35, the California Department of Public Health (CDPH) is in the final stage of adopting relevant sections of 10 CFR 35 as published January 1, 2008. The proposal was submitted to the Office of Administrative Law, who must approve the adoption, with a requested effective dated of January 1, 2011. A copy of 10 CFR 25 (January 1, 2008) is available at: http://www.access.gpo.gov/nara/cfr/waisidx_08/10cfr35_08.html.

To help licensees transition to the new requirements, the Radiologic Health Branch (RHB), will hold two informational workshops in both Southern and Northern California (pending stakeholder interest and budget approval). The Northern California workshop is scheduled for December 9, 2010, at 1500 Capitol Avenue, Sacramento, California at 9:00 am. The Southern California workshop is planned to be held in either Los Angeles or Orange County in early December. When the date and location of the Southern California workshop is known, the information will be posted on the RHB's Radioactive Materials Licensing webpage under "Hot Topics" at: http://www.cdph.ca.gov/certlic/radquip/Pages/RadioactiveMaterials.aspx.

Information Notice (1)

The purpose of the workshops is to present a summary of the significant changes a licensee needs to make to ensure their radiation safety program meets the new regulations. RHB plans to provide guidance on the following issues at the workshops:

1. Qualifying training and experience for:
   - Radiation Safety Officers (10 CFR 35.50, 10 CFR 35.57)
   - Authorized Medical Physicists (10 CFR 35.51)
   - Authorized Nuclear Pharmacists (10CFR 35.55) and
   - Authorized Users (10 CFR 35.190, 10 CFR 35.290, 10 CFR 35.390, 10 CFR 35.392, 10 CFR 35.394, 10 CFR 35.396, 10 CFR 35.490, 10 CFR 35.590 and 10 CFR 35.690)
2. Requirements for the use of High Dose Afterloader units (10 CFR 35.615)
3. Methodologies for measurement of dosages or doses (10 CFR 35.63)
4. Reformatting of existing licenses
5. Enforcement

California Department of Public Health CDPH

Division of Food, Drug and Radiation Safety
Radiologic Health Branch

Information Notice (1)

In addition, there will be a question and answer period at the end of the workshop during which licensees may have their specific questions answered by RHB staff.

Licensees and interested stakeholders who plan to attend one of the workshops should submit their reservation to the following email address: Ira.Schenider@cdph.ca.gov. If would be helpful for licensees to submit questions in advance so as to ensure that answers can be providedat the workshops. Questions may also be submitted to the above email address, or by contacting me at (916) 440-7976.

California Department of Public Health CDPH

Division of Food, Drug and Radiation Safety
Radiologic Health Branch

Information Notice (2)

To maintain compatibility with the US Nuclear Regulatory Commission (NRC) and other Agreement States that have adopted 10 CFR 35, the California Department of Public Health (CDPH) has adopted relevant sections of 10 CFR 35. The adoption of these regulations has been approved by the Office of Administrative Law, with an effective date of January 1, 2011. A copy of 10 CFR 35, (January 1, 2008), is available at: http://www.access.gpo.gov/nara/cfr/waisidx_08/10cfr35_08.html.

This information notice is the second in a series of information notices, designed to inform licensees of changes which will occur as a result of the adoption of 10 CFR 35, and also of how the Radiologic Health Branch (RHB) expects licensees to respond to the changes. Information notices such as this will be posted on RHB's Radioactive Materials Licensing webpage under "Hot Topics" at: http://www.cdph.ca.gov/certlic/radquip/Pages/RadioactiveMaterials.aspx.

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Division of Food, Drug and Radiation Safety
Radiologic Health Branch

Information Notice (2)

The following information is provided to specifically call out regulatory changes, and to provide clarifications regarding some of the new regulations that licensees may find applicable to their operations and radiation safety programs.

- While the State of California plans to adopt 10 CFR 35, the statements, representations, and procedures specified in a licensee's application, correspondence and actual license will continue to govern if they are more restrictive than the regulations in 10 CFR 35.
- All license amendment requests submitted prior to January 1, 2011, will follow current CDPH policies and standards. After January 1, 2011, California accepted 10 CFR 35 policies and standards will apply.

California Department of Public Health
CDPH
Division of Food, Drug and Radiation Safety
Radiologic Health Branch

Information Notice (2)

- In accordance with 10 CFR 35.40, the administration of Iodine-131 (I-131) in doses greater than 30 microcuries requires a written directive. This change may affect physicians who are currently authorized for the use of I-131 for diagnostic imaging under Groups 2 and 3, but who may now not meet the training and experience requirements of 10 CFR 35.300. Group 2 and 3 physicians who wish to be grandfathered for purposes of an authorization to administer I-131, requiring a written directive, for diagnostic imaging, must submit an amendment request before January 1, 2011. Attachment 1 should be used to submit your amendment request for grandfathering. After January 1, 2011, Attachment 1 cannot be used to submit an amendment request to authorize a physician to administer I-131, requiring a written directive for diagnostic imaging.

California Department of Public Health (CDPH)

Division of Food, Drug and Radiation Safety
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Information Notice (2)

- Presently, the State of California does not require a radioactive materials licensee with authorization for use of either a high dose rate (HDR) remote afterloader or a Strontium 90 Eye Applicator to list their Authorized Medical Physicist (AMP) on the license. In the future, an AMP who operates the devices must be named on the license as a HDR or Applicator user. If your facility is currently authorized for an HDR or Applicator and you do not currently have your AMP listed on your license, you must submit an amendment request to grandfather the AMP before January 1, 2011. Attachment 2 should be used to submit your amendment request for grandfathering. After January 1, 2011, Attachment 2 cannot be used to name an AMP to the license.
- In accordance with 10 CFR 35.615(f)(2), the use of an HDR remote afterloader will require the Authorized User (AU) and AMP to be physically present (within hearing distance of normal voice) during the initiation of all patient treatments involving the unit. In addition, the AMP and either an AU or a physician, under the supervision of an AU who has been trained in the unit's operation and emergency response for the unit, must be physically present during the continuation of all patient treatments involving the HDR remote afterloader unit.

California Department of Public Health CDPH

Division of Food, Drug and Radiation Safety
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Information Notice (2)

- After the adoption of 10 CFR 35, California medical radioactive materials licenses will be modified to reflect the NRC classifications regarding use authorizations. For example, rather than authorizations for Groups 1, 2, 3, etc., licenses will be rewritten for authorizations for 10 CFR 35.100, 10 CFR 35.200, etc.

Questions and comments may be submitted to Ira.Schneider@cdph.ca.gov.

California Department of Public Health CDPH

Division of Food, Drug and Radiation Safety
Radiologic Health Branch

Information Notice (2)

Attachment 1

Request for Administration of Iodine-131 Requiring a Written Directive for Diagnostic Imaging for Groups 2 and 3 Physician Authorized Users (Iodine-131 Administration Greater Than 30 microcuries)

Please add Dr. _____

to Radioactive Materials License Number _____

as a physician* who is authorized for the administration of Iodine-131, requiring a written directive. I certify that the above named physician has been performing uptake studies of Iodine-131, requiring a written directive, under this radioactive materials license:

RSO Print Name	RSO Signature	Date
Physician Print Name	Physician Signature	Date

*Complete for each Physician and return the form only (no other paperwork is necessary) to the Radiologic Health Branch at:

CDPH
Radiologic Health Branch
P.O. Box 997414, MS 7610
Sacramento, CA 95899-7414

Attachment 2

Request for Authorized Medical Physicist Listing on Radioactive Materials License

Please add _____

to Radioactive Materials License Number _____

as an Authorized Medical Physicist (AMP)*. I certify that the above named individual has sufficient training and experience, as well as appropriate educational credentials and is adequately qualified to perform the functions of an AMP for following devices(s) noted below:

- ☐ Strontium-90 Eye Applicator
- ☐ High Dose Rate Afterloader Units
- ☐ Gamma Strereotactic Radiosurgery Units (Gammaknife)
- ☐ Teletherapy Devices (Radioactive Material Only)

RSO Print Name	RSO Signature	Date
AMP Print Name	AMP Signature	Date

*Complete for each AMP and return the form only (no other paperwork is necessary) to the Radiologic Health Branch at:

CDPH
Radiologic Health Branch
P.O. Box 997414, MS 7610
Sacramento, CA 95899-7414

California Department of Public Health CDPH

Division of Food, Drug and Radiation Safety
Radiologic Health Branch

Information Notice (3)

To maintain compatibility with the US Nuclear Regulatory Commission (NRC) and other Agreement States that have adopted 10 CFR 35, the California Department of Public Health (CDPH) has adopted relevant sections of 10 CFR 35, as published January 1, 2008. The adoption of these regulations has been approved by the Office of Administrative Law, with an effective date of January 1, 2011. A copy of 10 CFR 35 (January 1, 2008), is available at: http://www.access.gpo.gov/nara/cfr/waisidx_08/10cfr35_08.html.

This Information Notice is the third in a series of Information Notices designed to inform licensees of changes which will occur as a result of the adoption of 10 CFR 35, and also how the Radiologic Health Branch (RHB) expects licensees to respond to the changes. Information Notices such as this will be posted on the RHB's Radioactive Materials Licensing webpage under "Hot Topics" at: http://www.cdph.ca.gov/certlic/radquip/Pages/RadioactiveMaterials.aspx

California Department of Public Health CDPH

Division of Food, Drug and Radiation Safety
Radiologic Health Branch

Information Notice (3)

The following information is provided to specifically call out changes and clarifications regarding the new regulations that licensees may find applicable to their operations and radiation safety programs.

- After January 1, 2011, physicians currently authorized for Groups 4 and 5 will have their authorization listed under the relevant section of 10 CFR 35 on the radioactive materials license. A Group 4 physician will be listed for 10 CFR 35.300, less than or equal to 33 millicuries of Iodine-131 (I-131) only, and a Group 5 physician will be listed for 10 CFR 35.300, greater than 33 millicuries of I-131 only. Please note that this change will be made automatically unless Attachment 1 is submitted before January 1, 2011, and the physician is grandfathered for the other authorizations under 10 CFR 35.300. After January 1, 2011, Attachment 1 cannot be used to submit an amendment request for physician authorizations under 10 CFR 35.300.
- In accordance with 10 CFR 35.60 (b), RHB will allow licensees to calibrate their dose calibrator in accordance with nationally recognized standards or the manufacturer's instructions, as alternatives to the procedures that were previously committed to in the license application. You may implement 10 CFR 35.60(b) without an amendment request.

Information Notice (3)

- In accordance with 10 CFR 35.63, a licensee must determine the activity of each dosage before medical use. The measurement of the activity for unit doses may be determined by the direct measurement of the activity or by decay correction. For other than unit doses, the determination of the activity must be made by direct measurement, by a combination of direct measurement of activity and mathematical calculations, or by a combination of volumetric measurements and mathematical calculations. Therefore, a dose calibrator may not be required by a licensee. Any of these methods for assaying doses will be acceptable to the RHB and may replace procedures previously committed to by the licensee. You may stop using a dose calibrator by implementing 10 CFR 35.63 without an amendment request.
- Note that the RHB has adopted a more restrictive standard regarding waste held for decay in storage than what is outlined in 10 CFR 35.92. In addition to complying with 10 CFR 35.92, licensees who are authorized for decay in storage of radioactive waste must still hold radioactive waste for at least ten half-lives prior to disposal, as is stated in the applicable Legally Binding Requirement listed on your license.
- *Errata:* Some sections of 10 CFR 35 were erroneously adopted. These sections are 10 CFR 35.24(a)(3) and 10 CFR 35.2026. Licensees will not be bound by these two cited provisions, and may disregard them.

California Department of Public Health

Division of Food, Drug and Radiation Safety
Radiologic Health Branch

Information Notice (3)

To help licensees transition to the new requirements, RHB will hold two free half-day informational workshops that are open to members of the general public. The Southern California workshop is scheduled for December 6, 2010, at the Irvine Marriott Hotel, 18000 Von Karman Avenue, Irvine, California at 9:00 am. The Northern California workshop is scheduled for December 9, 2010, at 1500 Capitol Avenue, Sacramento, California at 9:00 am. RHB will consider holding a second workshop at 1:00 pm, if needed, at both locations.

If you have any questions regarding this information notice and/or if you would like to reserve a space at the workshop, please contact me at Ira.Schneider@cdph.ca.gov or by telephone at (916) 440-7976.

California Department of Public Health (CDPH)

Division of Food, Drug and Radiation Safety
Radiologic Health Branch

Information Notice (3)

Radioactive Materials Licensees
Page 3

Attachment 1

Request for 10 CFR 35.300 Authorization

Please add *Dr. _____

to Radioactive Materials License Number _____ .

I attest that the physician has performed the following procedures under this radioactive materials license:

- ☐ Oral Administration of Iodine-131 Requiring a Written Directive Less Than or Equal to 33 millicuries
- ☐ Oral Administration of Iodine-131 Requiring a Written Directive Greater Than 33 millicuries
- ☐ Paraenteral Administration of Unsealed Radioactive Material Requiring a Written Directive
  List Radionuclide(s): _____
- ☐ Any Unsealed Radioactive Material Requiring a Written Directive

RSO Print Name	RSO Signature	Date
Physician Print Name	Physician Signature	Date

***After January 1, 2011 this form may no longer be used.**
*Complete for each Physician and return the form only (no other paperwork is necessary) to the RHB at:

California Department of Public Health
Radiologic Health Branch, MS 7610
P.O. Box 997414
Sacramento, CA 95899-7414

California Department of Public Health CDPH

Division of Food, Drug and Radiation Safety
Radiologic Health Branch

Information Notice (4)

To maintain compatibility with the US Nuclear Regulatory Commission (NRC) and other Agreement States that have adopted 10 CFR 35, the California Department of Public Health (CDPH) has adopted relevant sections of 10 CFR 35, as published January 1, 2008. The adoption of these regulations has been approved by the Office of Administrative Law, with an effective date of January 1, 2011. A copy of 10 CFR 35 (January 1, 2008), is available at: http://www.access.gpo.gov/nara/cfr/waisidx_08/10cfr35_08.html.

This information notice is the fourth in a series of information notices designed to inform licensees of changes which will occur as a result of the adoption of 10 CFR 35, and also how the Radiologic Health Branch (RHB) expects licensees to respond to the changes. Information notices such as this will be posted on the RHB's Radioactive Materials Licensing webpage at: http://www.cdph.ca.gov/certlic/radquip/Pages/RadioactiveMaterials.aspx

California Department of Public Health CDPH

Division of Food, Drug and Radiation Safety
Radiologic Health Branch

Information Notice (4)

The following information is provided to specifically call out regulatory changes and clarifications regarding the new regulations that licensees may find applicable to their operations and radiation safety programs.

- After January 1, 2011, physicians currently authorized for Group 6 will be listed on the radioactive materials license with authorization for manual brachytherapy as authorized under 10 CFR 35.400. In order to grandfather a Group 6 physician who is currently using a High Dose Rate Remote Afterloader unit or Yttrium-90 TheraSpheres and/or SIRSpheres, a Best Vascular, Inc. Beta-Cath Intravascular Brachytherapy System, a NeoVista, Inc. Epi-Rad Ophthalmic System, or other devices as authorized under 10 CFR 35.1000, the licensee must submit a request to specifically add the physician to the license for 10 CFR 35.600 and/or 10 CFR 35.1000, and specify the device for authorization. Please submit Attachment 1 to add a physician for authorizations under 10 CFR 35.600 and/or 35.1000. After January 1, 2011, Attachment 1 cannot be used to submit an amendment request to add a physician for authorizations under 10 CFR 35.600 and/or 35.1000. If a physician authorized user is authorized only for one of the above modalities, or is specifically listed for that use, then no amendment is required.

California Department of Public Health CDPH

Division of Food, Drug and Radiation Safety
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Information Notice (4)

Licensees may make the following minor radiation safety program changes without submitting an amendment request:

- Changes in the membership of the Radiation Safety Committee not involving the RSO or the Chairperson, as long as the selected individual will be providing similar representation as had the individual who is being replaced.
- Replacement of a diagnostic imaging camera if it will be installed in the same room as the previous camera and does not require a change in radioactive transmission sources.
- Replacement of radiation detection equipment if there is no change in the instrument type and function.
- Addition of the use of a full service mobile provider, as long as the provider does not use the licensee's facility, equipment or personnel.
- Changing the frequency of dosimetry exchange and evaluation as long as the maximum period is quarterly.
- Changing dosimetry providers as long as the new provider is NVLAP accredited.
- Change in the vendor who performs instrument calibrations as long as the vendor is licensed by the NRC, an Agreement State, or another Licensing State to perform the service.
- Change in the vendor who performs sealed source leak tests as long as the vendor is licensed by the NRC, an Agreement State, or another Licensing State to perform the service.

Information Notice (4)

- For clarification purposes, broad scope licensees may adopt the changes in these information notices, without RHB approval, as long as they are approved by the licensee's Radiation Safety Committee.
- In addition, Sections 30321 and 30321.1 of Title 17, California Code of Regulations will be repealed. These sections include, in part, the requirement that a hospital or clinic have a custodian of sealed sources. Since a custodian of sealed sources is no longer required by regulation, it will not be necessary to list a custodian of sealed sources on the license. However, since the RSO is responsible for the radiation safety program, the responsibility for sealed sources will reside with the RSO or the RSO's designee.

To help licensees transition to the new requirements, RHB will hold two free half-day informational workshops that are open to members of the general public. The Southern California workshop is scheduled for December 6, 2010, at the Irvine Marriott Hotel, 18000 Von Karman Avenue, Irvine, California at 9:00 am. The Northern California workshop is scheduled for December 9, 2010, at the California Department of Public Health building, 1500 Capitol Avenue, Sacramento, California at 9:00 am. If needed, RHB will consider holding a second workshop at 1:00 pm, at the Irvine location.


FIN