Radiologic Heath Branch and 10 CFR 35 Updates

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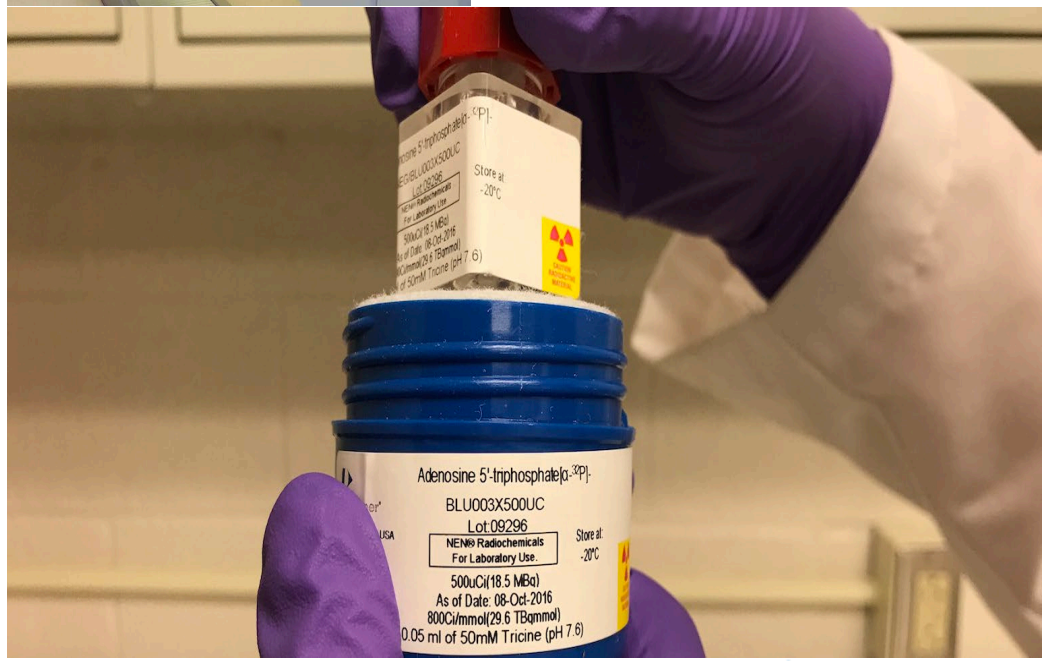
Introduction

Radiologic Health Branch (RHB) is within the Radiation Safety and Environmental Management Division of the State Department of Public Health. The Branch Enforces laws and Regulations addressing ionizing radiation, including radioactive materials, designed to protect the public, radiation workers, and the environment.



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Radioactive Materials Licensing

The Radiologic Health Branch (RHB) licenses users of radioactive material and registers persons possessing generally licensed devices (GLD) containing radioactive materials. Users of radioactive materials include:

- Universities and laboratories to conduct scientific research.
- Medical and veterinary hospitals and clinics to diagnose and treat human beings and animals.
- Nuclear pharmacies that manufacture and distribute radiopharmaceuticals.
- Blood banks to sterilize blood.
- Industrial Radiography, refineries, manufacturing industries, etc.
- Companies that provide services, such as sterilization of medical supplies, facility decontamination, and waste processing.

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RHB revised organization

RHB Chief Gonzalo Perez retired end of August.

Anthony Chu, Chief of Division of Radiation Safety and Environmental Management resumes interim responsibility.

Regarding RAM issues, please send email to
Ira Schneider, Supervising HP, Radioactive Materials Licensing.
Phone: (916) 440-7976
Email: ira.schneider@cdph.ca.gov

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RHB Reorganization

Certification section- Freida Taylor retired

- Rajiv Mishra, Ph.D. is the new Section Chief for the Certification Section
- Certifies physicians, technologists, chiropractors, podiatrists and permits technicians & physician assistants (PA) who use X-ray machines, certifies/permits NMTs to use/administer radiopharmaceuticals for diagnostic and therapeutic use
- Phone: (916) 440-7902

  Email: rajiv.Mishra@cdph.ca.gov

Registration, Regulation and Quality Assurance section

- Merged three units ant created the Registration, Regulation and Quality Assurance section.
- Phillip Scott is the new Supervising Health Physicist

  Phone: (916) 440-7978

  Email: phillip.scott@cdph.ca.gov

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Removal of Irradiators

California RAM users had about 150 Cat I and Cat II irradiators awaiting disposal. As part of the National Orphan Source Removal Program, more than half of these have been removed and recorded since Sep 2018. Following information required to request an amendment to RHB:

- Last leak test reports
- Dated and signed Transfer receipts of both parties, transferring and receiving
- All documents must include source and device information

Note: isotope, source and device make & model, SN must match with the source and device removing from the license

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Medical Use of Radioactive Material- 10 CFR 35 Updates

The Nuclear Regulatory Commission (NRC) revised regulations regarding medical use of byproduct Material in 2021 version. Major Changes include:

- Reporting requirement of some Medical Events Involving Brachytherapy
- Updated Training and Experience for Individuals involved in licensed activities. e.g. No preceptor attestation needed if AU, AMP, ANP, RSO applicants are specialty board certified
- Residency program directors can attest an AU
- Added Ophthalmic Physicist for Strontium-90 activity calculation
- Added Naming Associate Radiation Safety Officer (ARSO) with specific duties
- Added flexibility regarding diagnostic and therapeutic sealed sources and devices for medical uses

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35.2 and 35.24 Associate Radiation Safety Officer 10 CFR

Associate RSO as per 10 CFR 35.2 and 35.24

- Added naming ARSO option. An ARSO must meet the same RSO training requirements under 35.50 and 35.59. The Management shall appoint ARSO in writing.
- The RSO must assign in writing the ARSO to specific duties and tasks with written agreement with management, but must not delegate authority or responsibility for implementing the radiation protection program.
- In the documented absence of the RSO, management designates the ARSO as a temporary RSO for up to 60 days each year. A licensee may simultaneously appoint more than one temporary RSO.
- Added ARSO's appointment record shall be maintained for 5 years after the ARSO is removed from the license.

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10 CFR 35.433 Ophthalmic Physicist

10 CFR 35.433

- Added naming an Ophthalmic physicist on the license option to perform certain tasks, described under section 10 CFR 35.433, that he/she can be assigned to. e.g. calculate activity of Sr-90 source to determine treatment time, review treatment methodology
- Added the training requirement for an ophthalmic physicist
- Clarified expected duties of AMP and ophthalmic physicist for Strontium-90 sources used for ophthalmic treatments.
- Type A broad scope licensees are exempt from the requirement to identify an OP on the license, but will list on the permit

10 CFR 35.40 Written Directive For Permanent Implant Brachytherapy

Added clarification of permanent implant brachytherapy written directive (WD) components:

- Before the implantation, WD must include patient or research human's name treatment site, radionuclide and total source strength.
- After the implantation but before the patient leaves the post treatment recovery area, the WD must include date, treatment site, total source strength and number of sources implanted. Eliminated dose or radionuclide.

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10 CFR 35.41 Procedures for Administrations requiring written directive

For any administration requiring Written Directive, licensee shall develop procedures to

- Verify patient's or human research subject's identity before administration and verify the administration is with the treatment plan (No change)
- Check both manual and computer generated dose calculations, and transferred correctly to the console therapeutic units (No change)
- Added Licensees must have procedures to determine if a medical event occurred.
- Added for Permanent implant brachytherapy- licensees must have procedures to determine within 6o days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post implantation potion of the written directive.

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10 CFR 35.3045 Medical Events Reporting Permanent Implant Brachytherapy Notification

Differentiated Reporting Requirement Criteria for Permanent Brachytherapy (No change for Intervention or other administration of byproduct material or radiation from byproduct material): Excluded for permanent implants/seeds that were implanted in the correct site but migrated outside the treatment site:

- A criterion involving total source strength administered differing by 20% or more from the total source strength documented in the post-implantation WD.
- A criterion for when the total source strength implanted outside the treatment site exceeding 20 percent of the total source strength documented in the post-implant portion of the WD.
- An administration that includes Wrong patient or human research person, Wrong radionuclide, and when the administration is directly to a discontiguous site than the treatment site.
- Included a threshold of 50 rem to the organ or tissue from a leaking source
- Continued reporting requirement for an intervention to a patient or research human resulting an unintentional organ or physiological system damage. Unchanged

10 CFR 35.50, 35.51,35.55 Training and Experience (T&E) Requirements For RSO, AMP, ANP

- Changes Applies to 35.50, 35.51, 35.55
- No preceptor attestation required if Specialty Board certified, for RSO/ARSO, AMP, ANP

10 CFR 35.190, 35. 290, 35.390, 35.490, 35.690 Training and Experience (T&E) Requirements For Authorized User (AU)

Currently

- Specialty Boards using process recognized by NRC + Written attestation signed by preceptor with same authorization
- Training & Experience pathway + written attestation signed by preceptor with same authorization
- Approved if listed on Existing NRC or Agreement State License

Changes

Applies to 35.190, 35. 290, 35.390, 35.490, 35.690:

- Eliminates the attestation requirement for individuals if certified by Specialty Boards
- Residency Program Directors may now provide attestation
- 35.290 allows ANP to provide supervised work experience for 35.200 AU

35.390(b)(1)(ii)(G) Training for use of unsealed byproduct material for which a written directive is required.

- Oral administration of less than or equal to 1.22 gigabecquerel (33 mCi) of sodium iodide I-131, for which a written directive is required. (35.390 (b1)(ii)(G)(1). No change
- Oral administration of greater than 1.22 gigabecquerel (33 mCi) of sodium iodide I-131(35.390(b1) ii G(2). No change
- Revised training requirement for parental administration of any radioactive drug that contains a radionuclide that is used for its electron emission, beta radiation characteristics, alpha radiation characteristics or photon energy of less than 150 kev for which written directive is required (35.390 (b1)(ii)(G)(3)
- Deleted parental administration of any other radionuclide, for which a written directive is required (35.390 (b1)(ii)(G)(4)

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35.390 G Training for use of unsealed byproduct material for which a written directive is required.

- Added that radioactive drugs containing radionuclides in categories not included in the prior slide are regulated under section 35.1000.
- For example, Y-90

35.400 Use of sources for manual brachytherapy Upgrades

35.400 Current

- A licensee shall use only brachytherapy sources for therapeutic medical uses as approved in the Sealed Source and Device Registry (SSDR)

35.400 Changes (clarified)

- A licensee must use only brachytherapy sources:
- Approved in the SSDR for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not listed in the SSDR, but must be used in accordance with the radiation safety conditions and limitations described in the SSDR; or
- In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of § 35.49(a) are met.

10 CFR 35.500 and 35.590 Training for use of Sealed Sources and Medical Devices for Diagnosis

- 35.500 (a) Differentiated between use requirements for sources, and devices containing sources. A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the SSDR for diagnostic medicine. e.g. Transmission source.
- ADDED 35.590 (b) Authorization of an AU listed for medical use under 35.200, also as an AU for diagnostic sealed sources and medical devices authorized under 35.500.

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35.433 Strontium-90 for Opthalmic Treatment And Decay Calculation

Current 35.433(a): Strontium -90 Use

- (a), Only an Authorized Medical Physicist (AMP) shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under section 35.432.
- (b), A licensee shall retain a record of the activity of each strontium-90 source in accordance with section 35.2433.

Change: 35.433(a) Strontium-90 Use

- Added Ophthalmic Physicist (OP), and training requirement of OP
- (a) Licensees who use strontium-90 for ophthalmic treatments must ensure certain activities as specified in paragraph (b) of this section is either performed by authorized medical physicist or an Ophthalmic Physicist.
- -Included training & experience requirement for Ophthalmic Physicist
- (b) Authorizes an AMP or an OP to calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under section 35.432.
- (c)Record maintenance of the activity of each Sr-90 SS regarding decay remains unchanged.

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10 CFR 35.400, 35.500, 35.600 and 35.615 Updates

- 35.400 Added clarification that the use of brachytherapy sealed sources must be approved in the SSDR for manual brachytherapy medical use. It may be used for manual brachytherapy uses that are not explicitly listed in the SSDR, but Requires the use to be in accordance with radiation safety conditions and limitations in SSDR. - Licensee now has more flexibility
- 35.500 Added the requirement that both the sealed source contained in a medical device for diagnostic medical use and the medical device containing sealed sources must be approved in the SSDR for diagnostic medical uses.
- The specific diagnostic medical uses may not be explicitly listed in the SSDR, but must be in accordance with the radiation safety and limitations in the SSDR.

- Licensee now has more flexibility

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10 CFR 35.400, 35.500 and 35.600 Updates Contd, and Update on 10 CFR 35.590 Training for use of SS & Medical Devices for Diagnosis

Changed 10 CFR 35.600

- Licensees must only use sealed sources approved and provided for in the SSDR, in photon emitting remote afterloader unit, teletherapy unit or GSR unit to deliver therapeutic doses for medical uses.
- However, these devices may be used for therapeutic medical treatments that are not explicitly provided for in the SSDR, but must be used in accordance with radiation safety conditions and limitations described in the SSDR.

10 CFR 35.615 and 35.690 Safety Procedures and instruction for Remote afterloader units Teletherapy Units and GSR Units

- Added Requires Vendor training of 10 CFR 35.600 medical use devices when there are upgrades that affect the operation and safety of the unit

-Verify that operational and safety training was provided by device manufacturing or by individual certified by manufacturer before the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affected the operation and safety of the unit.

- Vendor training must be by the vendor or someone certified by the manufacturer
- All operational training and safety training is for all individuals including AUs, AMPs, operators and others that need to know how the new unit operates and how the upgrades affect safety and operations.
- Added that a Residency Program Director can attest affirming that a faculty AU meeting same type of therapeutic requirements is consensus with.

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10 CFR 35.1000- Subpart K

Other /medical Uses of Byproduct Material or Radiation From Byproduct Material

- Use of byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H
- Licensee has to submit application with information required by 35.12(b) through (d) and receive approval in a license or license amendment

NRC Guidance followed

- Regulations and specific conditions are in accordance with the NRC guidance developed specific to the new technology
- Examples: Yttrium-90 (Y-90) microspheres, Leksell Gamma Knife Icon Gamma Stereotactic Radiosurgery (GSR), Glia site beta cath, etc.

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Y-90 Microsphere AU Training Requirement

Y-90 Microsphere Brachytherapy Sources and Devices (Therasphere and SIR-Spheres) Licensing Guidance Rev 10

Though manual brachytherapy sources, microspheres have unique properties:

- small size
- the large number of microspheres used in a treatment,
- the route of administration

Training Requirement

Outlined in the NRC Guidance at:

https://scp.nrc.gov/asletters/tech/sp21020.pdf Rev. 10.2

- Includes 3 in-vitro simulated cases by manufacturer
- Must complete 3 in-vivo cases as well to become independent AU.
- NOTE: RHB adds AU conditionally for one year to complete 3 hands on clinical cases for each type

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Useful Websites

- NRC Specialty Board

  https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html

- 10 CFR 35

  https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/index.html

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Radiologic Health Branch Website

- Radiologic Health Branch
  https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/RHB.aspx

  RHBGLLicensingInfo@cdph.ca.gov

- Contact Email: RHBGLLicensingInfo@cdph.ca.gov

- 24 hrs. Emergency Response 1-800-852-7550

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Questions

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