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Information Notice

November 3, 2010

To: Radioactive Materials Licensees

Subject: Adoption of Title 10, Code of Federal Regulations, Part 35 (10 CFR 35)

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>

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.
- 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.

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.

Sincerely,

Original Signed By Ira Schneider

Ira Schneider
Senior Health Physicist
Radiologic Health Branch

