Arkansas Department of Health

4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000
Governor Mike Beebe
Nathaniel Smith, MD, MPH, Director and State Health Officer

ARKANSAS INFORMATION NOTICE 13-07

To: Medical Use Radioactive Material Licensees

From: Bernard Bevill, Section Chief
Radiation Control Section

Date: November 19, 2013

Subject: Procedures for administrations requiring a written directive, misadministration criteria, and notification/reporting requirements

This Information Notice (IN) is to remind those licensed for the use of radionuclides in the healing arts of requirements pertaining to administrations requiring a written directive, misadministration criteria, and the notification/reporting of misadministrations.

RH-8308.a. of the Arkansas State Board of Health Rules and Regulations for Control of Sources of Ionizing Radiation states that written procedures must be developed, implemented, and maintained in order to provide high confidence that the patient's or human research subject's identity is verified before each administration and that each administration is in accordance with the written directive. (The contents of a written directive are detailed in RH-8307.) These procedures are submitted for Department approval as part of a new or renewal license application or as an amendment request to add to a license administrations requiring a written directive. Procedures developed pursuant to RH-8308.a. must periodically be reviewed and updated, as needed, by the licensee.

RH-8308.b. states the following:

The procedures required by RH-8308.a. must, at a minimum, address the following items that are applicable for the licensee's use of radioactive material:

1. *Verifying the identity of the patient or human research subject;*
2. *Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;*
3. *Checking both manual and computer-generated dose calculations; and*
4. *Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by RH-8630 or RH-8670.*

A licensee may revise its radiation protection program without Department approval if the requirements in RH-8301 are met, one being that the revision does not require an amendment under RH-8011. Revisions to procedures developed pursuant to RH-8308.a. would require an amendment under RH-8011 if the revision consists of something other than a minor change. Please contact the Department when unsure if a certain revision would constitute a minor change. Appendix P, "Radiation Safety Program and Operating Procedures," of the Licensing Guide for the Use of Radioactive Material in the Healing Arts provides guidance regarding the development/maintaining of procedures that meet the requirements of RH-8307 and RH-8308. Appendix P is available at the following link to the Arkansas Department of Health website: http://www.healthy.arkansas.gov/programsServices/hsLicensingRegulation/RadiationControl/radioactiveMaterials/Pages/Medical.aspx.

Operating procedures, a copy of the Regulations, the radioactive material license itself, and conditions or documents incorporated into the license by reference and amendments thereto must be made available to workers in accordance with RH-2802.

As required by RH-8308, a determination will be made as to whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the treatment plan, if applicable, and the written directive. When deviations from the written directive are found, the cause of each deviation and the action required to prevent recurrence should be identified.

A misadministration is an event that meets the criteria found in RH-8800.a. or b. The term "misadministration" is not exclusive to "therapeutic administrations" or to those administrations requiring a written directive. All administrations of radioactive material or radiation from radioactive material are to be considered.

The licensee must notify the Department by telephone no later than the next calendar day after discovery of a misadministration and must submit a written report to the Department within 15 days after the discovery of a misadministration. RH-8800 contains other misadministration notification and reporting requirements that must be met as well.

Further information for licensees authorized for permanent implant brachytherapy can be found in the Nuclear Regulatory Commission's Regulatory Issue Summary 2013-10, "Permanent Implant Brachytherapy Medical Event Reporting Under 10 CFR Part 35." RIS 2013-10 is available at http://pbadupws.nrc.gov/docs/ML1315/ML13156A195.html.

Please share the information contained in this IN with all individuals involved in the above activities.

This IN requires no specific action or written response. If you have any questions regarding this notice, please contact Jared Thompson, Radioactive Materials Program Manager, at (501) 661-2173.