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Department of Health Services

INFORMATION NOTICE

TO: Department of Health Services
Radioactive Material Medical Use, Broadscope and Nuclear Pharmacy Licensees

FROM: Department of Health Services
Radioactive Materials Program

DATE: April 2, 2008

SUBJECT: Information notice concerning medical events caused by failure to properly perform tests on dose calibrators for beta- and low energy photon-emitting radionuclides

PURPOSE:

The Wisconsin Department of Health Services is reissuing a Nuclear Regulatory Commission information notice (IN 2002-19) to inform licensees of incidents involving mismeasurement of dosages for radiopharmaceutical therapies. It is expected that recipients will review this information for applicability to their licensed activities and consider actions, as appropriate, to avoid similar problems. Suggestions contained in this Information Notice are not new DHS requirements; therefore, no specific action or written response is required.

DESCRIPTION OF CIRCUMSTANCES

In 2002, the Nuclear Regulatory Commission issued Information Notice 2002-19 (enclosed) after they became aware of 61 misadministrations caused by inaccurate measurement of samarium-153 unit dosages at a commercial nuclear pharmacy.

DHS was recently notified of eight medical events at one facility in which patients being treated with samarium-153 received doses approximately 30% less than required by the written directive. The licensee's dose calibrator was calibrated to measure the activity of samarium-153 in a glass vial; however, nuclear medicine technologists likely measured the activity of samarium-153 in a plastic syringe.

DISCUSSION

On March 6, 2008, a DHS-licensed medical facility reported that from August 2006 through October 2007, up to eight dosages of samarium-153 with approximately 30% less activity than prescribed may have been administered to patients. The error was discovered on February 28, 2008 when a nuclear medicine technologist questioned why a plastic syringe known to contain 100 mCi of samarium-153 read 130 millicuries in the dose

calibrator. Subsequently, the licensee determined that its dose calibrator was calibrated to measure the activity of samarium-153 in a 10 cc glass vial, not in a plastic syringe.

The licensee's dose calibrator had been calibrated in accordance with the manufacturer's recommendations. The nuclear medicine technologists were not aware that the calibration standard was only valid for calibrations in a glass vial. They were not aware that a correction factor was needed to account for attenuation of the beta radiation and geometrical differences when using a plastic syringe.

The licensee had written procedures for how to perform administrations involving samarium-153; however, the procedures did not indicate that the dose activity for samarium-153 must be measured in a glass vial.

This Information Notice requires no specific action or written response. Be reminded that medical events must be reported to DHS by telephone or facsimile no later than the next calendar day after discovery. If you have any questions about the information in this notice, please contact Mark Paulson at (608) 264-6516 or email at Mark.Paulson@wi.gov or Megan Shober at (608) 287-4422 or email at Megan.Shober@wi.gov.