Radioactive Materials Unit
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Date: April 1, 2008

To: Medical Licensees

From: Radioactive Materials Unit

Subject: Revised Requirements for Sentinel Lymph Node Removal

Information Notice 2008-03

The Minnesota Department of Health is revising its requirements for the sentinel lymph node protocol to eliminate the need for surveys after surgical removal.

In the March 2006, issue of the Nuclear Material Safety and Safeguards (NMSS) newsletter, the US Nuclear Regulatory Commission (NRC) published an article on the licensing requirements for various aspects of the Sentinel Lymph Node Biopsy. The article summarized the NRC's policy for the administration of the radioactive material, the licensing requirements associated with the removal of the lymph node, and the requirements associated with the biopsy.

The injection of Technetium-99^{m} near the tumor, which is typically done several hours before the actual biopsy must be completed by a facility licensed by the NRC or an Agreement State (e.g., a hospital, clinic, or nuclear medical van that has a radioactive materials license to administer the radioactive dosage).

In surgical suites a Geiger counter is used to assess which lymph nodes have taken up the radionuclide prior to surgical removal. Studies proved that the sentinel lymph node was well below the exempt limit for Technetium-99^{m}. However, because some surgical waste, which included the "bio-mass" (a cluster of two or three nodes closest to the sentinel node), was above the exempt limit, the NRC required the surgery to take place only at a licensed facility.

In accordance with Minnesota Department of Health *Radioactive Materials Rules*, 4731.2200, all licensees were required to conduct sufficient surveys to evaluate the magnitude and extent of radiation levels; concentrations or quantities of radioactive material; and potential radiological hazards. Licensees were authorized to discontinue post surgery surveys when sufficient documentation was obtained to demonstrate that there was no radiological hazard.

To avoid the impact of health care in Minnesota, MDH also authorized surgical removal at non-licensed facilities provided surveys were conducted after all procedures involving the sentinel lymph node removal.

Regardless of whether the removal occurred in a licensed or non-licensed facility, MDH considered the licensee's responsibility concluded after the surgical waste is properly packaged as bio-hazardous waste. In addition, the subsequent examination by a pathologist to identify the presence of cancer was never considered a radiological issue.

The Advisory Committee on the Medical Use of Isotopes (ACMUI) has recommended that the surgical removal of the sentinel lymph node be considered an independent procedure. MDH is in agreement with the recommendation of the ACMUI. As such, the surgical procedure will no longer be regulated. **This Information Notice removes all licensees of the responsibility to conduct surveys of surgical suites after the sentinel lymph node removal.**