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Date: March 5, 2007

To: Nuclear Medical Van (Mobile Medical Service) Licensees

From: Radioactive Materials Unit

Subject: Sentinel Lymph Node Biopsy

Information Notice 2007-01

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 Minnesota Department of Health (MDH) has received several letters concerning the Sentinel Lymph Node Biopsies. MDH agrees that the procedure is within the scope of imaging and localization studies using unsealed radioactive material as authorized by Chapter 4731.4434. In addition, MDH agrees normally that a nuclear medical van (mobile medical service) is authorized to conduct such studies.

As indicated in the NMSS newsletter, the Sentinel Lymph Node Biopsy consists of three parts:

- The injection of Technetium-99^{m} near the tumor. Typically, this is done several hours before the actual biopsy.
- Use of a Geiger counter to assess which lymph nodes have taken up the radionuclide and surgical removal of the appropriate lymph node(s).
- Examination by a pathologist to identify the presence of cancer.

There is no dispute that the initial step 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). Locating and removing the sentinel lymph node is an integral part of the imaging and localization

procedure authorized by 4731.4434. As such, the licensee authorized to administer the radioactive material is also responsible for the removal portion of the procedure.

Studies have proven that the sentinel lymph node is well below the exempt limit for Technetium-99^{m}. However, the surgical waste, which includes the "bio-mass" (a cluster of two or three nodes closest to the sentinel node), can be above the exempt limit. Nevertheless, MDH will consider the licensee's responsibility concluded after the surgical waste is properly packaged as bio-hazardous waste.

In summary, a licensed facility (including a mobile medical van service) can administer the radiopharmaceutical for the Sentinel Lymph Node Biopsy provided the licensee assumes responsibility through the removal process. That responsibility includes surveys to ensure that the surgical suite can be released for unrestricted use.

Questions and Answers

The following is a summary of the questions concerning Sentinel Lymph Node Biopsy with MDH's responses:

Question: If a licensee administers Technetium-99^{m} and completes a study, the patient is released without any restrictions. Why would it be an issue if the patient undergoes a procedure after being released?

Answer: By design, the identification and surgical removal of the sentinel lymph node is an integral part of the localization procedure. As such, the two steps in the procedure cannot become disassociated.

Question: If a patient is administered a radiopharmaceutical, released, and suddenly develops a condition that requires emergency surgery, MDH has no restrictions. What is the difference?

Answer: Rules are written to address "normal" circumstances. MDH cannot generate rules to address emergency procedures such as surgery required to save a life.

Question: Studies have shown that the doses to the surgical staff are low. Why wouldn't MDH exempt the procedure from licensing?

Answer: MDH agrees that the doses to the surgical staff are relatively low; however, in addition to conflicting with NRC guidance, facilities without authorization to use radioactive material may not have sufficient expertise to address the radiological consequences of an unanticipated situation. There is no assurance that surgical staff will be sufficiently trained in radiation safety or have a resource available to address concerns.

Question: If the surgical waste is above exempt limits for $Tc\text{-}99^{m}$, why would MDH consider the licensee's responsibility concluded after the surgical waste is properly packaged as bio-hazardous waste?

Answer: Although studies have shown that as much as 22 percent of the administered activity can be found in the surgical swabs and that the tissues surrounding the sentinel lymph node can be above the exempt limit, MDH considered three factors in establishing the policy:

- The activity of the waste (swabs, bio-mass, etc.) is typically between 150 µCi and 200 µCi;
- The half-life of $Tc\text{-}99^{m}$ is six hours, which means that the activity will be below the exempt limit within six hours after surgery; and
- If properly packaged as bio-hazardous waste, MDH has no significant concerns regarding the radiation levels or the spread of contamination.