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U.S. Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
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DIVISION OF NUCLEAR MATERIALS SAFETY

March 22, 2006

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Subject: Request for Additional Information regarding sentinel node biopsies
License No. 25-27721-01; Docket No. 030-35944, Control No. 470901

The NRC has reviewed your request dated March 1, 2006, to include the facility at Central Montana Surgical Hospital on your license to perform the surgery for Sentinel Lymph Node Biopsy (SLNB). The NRC has evaluated non-licensed facilities to perform surgical procedures associated with SLNB. In its evaluation, the NRC determined that the Tc-99m used for the localization and surgical removal of radioactive tissue is not exempt from the requirements of having a byproduct material license authorizing 10 CFR 35.200 medical uses. Therefore, if the surgery is to be performed at a satellite location, the following set of specific set of conditions need to be satisfied.

1. The licensee must meet the general licensing requirements of 10 CFR 30.33 for the satellite site. To accomplish this, the licensee should describe its radiation safety oversight of the remote site and the day-to-day operating radiation safety program at the satellite site.

   This requirement is satisfied in your statement that the same radiation safety procedures will be implemented at the satellite location, as implemented at your licensed facility.

2. The licensee should provide a description of the satellite facility that includes a facility diagram showing areas where radioactive materials will be used and stored.

   You provided a drawing of the operating rooms; however, please clarify if radioactive materials will be stored at the satellite facility and provide a diagram of those areas.

3. The license should identify and delineate the responsibilities of key individuals responsible for radiation safety oversight at the satellite facility. The surgical aspects of the SLNB procedure are considered medical use of byproduct material and should be performed only under the supervision of the licensee's radiation safety program and under the supervision of the licensee's authorized user. The surgical aspect of the SLNB procedure is considered to be a localization as authorized under the provisions of 10 CFR 35.200, "Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required."

   Please provide this information.

4. The licensee should provide a description of those aspects of the licensee's radiation safety program that will be implemented at the satellite site. Examples of these radiation safety program components include commitments to provide radiation safety training to individuals at the satellite site commensurate with their duties, description of training provided to the surgeon and the individual responsible for day-to-day radiation safety at the remote site, a description of the instrumentation available for radiation safety, and a description of equipment and procedures to minimize contamination, release waste, and the methods to ensure tissue samples sent to the pathology laboratory contain 100 microcuries or less of Tc-99m.

   It is noted in 10 CFR 30.18 that any person is exempt from the requirements for a license to the extent that such person receives, possesses, uses , transfers, owns or acquires certain quantities of byproduct material. This regulation authorizes the transfer of the excised tissue from the SNLB procedure to the pathology laboratory for examination only if the tissue contains 100 microcuries or less of Tc-99m. If the SLNB pathology tissue samples contain more than 100 microcuries, they can only be transferred to another licensee. In such a case, the licensed pathology laboratory must be authorized to receive the radioactive tissue samples. The remote site would be required to ship the radioactive material in accordance with Department of Transportation (DOT) requirements and verify that the recipient (licensed pathology laboratory) is authorized by a license to receive the material.

   Please provide this information, including a statement that if the excised tissue exceeds 100 microcuries, then you will transfer the tissue in accordance with DOT requirements to a licensed pathology lab.

5. Additionally, please provide the relationship of Central Montana Surgical Hospital to Great Falls Clinic and if you have a letter signed by the management that permits the use of byproduct material at the surgical hospital and clearly delineates the authority and responsibility of Great Falls Clinic (licensee) and Central Montana Surgical Hospital (client).

When responding to this fax, please include the license, docket and control numbers, above. If there are any questions, please do not hesitate to call. Thank you for your cooperation.