

UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
OFFICE OF FEDERAL AND STATE MATERIALS AND  
ENVIRONMENTAL MANAGEMENT PROGRAMS  
WASHINGTON, D.C. 20555

December 01, 2008

**NRC REGULATORY ISSUE SUMMARY 2008-31  
LICENSING REQUIREMENTS FOR  
SENTINEL LYMPH NODE BIOPSY**

**ADDRESSEES**

All U.S. Nuclear Regulatory Commission (NRC) medical use licensees and NRC master material licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.

**INTENT**

The NRC is issuing this regulatory issue summary (RIS) to inform all licensees who perform sentinel lymph node (SLN) biopsy procedures that if the excised tissue does not contain more than 100 microcuries (microCi) (3.7 megabecquerels) of technetium-99m (Tc-99m), the surgical removal of lymph nodes does not require an NRC byproduct material license. No specific action or written response is required. The NRC is providing this RIS to Agreement States for their information and for distribution to their medical licensees, as appropriate.

**BACKGROUND INFORMATION**

An SLN biopsy is a diagnostic procedure used to identify the first lymph node(s) to which cancer is likely to spread from the primary tumor. The procedure consists of an injection of less than 1 millicurie (mCi) (37 megabecquerels) of Tc-99m in the tumor region, often followed by diagnostic nuclear medicine imaging of the lymphatic system. Depending on the protocol followed, the patient is instructed to return later that same day or the next day for surgery. In some cases, patients may go to facilities other than the licensed facility that performed the administration of the radionuclide and the imaging for the surgery. A hand-held radiation survey instrument with a probe capable of detecting gamma rays is used in surgery to detect the Tc-99m and locate the SLN for surgical removal. The excised tissue is then analyzed for pathological determination of potentially cancerous lymph nodes.

**SUMMARY OF ISSUE**

The NRC's current policy is being revised such that the surgical removal of lymph nodes may be performed without a NRC or Agreement State license, provided that the excised tissue does not contain more than 100 microCi (3.7 megabecquerels) of Tc-99m.

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The NRC's regulations applicable to the use of byproduct material for SLN biopsy procedures may be found in 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," and 10 CFR Part 35, "Medical Use of Byproduct Material." In the case of SLN biopsy procedures, the administered Tc-99m is regulated under 10 CFR 35.200, "Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required." After administration of the Tc-99m, the provisions of 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material," allow licensees to release from their control any individual who has been administered unsealed byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). In general, patients administered Tc-99m are releasable pursuant to 10 CFR 35.75. The regulations in 10 CFR Part 35, however, are not explicit as to whether subsequent activities involving the administered byproduct material shall be regulated following release of the patient (e.g., surgical removal of radioactive tissue or pathology study of radioactive tissue). In an Office of Nuclear Material Safety and Safeguards (NMSS) Quarterly Newsletter dated March 2006, the NRC summarized the licensing issues with SLN biopsy procedures as follows: (1) The injection of the Tc-99m (the first portion of the procedure) must be performed under an NRC medical use license; (2) the surgical removal of the radioactive tissue (the second portion of the procedure) must also be performed under an NRC medical use license; and (3) the pathology study of the radioactive tissue (the third portion of the procedure) may or may not have to be performed under an NRC license, depending upon whether the tissue contains an exempt quantity of Tc-99m and is thus exempt from licensing. 10 CFR 30.18, "Exempt quantities," allows an exemption from the requirements for a license if the quantity limits set forth in 10 CFR 30.71, "Schedule B," are not exceeded. The exempt quantity in Schedule B for Tc-99m is 100 microCi (3.7 megabecquerels).

Following the publication of the NMSS Quarterly Newsletter article, the NRC received several inquiries from surgical facilities that only perform the surgical excisions. In addition, stakeholders have expressed opposition to licensing these surgical facilities, citing the significant medical benefits provided by SLN biopsy procedures combined with the fact that the type of byproduct material used in the procedure is very low risk and that the dosage initially administered is very small compared to most nuclear medicine diagnostic procedures. As noted by stakeholders, the radiation risk in handling the excised radioactive tissue is minimized further by the fact that only a fraction of the Tc-99m localizes in the excised lymph node(s) and that the activity of the Tc-99m is reduced by radioactive decay by the time of the surgery (Tc-99m half-life is 6 hours). On June 13, 2007, the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) provided input on this issue and recommended by a unanimous vote that the NRC consider the surgical removal of an SLN a separate procedure from the administration of the radionuclide in order to exempt the surgical facilities from the requirements for a license.

The NRC's regulations do not specifically address whether the surgical excision is a licensed activity. NRC staff have, therefore, considered the issues raised by the ACMUI and stakeholders in the context of the NRC's risk-informed approach to regulating byproduct material.

It is the NRC's position that the rationale provided by ACMUI and stakeholders provides a basis

for re-evaluating the policy. NRC determined that facilities can be allowed to conduct the localization and surgical removal portion of the SLN biopsy without a license, provided that the excised tissue does not contain more than the exempt quantity limits set forth in 30.71, Schedule B, which is 100 microCi (3.7 megabecquerels) for Tc-99m. Under the definition of "Medical use" in 10 CFR 35.2, the surgeon's excision of the tissue does not amount to a "medical use" since the surgeon is not administering the byproduct material.

With regard to the pathology of excised SLN tissue, the NRC's position continues to be that excised SLN tissue may be transferred to a non-licensed facility for pathology analysis as long as the tissue does not contain more than 100 microCi (3.7 megabecquerels) of Tc-99m, which is based on the exemption criteria in 10 CFR 30.18. NRC recognizes that the surgical facility may not possess the necessary equipment to measure the activity in the tissue sample and therefore may rely on data provided by the administering institution.

### **BACKFIT DISCUSSION**

This RIS requires no action or written response. Any action on the part of addressees in accordance with the guidance contained in this RIS is strictly voluntary and, therefore, is not a backfit under any regulatory requirement in 10 CFR. Consequently, the staff did not perform a backfit analysis.

### **FEDERAL REGISTER NOTIFICATION**

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because this RIS is informational and does not represent a change from current regulatory requirements.

### **CONGRESSIONAL REVIEW ACT**

This RIS is not a rule as designated by the Congressional Review Act (5 U.S.C §§ 801-808) and, therefore, is not subject to the Act.

### **PAPERWORK REDUCTION ACT STATEMENT**

This RIS does not contain any information collections and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C 3501 et seq.).

**CONTACT**

This RIS requires no specific action or written response. Please direct any questions to the technical contact listed below or to the appropriate regional office.

***/RA/***

Robert J. Lewis, Director  
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Enclosure: List of Recently Issued Office  
of Federal and State Materials  
and Environmental Management  
Programs (FSME) Generic  
Communications

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<b>List of Recently Issued Office of Federal and State Material and Environmental Management Programs Generic Communications</b>			
<b>Date</b>	<b>GC No.</b>	<b>Subject</b>	<b>Addressees</b>
03/24/08	RIS-2008-09	Notice of Revision to Criteria for Nominating Materials Licensees for Discussion at the Agency Action Review Meeting	All U.S. Nuclear Regulatory Commission (NRC) materials licensees, master material licensees, Agreement State Radiation Control Program Directors, and State Liaison Officers
05/09/08	RIS-2008-12	Considerations for Extended Interim Storage of Low-level Radioactive Waste by Fuel Cycle and Materials Licensees	All holders of U.S. Nuclear Regulatory Commission (NRC) fuel cycle and materials licenses. All Radiation Control Program Directors and State Liaison Officers
05/12/08	RIS-2008-11	Precautions to Protect Children Who May Come in Contact with Patients Released After Therapeutic Administration of Iodine-131	All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees, master material licensees, Agreement State Radiation Control Program Directors, and State Liaison Officers
05/13/08	RIS-2008-10	Notice Regarding Forthcoming Federal Firearms Background Checks	All U.S. Nuclear Regulatory Commission licensees, certificate holders, and applicants for a license or certificate of compliance who use armed security personnel as part of their physical protection system and security organization. All Radiation Control Program Directors and State Liaison Officers.
05/16/08	IN-2008-03	Precautions to Take Before Sharing Sensitive Security-Related Information	All U.S. Nuclear Regulatory Commission (NRC) licensees who are implementing U.S. Nuclear Regulatory Commission's Order Imposing Increased Controls (IC Order) or implementing IC requirements by license condition; all Agreement State Radiation Control Program Directors and State Liaison Officers
06/16/08	RIS-2008-13	Status and Plans for Implementation of NRC Regulatory Authority for Certain Naturally Occurring and Accelerator-Produced Radioactive Material	All U.S. Nuclear Regulatory Commission (NRC) materials licensees, Radiation Control Program Directors, State Liaison Officers, and the NRC's Advisory Committee on the Medical Uses of Isotopes
<p>Note: This list contains the six most recently issued generic communications, issued by the Office of Federal and State Materials and Environmental Management Programs (FSME). A full listing of all generic communications may be viewed at the NRC public website at the following address:  <a href="http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html">http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html</a></p>			