

DEPARTMENT OF THE ARMY
HEADQUARTERS, U.S. ARMY MEDICAL COMMAND
2050 WORTH ROAD
FORT SAM HOUSTON TX 78234-6000

April 8, 2004

Proponency Office for Preventive Medicine – San Antonio

U.S. Nuclear Regulatory Commission
Nuclear Materials Licensing Section
Attention: Ms. Jacqueline D. Cook
611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011-8064

To Whom It May Concern:

In an attempt to standardize the policy for Sentinel Node Biopsy throughout the Army Medical Command, we have developed what we feel is viable standard procedure guidance for those facilities that do not possess a Nuclear Regulatory license but are capable of performing the surgical aspect of the biopsy. This would facilitate this procedure at non-NRC licensed military medical facilities. This policy proposal addresses patients who are injected with the radioactive material at licensed facilities (either civilian or military) and subsequently have their surgery at military treatment facilities that do not possess licenses. We are seeking approval for these non-licensed facilities to perform the surgical procedures and the analysis of the resulting pathology specimens.

We submitted our proposal as an enclosure for your review and approval prior to implementation in the Technical Assistance Request dated 27 October 2003. I am forwarding this correspondence for clarification of our initial request. Please be advised that if approved it will be implemented across all NRC regions that have Army Medical Treatment Facilities without licenses. I look forward to your recommendations. If you have any questions or concerns, please call Colonel Robert Eng, the United States Army Medical Command's Radiation Safety Staff Officer at (210) 221-6612.

Sincerely,

Regina L. Miller
Sergeant First Class, U.S. Army
Alternate Radiation Safety Staff Officer



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REPLY TO
ATTENTION OF

27 October 2003

Proponency Office for Preventive Medicine

U. S. Nuclear Regulatory Commission
Nuclear Materials Licensing Section
Attention: Ms. Jacqueline D. Cook
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064

Dear Ms. Cook:

Please find enclosed a Technical Assistance Request seeking clarification of the NRC's position concerning the release of nuclear medicine patients and the performance of Sentinel Lymph Node Biopsy (SNB) procedures. Your assistance in clarifying these issues will enhance our ability to provide high quality and cost effective medical care. I will use your response to generate guidance and instructions for US Army medical treatment facilities throughout the United States.

If there are questions, please call me at (210) 221-6612 or my action officer, Major Stephen A. Cima, at (210) 295-2458.

Sincerely,

A handwritten signature in black ink that reads "Robert R. Eng". The signature is written in a cursive style with a large, stylized "R" and "E".

ROBERT R. ENG
Colonel, U. S. Army
Radiological Safety Staff Officer

Enclosure

Technical Assistance Request
Sentinel Lymph Node Biopsy (SLNB) Procedures

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Proposal.

Some medical facilities are incurring additional costs and even delaying pathology sample analysis in efforts to maintain radiation exposures from patients released after the administration of radiopharmaceuticals As Low As Reasonably Achievable (ALARA). In most cases, these additional costs and delays in obtaining diagnostic information are not warranted in light of the insignificant radiation exposures involved. The NRC could resolve this situation by clarifying that licensees are not required to take any protective measures when releasing a patient following the administration of radiopharmaceuticals provided the dose any individual is likely to receive from the released patient will not exceed 1 mSv (0.1 rem).

The immediate impact of such guidance from the NRC will be to facilitate performance of Sentinel Lymph Node Biopsy (SLNB) procedures at non-NRC licensed medical facilities. This guidance would also support the recommendations of the Surgical Pathology Committee of the College of American Pathologists and the Association of Directors of Anatomic and Surgical Pathology for the safe handling of radioactive specimens obtained by sentinel lymphadenectomy⁽¹⁹⁾ (Appendix).

The NRC could reaffirm the licensee's responsibility extend to situations when it is anticipated a released patient

will promptly receive additional medical care. The model patient release procedures and default release criteria provided in NUREG 1556 V9 do not directly address the possibility patients will promptly receive additional medical care. Never the less, licensees releasing patients should consider anticipated medical procedures and ensure exposures to members of the public remain within the established limits. This would reassure non-NRC licensed medical facilities that licenses have considered potential exposures to their personnel and that the non-NRC licensed facilities are not required to take radiation protection precautions or treat patient samples, waste, or biopsy samples as radioactive waste.

Medical Rational.

SLNB can be performed in several manners. All being with the administration of Tc-99m at a NRC licensed institution. Less than 1 millicuries of Tc99m Sulfur colloid is administered (typical doses 400 to 800 microcuries) either filtered or non filtered. At some facilities the patient is then imaged in the nuclear medicine clinic with a gamma camera and the location of the sentinel node is marked on the patient's skin. The patients are then released in accordance with 10 CFR Part 35.75.

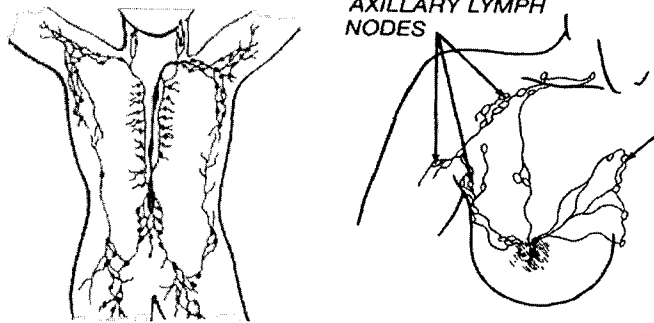
The use of probe directed lymphoscintigraph for sentinel node detection is the preferred methodology and tool for surgeons, although the surgeon can also use the marks made on the patient's skin in the nuclear medicine clinic. The use of a probe to find the sentinel node markedly decreases patient morbidity by avoiding complete axillary node dissection since only a single lymph node is removed from the axilla. Complete axillary node dissections can result in chronic arm swelling in patients who have undergone mastectomies for breast cancer. ENT cancer patients can also benefit from sentinel node procedures when attempting to locate the sentinel node in the neck.

Background Clinical Information

Sentinel Lymph Node is based on the concept that the tumor-bearing status of the sentinel node, i.e., the first node in the regional nodal basin that drains a primary tumor,

reflects the tumor status of the entire nodal basin whether from breast cancer or melanoma.

In the breast, a network of lymphatic vessels drain fluid and cells to the bean-shaped lymph nodes in the axilla (armpit). The "sentinel" node is the very first lymph node(s) to receive drainage from a cancer-containing area of the breast.



A SLNB requires the removal of only one to three lymph nodes for close review by a pathologist. If the sentinel nodes do not contain tumor (cancer) cells, this may eliminate the need to remove additional lymph nodes in the axillary area.

How is Sentinel Lymph Node Biopsy (SLNB) Performed?

Before going to the operating room, an NRC authorized physician injects a small dose technetium-99m (Tc^{-99m}) labeled sulfur colloid or dextran³⁷ one to 24 hours prior to operation. A lymphoscintigram is usually obtained preoperatively to determine the axillary drainage pattern from the primary tumor. In the OR, the surgeon injects a blue dye into the breast to help visually track the location of the sentinel node during surgery. The gamma ray counter is attached to a small probe that the surgeon traces over the axilla to locate the sentinel node(s). When the radioactive agent is found, the gamma ray counter will emit an audible tone, revealing the exact location of the sentinel node(s). Once the area has been pinpointed, the surgeon will make a small incision (usually one-half inch) and remove the sentinel node(s) for a pathologist to examine under a microscope.

Radiation Safety Considerations.

Exposures to Medical Personnel Supporting SLNB Procedures.

The radiation dose to surgical personnel performing SLNB procedures has been quantitatively assessed in a study performed at the Walter Reed Army Medical Center. The mean

dose to the fingers of surgical personnel ranged from 1.75 mrem to 14 mrem⁽¹²⁾ per procedure, depending on the type of cancer involved. Other researchers have reported similar results⁽¹⁹⁾. Even a surgeon or pathologist performing 100 procedures per year is unlikely to receive an annual TEDE exceeding 100 mrem.

NUREG 1556 Volume 9 provides procedures for releasing patients administered radiopharmaceuticals. Table U.1 of NUREG 1556 Volume 9 specifies levels of residual activities at which patients may be released from licensee control without providing the patient with written instructions for maintaining doses to other individuals ALARA. The limit for Tc-99m is 150 mCi, i.e. releasing patients containing up to 150 mCi of Tc-99m is unlikely to result in an exposure to a member of the public exceeding 1 mSv (0.1 rem).

NUREG 1556 Volume 9 does not specifically address the possibility that the released patients would promptly undergo SLNB or other medical procedures. Nevertheless, because an SLNB involves administration of less than 1% of the 150 mCi limit, the NUREG 1556 Volume 9 limits still support the conclusion that patients released after SLNB dosings are unlikely to result in a dose exceeding 0.1 rem, even for medical personnel involved in surgical or pathology care of these patients.

Radioactive Waste Considerations.

Essentially all patients released in accordance with 10 CFR Part 35.75 will contaminate some materials at some levels. When the contamination is caused by excreta or bodily fluids the contamination may be readily detectable. The NRC has considered this contamination in the public domain when establishing the acceptable criteria for the release of patients.

Contaminated materials in the public domain caused by released nuclear medicine patients have periodically created incidence at non NRC licensed facilities. The typical incident occurs when a conventional waste facility detects and rejects contaminated trash. When these incidents occur the NRC does not cite the licensee for violating any requirements for the control of radioactive materials. Nor does the NRC require the licensees to

implement greater controls of nuclear medicine patients. The only requirement the NRC imposes is to require licensee to accept (and treated as radioactive waste) trash rejected by the non NRC facilities because of its radioactive content⁽¹³⁾.

ALARA Considerations.

This proposal suggests foregoing all radiation protection precautions because exposures are so low that the dose reductions would not justify additional expense or impact on patient care. In the past, ALARA precautions were taken at some facilities performing SLNB. In order to ensure compliance with the highly prescriptive NRC regulations and license conditions in effect at that time, the ALARA principle, and to ensure there were no regulatory impediments to continued development of this promising medical technique, detailed radiation safety precautions for performing SLNB were proposed⁽¹²⁾⁽¹⁴⁾. These radiation safety precautions included:

- Establishing a "radiologic control level" that defined any sample with a specific activity exceeding 0.002 uCi/gm to be radioactive and require controls. This extremely conservative approach was based on the definition of radioactive material established by the DOT in Title 49 CFR. Radiation safety precautions were recommended for any sample exceeding the radiologic control level. Alternative levels, such as the NRC's exempt concentration (0.1 uCi/ml⁽¹⁵⁾) or the license exempt quantities (100 uCi⁽¹⁶⁾) for Tc-99m were not considered conservative enough.
- Recommending all samples exceeding the 0.002 uCi/gm "radiologic control level" be labeled as radioactive and segregated, far more restrictive than the NRC's 100 uCi labeling requirement for Tc-99m⁽¹⁷⁾.
- Controlled samples would be segregated and pathology analysis would be delayed for 48-72 hours.

These radiation protection recommendations were deemed necessary to avoid conflicts with the highly prescriptive regulations and license conditions in effect at the time and to fulfill the licensee's ALARA commitment. Even delaying the pathology results, noted to have a negative psychological impact on the patient⁽¹²⁾, was considered

acceptable to ensure the continued availability of this technology. Supporting these conservative radiation protection precautions was possible since the medical facilities initially supporting SLNB were all NRC licensees. Implementing any radiation protection precautions at non NRC licensed facilities would be less practical.

These initial precautions were developed and implemented prior to the NRC's Risk-Informed Regulation Implementation Plan (RIRIP)⁽¹⁸⁾ and subsequent revision of 10 CFR Part 35. An appropriate application of the ALARA principle, using a Risk-Informed approach, should conclude that radiation protection precautions are not required for SLNB procedures.

Regulatory Rational

Under 10 CFR 35.75 licensees can release patients when 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). If the dose is likely to exceed 1 mSv (0.1 rem) then the patient must be provided written instruction on precautions required to maintain exposures ALARA. When the likely dose to other individuals is less than 1 mSv then no instructions or precautions are required. Therefore no precautions should be taken when releasing patients scheduled to undergo SLNB or other medical procedures, provided the exposures to any member of the general public is no likely exceed 1 mSv (0.1 rem).

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Appendix B Recommendations for the Safe Handling of
Radioactive Specimens Obtained by Sentinel Lymphadenectomy

Special Article

Recommendations for Handling Radioactive Specimens Obtained by Sentinel Lymphadenectomy

Patrick L. Fitzgibbons, M.D., Virginia A. LiVolsi, M.D., the Surgical Pathology Committee of the College of American Pathologists, and the Association of Directors of Anatomic and Surgical Pathology

Sentinel lymph node biopsy has been shown to be an accurate predictor of axillary nodal status in invasive breast cancer and is a useful alternative to axillary dissection for some patients. Because radioactive materials are often used to identify the sentinel lymph node, concerns have been raised regarding the safe handling of tissue specimens obtained by this technique. The Surgical Pathology Committee of the College of American Pathologists and the Association of Directors of Anatomic and Surgical Pathology have developed recommendations for the safe handling of radioactive specimens obtained by sentinel lymphadenectomy.

Key Words: Radioactivity—Safety—Specimen handling—Sentinel lymphadenectomy—Technetium—Sulfur colloid.

Am J Surg Pathol 24(11): 1549-1551, 2000.

The U.S. Nuclear Regulatory Commission has regulatory jurisdiction for the medical use of radioactive materials. Title 10 of the Code of Federal Regulations contains the relevant standards for protection against radiation. The maximum occupational radiation exposure limit for radiation workers is 5000 mrem per year (total effective dose) or 50,000 mrem per year for skin or extremities.² Special training and individual radiation monitoring devices (film badges) are required only for those who are likely to be exposed to more than 10% of the annual exposure limits.³

The exposure limit for nonradiation hospital personnel, such as pathology staff, including pregnant women, is 500 mrem per year, provided that the institution is authorized by the Nuclear Regulatory Commission and has procedures to maintain the dose as low as reasonably achievable.⁴

From the Department of Pathology, St. Jude Medical Center, Fullerton, California, U.S.A. (P.L.F.); and the Department of Pathology, University of Pennsylvania, Philadelphia, Pennsylvania, U.S.A. (V.A.L.).

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Doses of 0.4 to 1.0 mCi ^{99m}technetium-sulfur colloid are typically used in sentinel lymphadenectomy for melanoma and breast cancer. Mean radiation dose to the skin of a surgeon's hand during sentinel lymphadenectomy has been reported to be approximately 10 mrem for breast cancer and 2 mrem for melanoma,¹⁴ whereas the total effective dose is estimated to be less than 0.1 mrem.¹⁵ At these measured exposure rates, a surgeon theoretically could perform several thousand such operations each year and not exceed statutory exposure limits.¹⁴ Mean radiation dose to pathology staff exposed to these specimens has been rarely measured but is much lower than that to the surgeon because of the shorter time spent handling the specimens.^{15,18}

The half-life of ^{99m}technetium is 6 hours, and radiation levels decrease to background levels after 10 half-lives (60 hrs). One group reported that film badge readings of pathology staff exposed to such specimens never exceeded minimum detectable levels of 10 mrem per month.^{12,17}

RECOMMENDATIONS

Institutional Policy and Procedure

Each institution should develop written procedures for handling radioactive pathology specimens. These procedures should encompass specimen handling and labeling, transportation, storage, and disposal and should be designed to keep radiation exposure to laboratory and other hospital workers as low as reasonably achievable.⁵ The policy should distinguish between tissue specimens obtained during sentinel lymphadenectomy, in which the amount of radiation is low, and radiation implant devices that may have significantly higher radiation levels. The institution should document that laboratory and surgery personnel handling such specimens are aware of the policy.⁶

The institution should also document that all personnel handling these specimens, including couriers, are aware

that the specimens contain low levels of radioactivity. Although the risk of radiation exposure is low, failure to inform workers fully that they are handling or transporting radioactive specimens may be considered a breach of the employer's responsibility.

Radiation Safety Officer

Procedures for handling radioactive tissue specimens must be developed in conjunction with the institution's radiation safety officer. The radiation safety officer has the overall responsibility for developing safety procedures, determining exposure risk to laboratory personnel, and determining whether swipe surveys or other measurements of radioactivity are needed. The radiation safety officer is also responsible for the training of surgical and pathology staff with respect to radiation safety issues.

Universal Precautions

Procedures for handling these specimens should follow standard safety guidelines established for all specimen types (that is, universal precautions). Because of the low risk of radiation exposure to pathology staff, universal precautions adequately cover most aspects of sentinel lymphadenectomy specimen handling.

Specimen Labeling

The policy should describe how specimen containers are labeled. The Code of Federal Regulations states that containers of licensed radioactive material must be labeled "Caution—Radioactive Material," but there are specific exceptions provided. Labeling is not required for containers holding less than 1000 μCi $^{99\text{m}}\text{Tc}$ or those attended by individuals who take the precautions necessary to prevent exposure in excess of the statutory limits. Labeling is also exempted if containers are accessed only by authorized individuals, provided that the contents are identified by a readily available written record.⁷ Thus, if procedures are in place to avoid specimen handling by unauthorized individuals, special labeling of containers other than that for any pathology specimen is not required.

The requisition slip that accompanies the tissue must indicate the nature of the specimen (for example, sentinel lymph node after technetium injection) and include the date and time of surgery. If labels indicating radioactive material have been attached to the container, they must be removed before disposal.⁸

Specimen Transportation

Specimens containing radioactive materials should be promptly transported from the operating room to the

laboratory in sealed, properly labeled specimen containers. The policy should specify how these specimens are transported to the laboratory and take into account the possible need for intraoperative pathology consultation. The specimen transportation policy should ensure that these specimens are not left unattended in unsecured holding areas before transport to the laboratory or frozen section room and that unsuspecting workers are not exposed for prolonged periods. Only those personnel given proper training, as determined by the radiation safety officer, should be authorized to handle radioactive specimens.

Specimen Processing

There is disagreement regarding whether these specimens should be quarantined before gross examination. Some authors have suggested holding specimens for as long as 72 hours before processing or until radioactivity decreases to background levels.^{1,13,14} Others think that this recommendation is unnecessary because the level of exposure to pathology staff is not a safety concern.^{11,12}

Besides the exceedingly low radiation exposure to pathology staff, holding specimens for one or more days delays the final diagnosis and may increase the chance of processing errors, such as misplaced specimens or sub-optimal fixation. For these reasons, holding sentinel lymph nodes before processing does not appear to be justified.

A quarantine of the primary tumor excision specimen may be considered because of the higher radioactivity levels in these specimens as compared with the sentinel lymph node. This decision, however, should be based on a determination by the radiation safety officer that measured exposure levels exceed acceptable limits.

Frozen Section Equipment

Because removable contamination is present in the cryostat immediately after frozen section analysis, one may choose to use a dedicated cryostat or clean the cryostat between uses.¹⁴ The amount of radioactive material present in frozen section shavings, however, is limited, and most authors have not recommended special precautions.¹⁷

Protective Wear

Protective wear such as disposable gloves, surgical scrubs, and plastic aprons should be worn when handling these specimens. Any protective wear used when handling radioactive tissue specimens should be removed before leaving the laboratory area.

Specimen Storage

The policy should specify how these specimens are stored until disposal. Radioactive specimens should be held in a secure location to prevent unauthorized access and premature disposal. Some institutions keep tissue specimens in shielded containers until disposal,¹⁷ but an acceptable alternative is to store these materials away from laboratory and other personnel.

Disposal

Federal law allows routine methods of solid medical waste disposal for radioactive specimens after decay in storage,⁹ which requires 10 half-lives.¹⁰ Because the half-life of ^{99m}technetium is 6 hours, sentinel lymphadenectomy specimens and related surgical materials can be disposed through ordinary medical waste disposal methods 60 hours after the time of surgery. If specimen containers have been specially labeled (that is, Caution—Radioactive Material), federal law requires that these labels be removed before disposal with regular medical waste.⁸

Film Badges

Personnel monitoring devices (film badges) are not necessary for pathology staff because of the low levels of radioactivity, rapid decay, and limited time of exposure.³

Transportation of Paraffin Blocks

It is recommended that paraffin blocks be held for 48 hours from the time of surgery before sending through the mail. □

Acknowledgments

These recommendations were developed by the Surgical Pathology Committee of the College of American Pathologists, composed of Patrick L. Fitzgibbons, MD (chair), Larry Burgart, MD, David Carter, MD, Cheryl Coffin, MD, Solon Cole, MD, Megan Dishop, MD, Max Elliott, MD, David Frishberg, MD, Lloyd Gardner, MD, Kathleen Kagan-Hallet, MD, Janice

Lage, MD, Virginia LiVolsi, MD, Raouf Nakhleh, MD, Mary Nielsen, MD, Frances O'Malley, MD, Henry Tazelaar, MD, Mark Weiss, MD, Bruce Wenig, MD, Reginald Wilson, MD, and endorsed by the Association of Directors of Anatomic and Surgical Pathology.

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