UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
WASHINGTON, DC 20555

September 14, 2006

NRC REGULATORY ISSUE SUMMARY 2006-19
AVAILABILITY OF GUIDANCE ON
RADIOACTIVE SEED LOCALIZATION

ADDRESSEES

All medical licensees.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this Regulatory Issue Summary (RIS) to inform addressees of the availability of guidance on radioactive seed localization. No specific action or written response is required.

BACKGROUND

The National Materials Program (NMP) is a term that was developed in late 1990 to define the collective framework within which both NRC and the Agreement States function in carrying out their respective radiation safety regulatory programs. NRC and the Agreement States recognize that, as regulators, consistent approaches in addressing and resolving radiation protection issues are important. The NMP is a vehicle to help accomplish this objective.

In 2002, NRC initiated five pilot projects under the NMP to address various regulatory issues. One of the projects was Pilot Project 4 - “State Guidance Development.” The goal of this project was to demonstrate that Agreement States can assume the responsibility for development of guidance for use by both NRC and Agreement States. The guidance was developed by the NMP Pilot Project 4 working group, which was led by the Organization of Agreement States, Inc. Membership on the working group included four Agreement States members and one NRC member.

The purpose of guidance developed under Pilot Project 4 was to create consistent approaches to the licensing and inspection of radioactive material used in emerging technologies.

SUMMARY OF ISSUE

Recently, guidance was developed for a 10 CFR 35.1000 medical-use procedure called radioactive seed localization. The purpose of radioactive seed localization of non-palpable

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lesions[1] is to localize suspicious tissues for excision with the use of radioactive seeds. Radioactive seed localization differs from current localization procedures, whereby a non-radioactive wire is implanted into the lesion site and excised along with affected tissue. The radioactive seed localization technique offers advantages, over the wire implantation technique for localizing lesions. For example, with the use of radioactive seed localization, the bracketing of lesions and the post-localization of mammograms is not impeded by wires, and radioactive seed localization can be performed up to 5 days before surgery, minimizing schedule conflicts.

Recipients of this RIS that intend to use this 10 CFR 35.1000 medical use are encouraged to review the radioactive seed localization guidance located at any one of the following websites:

- NRC's medical user's Licensee Toolkit at http://www.nrc.gov/materials/miau/med-use-toolkit.html;
- NRC's Office of State and Tribal Programs website at http://nrc-stp.ornl.gov/materials.html; and
- The Organization of Agreement States website at http://www.agreementstates.org/whatsnew.html.

NRC licensees desiring to use radioactive seed localization must submit an amendment request for the 10 CFR 35.1000 medical use to the appropriate NRC regional office.

BACKFIT DISCUSSION

This RIS requires no action nor written response and is, therefore, not a backfit under 10 CFR Part 72. 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 departure from current regulatory requirements.

CONGRESSIONAL REVIEW ACT

This RIS is not a rule as designated by the Congressional Review Act (5 U.S.C. §§ 801-886) and, therefore, is not subject to the Act.

PAPERWORK REDUCTION ACT STATEMENT

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

[1] An area of suspicious tissue detected by mammography that needs further evaluation.

CONTACT

This RIS requires no specific action or written response. If you have any questions about this summary, please contact the individual listed below or the appropriate regional office.

/RA/

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Enclosure: "List of Recently Issued NMSS
Generic Communications"