UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

October 13, 2016

ALL AGREEMENT STATES, VERMONT, WYOMING

NOTIFICATION OF ISSUANCE OF THE RADIOACTIVE SEED LOCALIZATION LICENSING GUIDANCE, REV. 1 (STC-16-082)

Purpose: To inform the Agreement States that the "Low Activity Radioactive Seeds Used for Localization of Non-Palpable Lesions and Lymph Nodes Licensing Guidance, Rev. 1" was published in October 2016.

Background: The licensing guidance for the "Iodine-125 and Palladium-103 Low Dose Rate Brachytherapy Seeds Used for Localization of Non-Palpable Lesions," hereafter referred to as "existing licensing guidance," was initially published in 2006 by an Agreement State working group (WG), with the assistance of staff from the U.S. Nuclear Regulatory Commission (NRC). In the radioactive seed localization (RSL) procedure, low activity radioactive seeds, including, but not limited to, iodine-125 (I-125) and palladium-103 (Pd-103), are implanted for localization and are not intended to deliver a therapeutic dose to tissue. RSL may use decayed radioactive seeds previously approved for the treatment of cancerous tumors under Title 10 *Code of Federal Regulations* (10 CFR) Part 35, Subpart F, "Manual Brachytherapy," or low activity radioactive seeds approved by the U.S. Food and Drug Administration (FDA) specifically for RSL use. RSL procedures are localization procedures and not therapeutic procedures; therefore, 10 CFR Part 35, Subpart F, "Manual Brachytherapy," would not apply for this use. The use of byproduct material for localization procedures is regulated under 10 CFR Part 35, Subpart D, "Unsealed Byproduct Material – Written Directive Not Required," but would not apply to this use because it uses sealed byproduct material. The use of sealed sources for diagnosis is regulated under 10 CFR Part 35, Subpart G, "Sealed Sources for Diagnosis," but is limited to sealed sources that have been approved for diagnostic medical use in the Sealed Source and Device (SS&D) Registry. This would not apply to RSL because these sealed sources (seeds) are approved in the SS&D for therapeutic use or "other use" (to denote 10 CFR 35.1000 user). Because RSL procedures are not regulated under 10 CFR Part 35, Subparts D, F or G, the use of these seeds for RSL procedures is regulated under 10 CFR Part 35, Subpart K, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material."

The Organization of Agreement States and NRC created a joint working group to: (1) review and evaluate the existing guidance, available documents, comments submitted from stakeholders and the ACMUI's recommendations; (2) determine if the existing guidance needed to be revised; and (3) develop the revised 10 CFR 35.1000 licensing guidance document. The working group determined that the licensing guidance needed to be revised to address radiation safety risks, how RSL procedures are currently performed, and the fact that low-activity seeds have been approved by the FDA specifically for RSL use. The existing licensing guidance has been amended to incorporate this additional information. The document is intended to be guidance in licensing RSL procedures for applicants, licensees and NRC staff and is also available to the Agreement States to use.

Discussion: This current licensing guidance (published in October 2016) supersedes the previous RSL licensing guidance. Therefore, it shall be considered revision 1. Notable changes in the guidance include: (1) the title and purpose change to include RSL use for lymph nodes; (2) the low activity seeds that have been approved by the FDA for RSL use; (3) a new pathway for radiologists who have completed the specific training and experience requirements to become an authorized user; (4) the removal of the written directive requirement; (5) the medical event reporting criteria for RSL use; (6) the grandfathering of individuals authorized for RSL use under the previous licensing guidance; (7) the change in inspection frequency from two years to five years; and (8) the change in program code to include 02121 or 02201.

This licensing guidance may also be found on the NRC Medical Uses Licensee Toolkit at: http://www.nrc.gov/materials/miau/med-use-toolkit.html.

If you have any questions regarding this correspondence, please contact me at 301-415-3340 or the individual named below:

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Enclosure:
Low Activity Radioactive Seeds Used
for Localization of Non-Palpable Lesions
and Lymph Nodes Licensing Guidance, Rev.1

Discussion: This current licensing guidance (published in October 2016) supersedes the previous RSL licensing guidance. Therefore, it shall be considered revision 1. Notable changes in the guidance include: (1) the low activity seeds that have been approved by the FDA for RSL use; (2) a new pathway for radiologists who have completed the specific training and experience requirements to become an authorized user; (3) the removal of the written directive requirement; (4) the medical event reporting criteria for RSL use; (5) the grandfathering of individuals authorized for RSL use under the previous licensing guidance; (6) the change in inspection frequency from two years to five years; and (7) the change in program code to include 02121 or 02201.

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