Advisory Committee on the Medical Uses of Isotopes
TELECONFERENCE AGENDA
Friday, June 24, 2016
3:00 PM – 5:00 PM (ET)

OPEN SESSION

3:00 – 4:00 pm
Discuss the Draft ACMUI Radioactive Seed Localization Subcommittee Report

4:00 – 5:00 pm
Discuss Potential Rulemaking to Expand the Financial Assurance Requirements for Some Radioactive Byproduct Material in Title 10 *Code of Federal Regulations* Section 30.35

Nuclear Regulatory Commission (NRC)
Advisory Committee on the Medical Use of Isotopes (ACMUI)

Subcommittee on
Radioactive Seed Localization for Non-Palpable Breast Lesions
Response to NRC Working Group Draft "Low Activity Radioactive Seeds Used for Localization of Non-palpable Lesions and Lymph Nodes Guidance"

Subcommittee Members:
Dr. Ronald Ennis (Chair)
Mr. Frank Costello
Dr. Darlene Metter
Dr. Pat Zanzonico

Introduction

This subcommittee has previously presented on this topic in a report dated September 21, 2015. The recommendations in that report were presented to the ACMUI at its meeting on October 12, 2015. Since then, Dr. Philip Alderson has been appointed Chairman of the ACMUI. As a result, he can no longer serve on this subcommittee and has been replaced by Dr. Darlene Metter.

Written Directive

The most significant change from our subcommittee's recommendations in the NRC Working Group (WG) Draft, "Low Activity Radioactive Seeds Used for Localization of Non-Palpable Lesions and Lymph Nodes Guidance," hereafter referred to as NRC WG Draft Guidance, is the elimination of the requirement for a written directive (WD). The rationale for the WG's recommendation is that a WD is required for therapeutic procedures. Since this is a diagnostic procedure, a WD is not necessarily required. Furthermore, elimination of a WD does not eliminate the possibility of a Medical Event (ME) and all of the standard ME criteria still apply. The subcommittee accepts this change on the basis of an implicit understanding that there will be documentation in the patient's medical record of the Authorized User (AU)'s intention prior to the Radioactive Seed Localization (RSL) procedure and post-procedure documentation in the medical record documenting what was actually performed. It is the understanding of the subcommittee that this documentation will provide regulators with the required information to assess that an RSL procedure had been performed in accordance with the applicable regulations.

Authorized User

Another significant change in the NRC WG Draft Guidance is the creation of an alternative pathway to become an AU for RSL. In this pathway, radiologists whose training and experience did not qualify them for AU status under 35.290 or surgeons can become AUs for RSL with 80 hours of training and experience including a minimum of 40 hours of classroom and laboratory training in basic handling techniques applicable to the medical use of sealed sources (details of

which are listed in the NRC WG Draft Guidance in (3) i-ii (page 4)). The subcommittee understands that a gap in training and experience exists for some radiologists who are active in the area of needle localizations and biopsies under image guidance (e.g. mammographers who routinely perform biopsies and place clips in the breast). Such physicians are the ones who most naturally would be called upon to place radioactive seeds for this diagnostic purpose. However, even if their training and experience was not enough to achieve 35.290 AU status, their radiology training (i.e. a residency in radiology) provided substantial background in all aspects of the medical use of radiation including safety, protection, biology and physics. Accordingly, the subcommittee supports an alternative (i.e. non-35.290) pathway for these radiologists to achieve AU status for RSL. However, the subcommittee believes strongly that surgeons or others without a significant background in radiation (from a residency or some other similarly intense education and practical experience) would be entirely unqualified to function as an AU for RSL with only 80 hours of training .

Medical Event

The NRC WG Draft Guidance has eliminated the time component from the definition of ME. This component is replaced with the following criterion: an ME has occurred "…if the licensee fails to perform the explantation surgery," with the caveat that such an outcome would not be an ME if "the physician makes the determination not to explant the seed for various patient conditions (e.g. doing so would jeopardize the patient's well-being.)" The subcommittee accepts this change and support the exclusion from ME the situation in which the physician deems removal not to be in the best interest of the patient. Additionally, the subcommittee supports the position that an ME has not occurred in the event the patient failed to return for the surgical removal procedure, considering this to be an instance of "patient intervention".

Safety Precautions

The subcommittee is disappointed the NRC WG Draft Guidance does not include an explicit requirement to advise patients who have undergone RSL of the breast not to breast feed with the implanted breast until the seed has been explanted. The subcommittee is concerned about the exposure of a newborn child to even small doses of unnecessary radiation and the potential risk to that child later in life. It is well known to those trained in radiation safety and human health that the damaging effects of radiation are much more pronounced in children. However, the public and medical professionals who are not highly educated in issues of radiation safety and human health may be unaware of this distinction. Therefore, a mother may assume if it is safe for her to have this radioactive seed in her breast, it is also safe for her baby to be exposed to the radiation via breast feeding. The subcommittee, therefore, feels this is an important omission and recommends inclusion of the following in the Draft Guidance: "Patient should be advised not to breast feed from a breast into which one or more radioactive seeds been implanted and not yet removed. Breast feeding is, of course, permissible once the seed(s) has(ve) been removed. In the event of seed rupture within the breast, the subcommittee recommends the patient be advised to never breast feed from the effected breast for this child." (Note: The end time of the restriction on breast feeding in the setting of a ruptured seed has been changed from "10 half-lives", which had been recommended in our previous recommendation, to "this child" to make this recommendation consistent with the recommendations for I-131.)

Other recommendations

The subcommittee agrees with the remainder of the NRC WG Draft Guidance, including those portions related to previous recommendations of the subcommittee (see Subcommittee's previous report dated September 21, 2015).

Respectfully submitted, June 10, 2016
Subcommittee on **Radioactive Seed Localization for Non-Palpable Breast Lesions,**
Advisory Committee on the Medical Use of Isotopes (ACMUI),
Nuclear Regulatory Commission (NRC)

Financial Planning for Management of Radioactive Byproduct Material
ACMUI Public Teleconference – 6/24/16

Background

- NRC regulations in 10 CFR 30.35, "Financial Assurance and Recordkeeping for Decommissioning," require a fixed dollar amount financial assurance or a decommissioning funding plan (DFP) for licensees possessing byproduct material with a half-life greater than 120 days and at activity levels above certain thresholds.

- The regulations do not require decommissioning financial assurance for a majority of Category 1 and 2 (and lower category) radioactive sealed sources (RSSs). Reports prepared by both interagency and external groups have recommended that NRC revisit the need for financial planning for end-of-life management of RSSs.

- End-of-life costs for byproduct material, including many Category 1 and 2 RSSs, can be significant and unpredictable. These costs may include steps such as interim storage, packaging and conditioning, transportation, and costs associated with the selected disposition option. Licensees are not required to declare when RSSs in their possession are disused, nor are they required to provide for prompt disposition. If a licensee has not anticipated and planned for the cost of disposition, this may represent a significant financial burden.

- For some RSSs, disposal may not be a viable option for a variety of reasons, including lack of access to a LLW disposal facility, prohibitive disposal cost, and/or lack of a certified shipping container. As a result, licensees may choose indefinite long-term secure storage as the most practical management option.

- The NRC staff's financial scoping effort arose from a Commission briefing on radioactive waste issues in September 2014. SRM-M140918, dated September 24, 2014, directed the NRC staff to provide the results of the byproduct financial scoping study and recommendations for next steps. NRC staff subsequently initiated a scoping study to determine whether additional financial planning requirements are necessary for end-of-life management of some byproduct material, particularly RSSs.

- To inform the scoping study, NRC staff issued a *Federal Registe*r notice (FRN) on August 3, 2015, to solicit stakeholder comments. The comment period closed on October 19, 2015. Eleven comment letters were received from a range of Federal and State agencies, organizations such as the LLW Forum and the Organization of Agreement States, industry, and the public. Staff also convened a public meeting and webinar at NRC headquarters on October 7, 2015, to obtain stakeholder feedback. Approximately 35 stakeholders participated either in-person or through the webinar.

- The scoping study is documented in SECY-16-0046, dated April 7, 2016. It is publicly available on the NRC Website.

Scoping Study Results

- In its scoping study, the NRC staff reviewed current NRC regulations and guidance, relevant internal and external reports, and stakeholder feedback in areas such as financial assurance methods and funding mechanisms, timeliness in declaring and dispositioning disused sources, and compatibility with Agreement State requirements. The staff also considered other relevant domestic and international activities such as:

    - Availability of new disposal capacity
    - Availability of and limitations associated with Type B transportation containers
    - NRC's revised branch technical position on concentration averaging
    - The Conference of Radiation Control Program Directors' (CRCPD's) initiative to revisit financial surety criteria for radioactive material
    - DOE/NNSA's Off-Site Source Recovery Project and the Source Collection and Threat Reduction Program administered by CRCPD

- The NRC staff notes in the scoping study that it agrees with the assessments of numerous stakeholders that providing financial assurance for RSS disposition supports safety and security goals, facilitates timely disposition of disused sources, and ensures that the full cost of using RSSs is appropriately considered by licensees.

- The scoping study also recognizes that current NRC regulations ensure the safe and secure management of RSSs. Implementation of new financial assurance requirements would impose additional regulatory costs and has the potential to adversely affect beneficial uses of radioactive material.

- In SECY-16-0046, the NRC staff recommends that the financial assurance requirements in 10 CFR 30.35 be expanded to include all byproduct material Category 1 and 2 RSSs tracked in the National Source Tracking System (NSTS). The NRC staff is preparing a rulemaking plan SECY paper, due in fall 2016, to further evaluate potential regulatory changes as required by SRM-SECY-15-0129, "Commission Involvement in Early Stages of Rulemaking".

- The NRC staff's recommendation focuses on those sources with the highest risk significance. Staff believes these additional requirements:

    - should reduce the likelihood that some licensees will be unprepared for end-of-life disposition costs
    - may help reduce the use of long-term storage as a management option
    - would complement NRC's existing regulatory framework

- The rulemaking plan SECY paper will include a discussion of the estimated schedule for rulemaking, costs and benefits, cumulative effects of regulation, Agreement State considerations, and other regulatory options.

- The Commission will decide whether to approve the staff's recommendation after reviewing the rulemaking plan SECY paper.

What about Category 3 and lower sealed sources?

Staff considered whether rulemaking should include other categories of RSSs such as Category 3 (and below) sources, as recommended by several stakeholders. Staff elected to focus on Category 1 and 2 sources at this time based on the following:

- Category 1 and 2 sources have the highest risk significance and are generally the most likely RSSs to face disposition challenges. As a group, disposition costs are likely to be higher for Category 1 and 2 sources compared to other source categories.

- Developing the necessary infrastructure to implement financial assurance for more than 76,000 Category 1 and 2 RSSs tracked in the NSTS, held by approximately 1400 NRC and Agreement State licensees, will be a complex and resource intensive task. Staff felt that the most prudent use of Federal and Agreement State resources would be to focus on these RSSs before further considering lower category sources.

- Should NRC elect to explore financial assurance requirements for other RSSs in the future, experience in developing and implementing requirements for Category 1 and 2 RSSs will help ensure effective and efficient use of Federal and State regulatory resources.

- Agreement States can continue to implement more comprehensive financial assurance requirements for RSSs, including Category 3 and lower sources, based on current compatibility categories with NRC financial assurance requirements.