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"

Final Report

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 August 11, 2015. The recommendations in that report were presented to the ACMUI at its meeting on October 08, 2015. Since then, Dr. Philip Alderson has been appointed Chairman of the ACMUI. As a result, he has chosen not serve on this subcommittee for neutrality purposes. In addition, Dr. Darlene Metter was appointed to the ACMUI in March 2016 as the Diagnostic Radiologist representative. With the departure of Dr. Alderson from the subcommittee and
Dr. Metter's appointment and expertise, she was added to the subcommittee membership.

Written Directive

The most significant change from our subcommittee's recommendations in the NRC/Agreement State Working Group (WG) Draft, "Low Activity Radioactive Seeds Used for Localization of Non-Palpable Lesions and Lymph Nodes Guidance," hereafter referred to as WG Draft Guidance, is the elimination of the requirement for a written directive (WD).The rationale for this recommendation is that a WD is required for therapeutic and certain diagnostic procedures. Since RSL is neither a therapeutic nor a diagnostic procedure, but rather a localization procedure, a WD is not 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Another significant change in the WG Draft Guidance is the creation of an alternative pathway to become an AU for RSL.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. 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 Reporting

The WG Draft Guidance has added a new section for ME reporting. The WG Draft Guidance did not include the time component from the definition of ME that was recommended in the previous RSL Subcommittee Report (administration of radioactive byproduct material for more than 20% longer than planned). 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", provided the patient has been properly counseled about the importance of returning for the procedure and the risk of radiation exposure should the sources not be removed. Documentation of this counseling should be made in the patient's medical record.

Safety Precautions

The subcommittee is disappointed the 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 either 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 WG Draft Guidance, including those portions related to previous recommendations of the subcommittee (see Subcommittee's previous report dated August 11, 2015).

Respectfully submitted, June 24, 2016
Subcommittee on **Radioactive Seed Localization for Non-Palpable Breast Lesions,**
Advisory Committee on the Medical Use of Isotopes (ACMUI),
Nuclear Regulatory Commission (NRC)

This report was unanimously approved by the Committee during its public teleconference meeting held on June 24, 2016.