Joint U.S. Nuclear Regulatory Commission/Agreement State Working Group for Yttrium-90 Microsphere Brachytherapy Licensing Guidance

Charter
Revision 1

PURPOSE

To evaluate recommendations from the Advisory Committee on the Medical Uses of Isotopes (ACMUI) and the U.S. Nuclear Regulatory Commission (NRC) staff and to revise the licensing guidance for Yttrium-90 (Y-90) microsphere brachytherapy, if needed.

BACKGROUND

The licensing guidance for Y-90 microsphere brachytherapy, hereafter referred to as "licensing guidance," was initially published in October 2002 and subsequently revised in 2004, 2007, 2008, and 2011. The most recent licensing guidance was published in June 2012 and can be found in the NRC's Agencywide Documents Access Management System (ML12179A353). Significant updates over the years are described below:

- Stasis in the written directive;
- Nuclear medicine physician and interventional radiologist pathway for Authorized User (AU) status—later several revisions and clarifications to the training and experience;
- Manufacturer name in written directive;
- Dose(s) that will result to the specified site(s) due to shunting;
- Multi-disciplinary team approach (cancer management, catheter placement, radiation dosimetry, and safe handling of unsealed byproduct material);
- Waste disposal issues (e.g., consideration for potential long-lived contaminants);
- Existing AUs can be named on a different license;
- AUs approved under previous versions of the guidance are grandfathered;
- Training in the manufacturer's procedures provided to all individuals involved in Y-90 microsphere use;
- Commitments in guidance will be incorporated into the license either by license condition or incorporation by reference;
- General requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, Subparts A, B, C, L, and M are still applicable to 10 CFR 35.1000 licensees;
- Use of activity (mCi or GBq) in lieu of dose (rad or Gy) in the written directive and for medical event reporting criteria;
- Licensee to record the activity administered in written directive within 24 hours—AU signature not required unless variation from what was prescribed;
- Follow manufacturer procedures for calculating/documenting the dose to the treatment and other sites, prepare the dose for administration, and perform pre/post vial dose measurements;
- Retain semi-annual physical inventory records for 3 years;
- Clarification for the meaning of "after implantation but before completion of the procedure" in the written directive;

- Allowance for revisions to the written directive post-procedure for emergent patient conditions (e.g., vascular spasm), which are "not considered not patient" intervention; and
- Reference to NUREG 1556, Volume 9, Appendix N for decontamination procedures.

TASK 1

ACMUI RECOMMENDATIONS

In 2013 the NRC staff requested the ACMUI determine whether and under what conditions deposition of Y-90 microspheres in the gastrointestinal (GI) tract constitutes a medical event. In September of 2014, the ACMUI provided recommendations for revisions to the existing guidance to conform to the current state of medical practice and to provide regulatory relief, as needed. ACMUI's recommendations are summarized below. The full ACMUI report can be found in ADAMS (ML14300A138).

1. Remove specifications for GI tract and lung dose/activity in the written directive because GI and lung irradiation from Y-90 microsphere brachytherapy should be considered known risks of the procedure.

2. Revise guidance to state that implantation of the microsphere brachytherapy sources is considered to be in accordance with the written directive, if the total activity administered does not vary from the prescribed activity by 20 percent or more, except when the procedure is terminated due to stasis.

NRC STAFF RECOMMENDATIONS

The NRC Headquarters staff receives licensing guidance questions and comments from Regional staff, the Agreement States, licensees, manufacturers, and other stakeholders. The NRC staff evaluates and discusses these issues and considers updates to the guidance, as needed. The NRC staff proposes the following for working group (WG) consideration:

1. Add language for interventional radiologists certified by the American Osteopathic Board of Radiology with subspecialty certification in Vascular & Interventional Radiology to become AUs.

2. Add standard language developed by the NRC's Medical Radiation Safety Team for all emerging technology licensing guidance documents (e.g., cover page; table of contents; document revision date; page numbers; sensitive security-related information, if applicable; example license language for radionuclide, form, possession limits, and purpose of use; and program code information).

TASK 2

NRC STAFF RECOMMENDATIONS

The NRC staff proposes the following for WG consideration:

1. Update the Waste Disposal Issues section for long-lived contaminants for both types of microspheres and consider development of an updated Information Notice.

2. Add language to the Waste Disposal Issues section for radiation safety issues related to autopsy and cremation.

3. Consider revising the training section to the remove the pathway for manufacturer provided work experience.

OBJECTIVES

The WG's objectives include, but are not limited to, the following:

- Review and evaluate the ACMUI and the NRC staff recommendations to determine if updates to the licensing guidance are necessary. Provide rationale.

- Draft revised licensing guidance in accordance with the outcome of the recommendations above.

MEMBERSHIP

The WG is sponsored by the NRC Office of Nuclear Material Safety and Safeguards (NMSS), Division of Material Safety, State, Tribal, and Rulemaking Programs (MSTR). It will operate as an NRC/Agreement State WG as described under the NRC Management Directive 5.3, "Agreement State Participation in Working Groups." The WG will be co-chaired by an NRC staff member and a representative from the Organization of Agreement States (OAS). Membership and responsibilities are as follows:

Ashley Cockerham, NRC, Co-Chair
Penny Lansizera, NRC Region I
Sara Forster, NRC Region III (Task 2 only)

Michael Ortiz, NM, Co-Chair
Victor Diaz, NM

The WG co-chairs may request, and the MSTR director may designate, an ACMUI member to serve as a WG member or advisor, if needed. The WG may also seek additional technical expertise on an as-needed basis.

SCHEDULE

For Task 1, the WG began activities in June 2015 with plans to submit a draft to ACMUI in August 2015. Final publication following ACMUI, the NRC management, and OAS review is expected in December 2015.

For Task 2, the WG anticipates starting activities in December 2015 with a draft to the ACMUI in February 2016. Final publication following ACMUI, the NRC management, and OAS review is expected in the summer of 2016.

MEETINGS

It is anticipated that all meetings will be conducted remotely. Staff will utilize electronic communication options (e.g., audio and/or video conference calls, e-mail, SharePoint, GoToMeeting) to facilitate interaction for the WG members.

LEVEL OF EFFORT

For Task 1, the expected level of effort is approximately 4-6 hours per week with weekly meetings for the first 6 weeks, and thereafter on an as-needed basis until the guidance revisions are complete.

For Task 2, the expected level of effort is approximately 2-3 hours per week with weekly meetings for the first 8 weeks, and thereafter on an as-needed basis until the guidance revisions are complete.

For NRC staff, work associated with the WG (e.g., meeting coordination and setup, WG discussions) should be charged to J00140 Working Groups and Guidance (348102-N). All other work on the guidance (e.g., research, review, editing and revisions) should be charged to J30140 Part 35 Guidance Document (344149).

APPROVAL

/RA/	***August 3, 2015***
Catherine Haney, Director, NRC/NMSS	Date
/RA/	***July 21, 2015***
Michael Welling, Chair, OAS	Date

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APPROVAL

Catherine Haney, Director, NRC/NMSS Date

Michael Welling, Chair, OAS Date

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