

Joint NRC/Agreement State Working Group

Iodine-125 and Palladium-103 Low Dose Rate Brachytherapy Seeds Used for Localization of Non-Palpable Lesions

Charter

PURPOSE

To evaluate if the existing Title 10 of the *Code of Federal Regulations* (10 CFR) 35.1000 guidance for Iodine-125 and Palladium-103 Low Dose Rate Brachytherapy Seeds Used for Localization of Non-Palpable Lesions, hereafter referred to as “existing guidance,” needs to be revised.

BACKGROUND

The existing guidance was developed in 2006 by an Agreement State working group (WG), with the assistance of staff from the U.S. Nuclear Regulatory Commission (NRC). This guidance was intended for the use of radioactive seeds to localize tissues in non-palpable lesions in the breast. These seeds, typically iodine-125 and palladium-103, were previously approved for the treatment of cancerous tumors under 10 CFR 35.400, but had decayed to a range between 200-300 $\mu\text{Ci}/\text{seed}$. The seeds were not intended to deliver a therapeutic dose to the tissue(s); therefore, the working group determined that the seeds used for radioactive seed localization procedures would be regulated under 10 CFR 35.1000.

The seed(s) were temporarily implanted within mammography or ultrasound suites and either surgically removed from the tissue specimen or removed by pathology and analyzed within 2 to 5 days post-implantation. The authorized user(s) who performed the seed implantation and explantation had to meet the criteria in 10 CFR 35.490 or 10 CFR 35.290 with supervision of a 10 CFR 35.490 authorized user and preceptor, and a minimum supervised work experience of three cases.

As stated on the NRC’s Medical Use Licensee Toolkit, 10 CFR 35.1000 licensing guidance will be updated when necessary to address comments from stakeholders. Since then, additional experience has been acquired. On March 19, 2015, a licensee delivered a presentation to the Advisory Committee on the Medical Uses of Isotopes (ACMUI) regarding his concerns with the existing guidance. In response to the presentation, the ACMUI Chairman formed a subcommittee to provide review, evaluate and provide recommendations for revisions to the existing guidance. The ACMUI will hold a public teleconference to discuss the subcommittee’s recommendation(s). Those recommendations will then be provided to this working group for consideration.

Given the above, the NRC and the Organization of Agreement States (OAS) believe that the existing guidance should be revisited by a joint NRC/OAS WG. The WG will review comments from stakeholders and the ACMUI to determine whether or not to revise the existing guidance document. In addition, all existing 10 CFR 35.1000 licensing guidance documents will be updated with administrative changes to include certain standard language and formatting.

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 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 OAS. The membership and responsibilities are depicted in the following table:

Organization	Working Group Members
OAS	Robert Dansereau (NY), Co-Chair
NRC NMSS/MSTR	Sophie Holiday, Co-Chair
NRC Region I Office/Division of Nuclear Materials Safety	Robert Gallagher
OAS	Philip Griffin (UT)

The WG may choose to designate a member from the NRC's ACMUI to serve as a WG member or advisor. The WG may seek additional technical expertise from the ACMUI or an NRC medical consultant on an as-needed basis.

OBJECTIVE

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

- a) Review and evaluate the existing guidance, available documents, comments submitted from stakeholders and the ACMUI's recommendations, and determine if the guidance needs to be revised. If so, document what revisions are needed and why.
- b) Add standard language and formatting that appears in 10 CFR 35.1000 licensing guidance established after the initial publication of this existing guidance (2006).
- c) Issue a revised 10 CFR 35.1000 licensing guidance document in accordance with the outcomes of the tasks above.

SCHEDULE

The WG will begin meeting after both NRC and OAS approve this charter, by May 2015. The goal is for the WG to complete a final draft document for submission to NRC management and OAS for review by April 2016.

LEVEL OF EFFORT

WG members should expect to provide a substantial commitment to this activity until the objectives are completed. The expected level of effort is 4-8 hours per week, with bi-weekly meetings.

All work associated with the development of this supplemental inspection guidance (i.e., meetings, reviews, and revisions), should be charged to TAC J00140, Working Groups and Guidance.

MEETINGS

It is anticipated that all meetings will be via teleconference. Maximum use will be made of available electronic communication options to facilitate interaction within the WG and among its members. Examples of these options include conference calls, e-mail, SharePoint, and the "go to meeting" service.


Catherine Haney, Director, NRC/NMSS

5/19/15
Date



Michael Welling, Chair, OAS

5/20/15
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/RA Keith McConnell for/	May 19, 2015
Catherine Haney, Director, NRC/NMSS	Date

/RA/	May 20, 2015
Michael Welling, Chair, OAS	Date

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OFC	MSTR/MSEB	MSTR/MSEB	NMSS/MSTR	Tech Ed	NMSS
NAME	S. Holiday	R. Sun for D. Bollock	P. Henderson for L. Dudes	C. Poland	K. McConnell for C. Haney
DATE	04/16/15	04/17/15	04/24/15	04/28/15	05/19/15

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