Regulatory Guide Periodic Review

Regulatory Guide Number: **6.9**
Revision: **1**

Title: **Establishing Quality Assurance Programs for the Manufacturing and Distribution of Sealed Sources and Devices Containing Byproduct Material**

Office/Division/Branch: **NMSS/DFCSS/FMB**
Technical Lead: **Herrera Thomas**

Staff Action Decided: **Reviewed with Issues Identified for Future Consideration**

1. What are the known technical or regulatory issues with the current version of the regulatory guide (RG)?

This RG references 10 CFR 32.110, "Acceptance Sampling Procedures under Certain Specific Licenses," that was removed from the regulations in a 2012 rulemaking. The RG should be revised to remove this reference.

2. What is the impact on internal and external stakeholders of <u>not</u> updating the RG for the known issues, in terms of numbers of licensing and inspection activities?

In addition, NMSS is revising its NUREG-1556 guidance documents. NUREG-1556, Volume 3, Revision 1, which is referenced in the RG, is in the process of being revised and Revision 2 is expected be issued later in 2015.

3. What is an estimate of the level of effort needed to address identified issues in terms of full-time equivalent (FTE) and contractor resources?

An estimate of the effort needed to revise this RG is between 0.10 FTE and 0.20 FTE.

4. Based on the answers to the questions above, what is the recommended staff action for this guide (Reviewed with no issues identified, Reviewed with issues identified for future consideration, Revise, or Withdraw)?

Reviewed with issues identified for future consideration.

5. If a RG should be revised, provide a conceptual plan and timeframe to accomplish this.

Publish the draft revision of this guide for public comment during the first quarter of calendar year 2015.

NOTE: This review was conducted in March 2015 and reflects the staff's plans as of that date. These plans are tentative and subject to change.