

Regulatory Guide Number: 6.6, Revision 0

Title: Acceptance Sampling Procedures for Exempted and Generally Licensed Items Containing Byproduct Material

Office/Division/Branch: NMSS/MSTR/MSLB

Technical Lead: Richard Struckmeyer

SUBJECT: Basis for Withdrawal

1. What regulation(s) did the Regulatory Guide support?

Regulatory Guide (RG) 6.6, "Acceptance Sampling Procedures for Exempted and Generally Licensed Items Containing Byproduct Material," was published in June 1974, to provide guidance to comply with the requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) 32.110, "Acceptance Sampling Procedures Under Certain Specific Licenses."

2. What was the purpose of the Regulatory Guide?

The information in RG 6.6 describes sampling procedures intended to limit the risk of products with excessively poor conformance to specifications from reaching the public.

3. How was the Regulatory Guide used?

This RG describes specific procedures concerning acceptance sampling plans that could be used by applicants and licensees, as well as the NRC staff, in license applications and inspection activities.

4. Why is the Regulatory Guide no longer needed?

RG 6.6 describes a prescriptive methodology for determining whether a product should be accepted or rejected based on statistical sampling methods. In 2012, the NRC amended its regulations in 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," to delete 10 CFR Part 32.110 (77 FR 43673; July 25, 2012), so that it was no longer required. As stated in the *Federal Register* (77 FR 43673; July 25, 2012), "[t]he Commission determined that the requirements for manufacturers or initial distributors of exempt and generally licensed products were in some cases overly prescriptive, particularly in the areas of prototype testing and acceptance sampling/quality control (QC) procedures. Such a prescriptive approach is easy to implement and regulate, but is relatively inflexible. This rule is intended to focus the regulations on performance, rather than procedures. The regulations retain general requirements and provide general standards by which performance may be judged, rather than specifying detailed procedures that must be followed." Thus, the NRC decided to allow acceptance sampling to be performance-based, rather than specifying procedural details.

The staff believes that there was limited use of the guidance in RG 6.6 since its publication in 1974. The acceptance sampling procedures and tables included in the guide became obsolete since licensees can now easily use widely available computer software to determine their own acceptance sampling procedures. This allows licensees to select procedures that would best monitor their manufacturing processes to provide sufficient evidence that the appropriate components are capable of performing their intended functions.

5. What guidance is available once the Regulatory Guide is withdrawn?

Specific guidance is not needed since the NRC made the decision to amend its regulations in 2012 to use a more performance-based approach.

6. Is the Regulatory Guide referenced in other documents and what are the “ripple effects” on these documents if it is withdrawn?

No reference to Regulatory Guide 6.6 is found in various NRC documents that discuss topics of this or a similar nature such as the materials Inspection Manuals and Procedures, NUREGs, and Regulatory Guides. In particular, this includes the NRC Inspection Manual Chapter 2800, “Materials Inspection Program,” all volumes of the NUREG-1556 series, “Consolidated Guidance about Materials Licensees,” NUREG-1717, “Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials,” NUREG/CR-5883, “Health Risk Assessment of Irradiated Topaz,” and Regulatory Guides in Division 6, “Products” (it should be noted that NUREG-1556, Volume 12 lists a series of RGs including RG 6.6; however, it is not mentioned in the text.)

Some licensees may have included this guidance in their licensing basis. Although a RG is withdrawn, current licensees may continue to use it, and withdrawal does not affect any existing licenses or agreements. Withdrawal means that the guide should not be used for future NRC licensing activities.

7. What is the basis for believing that no guidance similar to that in the Regulatory Guide will ever be needed?

In 2012 the Commission determined that the requirements for manufacturers or initial distributors of exempt and generally licensed products were in some cases overly prescriptive. As a result, the NRC regulations in 10 CFR Part 32, “Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material,” were amended to remove 10 CFR Part 32.110 (77 FR 43673; July 25, 2012). The rulemaking focused the regulations on performance rather than procedures. Therefore, the guidance in RG 6.6 was not needed. The staff does not intend to require prescriptive guidance in the future.

8. Will generic guidance still be needed?

Generic prescriptive guidance will not be needed since the staff now requires a performance-based approach.

s

9. What is the rationale for withdrawing this Regulatory Guide instead of revising it?

The guidance contained in RG 6.6 is no longer needed to meet an NRC regulation since 10 CFR Part 32.110 was deleted from the regulations (77 FR 43673; July 25, 2012) and the RG will not be used for future license applications. Although a RG is withdrawn, current licensees may continue to use it, and withdrawal does not affect any existing licenses or agreements. Withdrawal means that the guide should not be used for future NRC licensing activities. However, if a licensee has committed to such guidance the NRC inspectors will continue to review their commitment for compliance.

10. Do other agencies rely upon the Regulatory Guide, e.g., the Agreement States, National Aeronautical and Space Administration, Department of Energy?

The staff is unaware of any other agency or an Agreement State that uses or relies on this guidance.