

REGULATORY ANALYSIS

DRAFT REGULATORY GUIDE (DG-8054) “APPLICATIONS OF BIOASSAY FOR URANIUM” (Proposed Revision 1 of Regulatory Guide 8.11)

Regulatory Guide 8.11, “Applications of Bioassay for Uranium,” describes methods that the staff of the U.S. Nuclear Regulatory Commission (NRC) consider acceptable for the development and implementation of a bioassay program by NRC licensees that will monitor the intake of mixtures of the naturally occurring isotopes of uranium (U-234, U-235, and U-238) by occupational workers. A bioassay is a determination of the kind, quantity, location, or retention of radionuclides in the body by direct (in vivo) measurement or by indirect (in vitro) analysis of material excreted or removed from the body. The purpose of the proposed Revision 1 to Regulatory Guide 8.11 is to update the references to NRC regulations, to approve for use sections of a voluntary consensus standard, namely, the American National Standards Institute/Health Physics Society (ANSI/HPS) N13.22-2013 standard, “Bioassay Program for Uranium,” as a means for licensees to demonstrate compliance with certain NRC requirements, and to identify the bioassay interpretation method in the NRC document NUREG/CR-4884, “Interpretation of Bioassay Measurement,” as an acceptable method to comply with NRC requirements.

1. Statement of the Problem

The NRC published Regulatory Guide 8.11, “Application of Bioassay for Uranium,” in June 1974 to provide licensees and applicants with agency-approved guidance for complying with the then-current version of Title 10, of the *Code of Federal Regulations* (10 CFR) Part 20, “Standards for Protection against Radiation,” with respect to uranium bioassay methods. In a 1991 rulemaking, the NRC promulgated amendments to its radiation protection regulations in 10 CFR Part 20 (May 21, 1991; 56 FR 23360). The 1991 rulemaking included substantive amendments to the 10 CFR Part 20 regulations as well as a wholesale renumbering of those regulations. As such, the current version of Regulatory Guide 8.11 does not reference the correct regulation numbers. In addition, substantial scientific and technical advancement in health physics, including in the area of bioassays, has occurred since Regulatory Guide 8.11 was first issued in 1974. Notably, the NRC published NUREG/CR-4884 in 1987 and the ANSI/HPS published its N13.22-2013 standard in 2013 (the 2013 standard reaffirmed ANSI/HPS N13.22-1995, which was published in October 1995).

2. Objective

The objective of this proposed regulatory action is to update Regulatory Guide 8.11, by aligning its regulatory references with the current 10 CFR Part 20 regulations, by aligning the guidance in Regulatory Guide 8.11 with the recommended uranium bioassay criteria and methodologies provided in the ANSI/HPS N13.22-2013 standard as a means for licensees to demonstrate compliance with paragraph (e) of the NRC regulation, 10 CFR 20.1201, “Occupational Dose Limits for Adults,” which requires licensees to limit the soluble uranium intake to an occupational worker to 10 milligrams in a week, in addition to annual occupational dose limits, and paragraph (a) of the NRC regulation, 10 CFR 20.1204, “Determination of Internal Exposure,” which requires licensees to take suitable and timely measurements of concentrations of radioactive materials in air in work areas and the quantities of radionuclides in

the bodies of occupational workers. A further objective of this proposed regulatory action is to identify the bioassay interpretation methods described in NUREG/CR-4884 as being acceptable methods for the interpretation of bioassay data to estimate intakes and doses (for purposes of compliance with 10 CFR 20.1201(e) and 10 CFR 20.1204(a)).

The proposed revision to Regulatory Guide 8.11 to endorse portions of a voluntary consensus standard is consistent with the NRC policy of evaluating the latest versions of national consensus standards to determine their suitability for endorsement by NRC regulatory guides. This approach also will comply with the NRC's Management Directive (MD) 6.5, "NRC Participation in the Development and Use of Consensus Standards" (Agencywide Documents Access and Management System Accession No. ML100600460) and is in accordance with the National Technology Transfer and Advancement Act of 1995, Public Law 104-113.

3. Alternative Approaches

The NRC staff considered the following alternative approaches:

1. Do not revise Regulatory Guide 8.11;
2. Withdraw Regulatory Guide 8.11; and
3. Revise Regulatory Guide 8.11 to update regulatory cross-references and to endorse a voluntary consensus standard that will serve as a means for licensees to demonstrate compliance with certain NRC requirements.

Alternative 1: Do Not Revise Regulatory Guide 8.11

Under this "no-action" alternative, the NRC would not revise Regulatory Guide 8.11, and the current guidance, issued in 1974, would be retained. If the NRC does not take action, there would not be any changes in costs or benefit to the public, licensees, or the NRC. However, the "no-action" alternative would not address identified concerns with the current version of the regulatory guide. The NRC would continue to review each application on a case-by-case basis. This alternative is considered the "no-action" alternative and provides a baseline condition from which any other alternatives will be assessed.

Alternative 2: Withdraw Regulatory Guide 8.11

Under this alternative, the NRC would withdraw Regulatory Guide 8.11. This alternative would eliminate the need to update Regulatory Guide 8.11. This alternative, however, would eliminate the only readily available description of the methods the NRC staff considers acceptable for demonstrating compliance with 10 CFR 20.1201(e) and 10 CFR 20.1204(a).

Alternative 3: Revise Regulatory Guide 8.11

Under this alternative, which is the proposed alternative, the NRC would revise Regulatory Guide 8.11. The proposed revision would update the regulatory cross-references in the Regulatory Guide to the current version of the NRC's radiation protection regulations in 10 CFR Part 20. In addition, the proposed revision would endorse the use of a consensus standard, ANSI/HPS N13.22-2013, and a NRC document, NUREG/CR-4884, as a means for NRC licensees to demonstrate compliance with the requirements of NRC regulation 10 CFR 20.1201(e) and 10 CFR 20.1204(a).

The impact to the NRC would be the costs associated with preparing and issuing the regulatory guide revision. The impact to the public would be the voluntary costs associated with reviewing and providing comments to the NRC during the public comment period. The value to NRC staff and the NRC's licensees would be the benefits associated with enhanced efficiency and effectiveness in using common guidance documents as the technical basis for license applications and other interactions between the NRC and its regulated entities.

Conclusion

Based on this regulatory analysis, the NRC staff concludes that the proposed revision of Regulatory Guide 8.11 is warranted. The action will enhance the health and safety of occupational workers at NRC licensed facilities by providing guidance for monitoring the unwanted and unexpected intake of mixtures of the naturally occurring isotopes of uranium (U-234, U-235, and U-238).