



DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-8054

(Proposed Revision 1 of Regulatory Guide 8.11, dated June 1974)

APPLICATIONS OF BIOASSAY FOR URANIUM

A. INTRODUCTION

Purpose

This regulatory guide describes methods that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable for the development and implementation of a bioassay program that will monitor the intake of mixtures of the naturally occurring isotopes of uranium (U-234, U-235, and U-238) by occupational workers. It would apply to current and future holders of special nuclear material licenses under Title 10 of the *Code of Federal Regulations* (10 CFR), part 70, “Domestic Licensing of Special Nuclear Material,” (Ref. 1) and certificates of compliance or approvals of a compliance plan for gaseous diffusion plants under 10 CFR part 76, “Certification of Gaseous Diffusion Plants,” (Ref. 2) if they are also applicants for or holders of special nuclear materials licenses under 10 CFR part 70.

Applicable Rules and Regulations

- The NRC regulation, 10 CFR 20.1204(a), “Determination of Internal Exposure” (Ref. 3), states that each licensee shall, when required under 10 CFR 20.1502, “Conditions Requiring Individual Monitoring of External and Internal Occupational Dose,” take suitable and timely measurements of: (1) concentrations of radioactive materials in air in work areas, (2) quantities of radionuclides in the body, (3) quantities of radionuclides excreted from the body, or (4) combinations of these measurements.
- The NRC regulation, 10 CFR 20.1201(e), “Occupational Dose Limits for Adults,” requires licensees to limit the occupational intake by an individual of soluble uranium to 10 milligrams (mg) per week in consideration of the chemical toxicity.
- The NRC regulation, 10 CFR part 70, “Domestic Licensing of Special Nuclear Material.”
- The NRC regulation, 10 CFR part 76, “Certification of Gaseous Diffusion Plants,” requires a quality assurance (QA) program satisfying the applicable provisions of the American Society of Mechanical

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received final staff review or approval and does not represent an official NRC final staff position. Public comments are being solicited on this draft guide and its associated regulatory analysis. Comments should be accompanied by appropriate supporting data. Comments may be submitted through the Federal-rulemaking Web site, <http://www.regulations.gov>, by searching for Docket ID: NRC-2014-0210. Alternatively, comments may be submitted to the Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Comments must be submitted by the date indicated in the *Federal Register* notice.

Electronic copies of this draft regulatory guide, previous versions of this guide, and other recently issued guides are available through the NRC’s public Web site under the Regulatory Guides document collection of the NRC Library at <http://www.nrc.gov/reading-rm/doc-collections/reg-guides/>. The draft regulatory guide is also available through the NRC’s Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html> under Accession No. ML14133A599. The regulatory analysis may be found in ADAMS under Accession No. ML14133A612.

Engineers (ASME) standard NQA-1-1994, "Quality Assurance Program Requirements for Nuclear Facilities (with Addenda)" (Ref. 4).

Related Rules and Regulations

- The NRC regulation, 10 CFR 20.1703(i), "Use of Individual Respiratory Protection Equipment," allows for an estimated dose based upon an assumption that the concentration of radioactive material that is inhaled when respirators are worn is equal to the ambient concentration in air without respiratory protection divided by the assigned protection factor. This regulation requires that if the dose is later found to be greater than the estimated dose, the corrected value must be used; if the dose is later found to be less than the estimated dose, the corrected value may be used.
- The NRC regulation, 10 CFR 20.2202, "Notification of Incidents," sets forth the criteria for those events involving byproduct, source, or special nuclear material possessed by the licensee that require either immediate notification or notification within 24 hours.
- The NRC regulation, 10 CFR 20.2203, "Reports of Exposure, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits," sets forth the criteria for submitting a written report to the NRC on a reportable event.
- The NRC regulation, 10 CFR 20.2205, "Reports to individuals of exceeding dose limits," require that when a licensee is required by sections 20.2203 or 2204 to send a report to the Commission of any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee shall also provide the individual a report of the data included in the report to the Commission.

Related Guidance

- Regulatory Guide (RG) 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program" (Ref. 5), provides methods acceptable to the NRC staff for estimating intake of radionuclides using bioassay measurements.
- RG 8.22, "Bioassay at Uranium Mills" (Ref. 6), describes a bioassay program acceptable to the NRC staff for uranium mills (and applicable portions of uranium conversion facilities where the possibility of exposure to yellowcake dust exists), including exposure conditions with and without the use of respiratory protection devices.
- RG 8.25, "Air Sampling in the Workplace" (Ref. 7), provides guidance on air sampling in restricted areas of the workplace.
- RG 8.30, "Health Physics Surveys in Uranium Recovery Facilities" (Ref. 8), provides guidance on health physics surveys that are acceptable to the NRC staff for protecting workers at uranium recovery facilities (e.g., uranium mills, in-situ leach facilities, ion exchange recovery facilities, heap leach facilities) from radiation and the chemical toxicity of uranium.
- RG 4.15, "Quality Assurance for Radiological Monitoring Programs (Inception through Normal Operations to License Termination) - Effluent Streams and the Environment" (Ref. 9), provides necessary QA guidance on monitoring measurements that support the radiation and environmental protection programs are reasonably valid and of a defined quality.

- The National Council on Radiation Protection and Measurements (NCRP) Report 161, “Management of Persons Contaminated with Radionuclides” (Ref. 10), provides guidance for emergency treatment if a severe intake of uranium substances were to occur.

Purpose of Regulatory Guides

The NRC issues regulatory guides to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency’s regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required. Methods and solutions that differ from those set forth in regulatory guides will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

Paperwork Reduction Act

This regulatory guide contains information collection requirements covered by 10 CFR part 20 “Standards for Protection against Radiation,” and 10 CFR part 70 “Domestic Licensing of Special Nuclear Material,” that the Office of Management and Budget (OMB) approved under OMB control number 3150-0014 and 3150-0009, respectively. The NRC may neither conduct nor sponsor, and a person is not required to respond to, an information collection request or requirement unless the requesting document displays a currently valid OMB control number.

B. DISCUSSION

Reasons for Revision

RG 8.11 was issued in June 1974 to provide guidance to NRC licensees on methods the staff found acceptable to demonstrate compliance with the then-current version of NRC’s radiation protection regulations in 10 CFR part 20. In a 1991 rulemaking, the NRC promulgated substantive amendments to its 10 CFR part 20 regulations. As such, this revision to the guide updates the guide’s cross-references to the current 10 CFR part 20 regulations.

In addition, this revision identifies the bioassay interpretation methods described in NUREG/CR-4884, “Interpretation of Bioassay Measurement” (Ref. 11) and RG 8.9, “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program,” as being acceptable methods for the interpretation of bioassay data to estimate intakes and doses. This revision also approves for use certain 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,” (Ref.12) as a means for licensees to demonstrate compliance with the NRC regulations 10 CFR 20.1201(e) and 10 CFR 20.1204(a).

Background

This RG pertains to uranium bioassay programs in general; however, it does not address issues related to bioassay measurement techniques such as whole body counting and excreta bioassay sampling and measurements.

Specific information regarding uranium intake during mining (extracting natural uranium ore from the earth) and milling (leaching uranium from the ore and concentrating it to produce yellowcake,

including UO_2F_2 , ammonium diuranate $((\text{NH}_4)_2\text{U}_2\text{O}_7)$, uranyl peroxides $(\text{UO}_4 \cdot n\text{H}_2\text{O})$, and uranium trioxide) can be found in RG 8.22, “Bioassay at Uranium Mills.”

Licensee determinations regarding participation in the uranium bioassay program should be based on estimates of the type and quantity of intakes that may occur using procedures that are expected to take place at each facility during the monitoring year. The program is confirmatory in that low or zero results may indicate that the measures in the workplace to control uranium materials are effective and that no unexpected intakes would occur. Based on operational experience, licensees may be able to justify adjustments in their bioassay program, such as a reduction in bioassay routine monitoring frequency, the inclusion of fewer workers in the bioassay program, or licensees may seek an alternative bioassay program.

Harmonization with International Standards

The NRC has a goal of harmonizing its guidance with international standards, to the extent practical. The International Commission on Radiological Protection (ICRP) and the International Atomic Energy Agency (IAEA) have issued a significant number of standards, guidance and technical documents, and recommendations addressing good practices in most aspects of radiation protection. The guidance of this RG is generally consistent with the guidance in the following documents:

- ICRP Publication 30, “Limits for Intakes of Radionuclides by Workers” (Ref. 13)
- ICRP Publication 60, “Recommendations of the International Commission on Radiological Protection” (Ref. 14)
- ICRP Publication 68, “Dose Coefficients for Intakes of Radionuclides by Workers” (Ref. 15)
- ICRP Publication 71, “Age-Dependent Doses to Members of the Public from Intake of Radionuclides—Part 4 Inhalation Dose Coefficients” (Ref. 16)
- National Radiological Protection Board (NRPB)-W22, “Industrial Uranium Compounds: Exposure Limits, Assessment of Intake and Toxicity after Inhalation” (Ref. 17)
- IAEA Safety Guide RS-G-1.2, “Assessment of Occupational Exposure due to Intake of Radionuclides” (Ref. 18)

The NRC encourages licensees to consult these and other international documents and implement good practices, where applicable, that are consistent with NRC regulations. It should be noted that some of the recommendations issued by these international organizations do not correspond to the requirements specified in the NRC’s regulations. In such cases, the NRC’s requirements take precedence.

Documents Discussed in Staff Regulatory Guidance

This RG endorses, in part, the use of one or more codes or standards developed by external organizations and other third party guidance documents. These codes, standards, and third party guidance documents may contain references to other codes, standards, or third party guidance documents (“secondary references”). If a secondary reference has itself been incorporated by reference into NRC regulations as a requirement, then licensees and applicants must comply with that standard as set forth in the regulation. If the secondary reference has been endorsed in an RG as an acceptable approach for meeting an NRC requirement, then the standard constitutes a method acceptable to the NRC staff for

meeting that regulatory requirement as described in the specific RG. If the secondary reference has neither been incorporated by reference into NRC regulations nor endorsed in an RG, then the secondary reference is neither a legally binding requirement nor a “generic” NRC approved acceptable approach for meeting an NRC requirement. However, licensees and applicants may consider and use the information in the secondary reference, if appropriately justified, consistent with current regulatory practice, and consistent with applicable NRC requirements.

C. STAFF REGULATORY POSITION

The NRC staff considers certain sections of ANSI/HPS N13.22-2013, “Bioassay Programs for Uranium,” acceptable for use as stated in the staff regulatory positions listed below.

1. Participation Criteria

Licensees must ensure that the appropriate individuals are assigned on a scheduled and repeatable basis to submit specimens for bioassay or to report for in-vivo measurements in the bioassay program. Decisions about which individuals should participate in bioassay programs should be based on the criteria described below:

- a. individuals who could receive certain dose as stated in 10 CFR 20.1502(a) and 20.1502(b);
- b. individuals who work with uranium or who are close enough to the chemical process using uranium (e.g., enrichment) that exposure and intake is possible (e.g., within a few meters and in the same room as the worker handling the radioactive material); or
- c. individuals described in Section 5 (“Selection of Individuals for Bioassay”) of ANSI/HPS N13.22-2013 and individuals who work under the specified conditions listed in Table 1 (“Implementation Levels: Mass or Activity Levels Above Which at Least Minimum Uranium Bioassay Program Shall be Implemented”) of ANSI/HPS N13.22-2013.

2. Conditions under which Bioassay Should Be Performed

Licensees must ensure that bioassays are performed for appropriate conditions. The conditions under which a uranium bioassay should be performed that are described in Section 3 (“Establishing the Need for an Internal Dosimetry Program”) of ANSI/HPS N13.22-2013, are acceptable.

3. Types of Bioassay that Should Be Performed

Licensees must ensure that the appropriate types of bioassay are performed. The bioassay types that should be performed based on the solubility (i.e., lung classes) of uranium materials in the body that are described in Table 8 (“Minimum Frequencies of Bioassay”) of ANSI/HPS N13.22-2013, are acceptable.

4. Bioassay Frequency

In any particular facility, the frequency of bioassays should be based on estimates of the type and quantity of intakes that are likely to occur during the monitoring year.

The bioassay frequencies for routine sampling, as well as for bioassays in other situations, that are described in Section 4.2 (“Frequencies”) of ANS/HPS N13.22-2013, are acceptable. If special circumstances exist at the licensee’s facility, a submittal should be provided to NRC for review and assessment of the proposed frequencies. Table 8 of ANS/HPS N13.22-2013 prescribes the minimum frequencies of bioassays that are acceptable. Section 4.2.2 (“Other Frequency Situations”) of ANS/HPS N13.22-2013 describes those situations where it may be necessary to sample more frequently than is indicated in Table 8.

5. Action Levels and the Associated Actions

Licensees should ensure that the appropriate actions are taken based on bioassay results. The action levels for bioassay that are listed in Table 2 (“Urinalysis Action Levels”) and Table 7 (“Action Levels for Special Class Y Uranium”) and described in Section 6 (“Action Levels and Follow-up Actions”) of ANS/HPS N13.22-2013 are acceptable. However, where exposure conditions and the characteristics of the materials differ significantly from those recommended in the ANSI standard, the licensee may modify the derivation of the action levels to conform to local conditions at the facility.

6. Limiting Chemical Toxicity and Work Restrictions

The NRC regulation, 10 CFR 20.1201(e), “Occupational Dose Limits for Adults,” requires that licensees limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity, which may cause damage to the kidneys. Paragraph 20.1201(e) also directs licensees to footnote 3 of appendix B of 10 CFR part 20; footnote 3 concerns soluble mixtures of U-238, U-234, and U-235 in air. Licensees should develop the required procedures to prevent uranium exposures from exceeding this non-radiological limit.

7. Bioassay Interpretation

Licensees should ensure that bioassay data should be interpreted to estimate intakes and doses using the retention and excretion data. RG 8.9, Section 4 (“Interpretation of Bioassay Measurements”), or NUREG/CR-4884, “Interpretation of Bioassay Measurements,” provide guidance on bioassay interpretation.

In addition, commercial software is available for bioassay interpretations and internal dose calculations. For NRC staff to accept the computer results, all conditions related to the results for the computations should be presented to NRC. The assumptions, including the conditions of the uranium and sampling information associated for the bioassay result, should be ensured to be accurate (i.e., by verification and validation).

8. Uranium Air Concentrations

Licensees should ensure that uranium concentration in air is appropriately determined. Methods for airborne uranium surveillance and for determining uranium air concentrations are described in RG 8.25, “Air Sampling in the Workplace” and in RG 8.30, “Health Physics Surveys in Uranium Recovery Facilities.” The guidance in RG 8.22, “Bioassay at Uranium Mills,” may also be applicable depending on involvement of uranium materials at the licensee’s facility.

9. Quality Assurance (QA)

The NRC regulation, 10 CFR 76.93, “Quality Assurance,” requires a QA program satisfying the applicable provisions of the ASME standard NQA-1-1989, “Quality Assurance Program Requirements

for Nuclear Facilities.” The reference to this ASME standard is also included in RG 4.15, “Quality Assurance for Radiological Monitoring Programs (Inception through Normal Operations to License Termination)—Effluent Streams and the Environment” and in ANSI/HPS N13.22-2013, Section 7, “Quality Assurance and Control.”

10. Reports and Notifications to the NRC and Exposed Individual

If an overexposure occurs, immediate or 24-hour notifications shall be made to the NRC. In addition, the NRC regulations in 10 CFR 20.2203 and 20.2205 also require that a report of the exposure shall be submitted to the NRC and sent to the individual, respectively, timely.

D. IMPLEMENTATION

The purpose of this section is to provide information on how licensees may use this RG. In addition, it describes how the NRC staff complies with the backfitting provisions in 10 CFR 70.76(a)(1) and 10 CFR 76.76(a)(1).

Use by Licensees

Licensees may voluntarily use the guidance in this RG to demonstrate compliance with the underlying NRC regulations. Methods or solutions that differ from those described in this RG may be deemed acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations. Current licensees (i.e., persons holding a NRC issued license as of the date of issuance of this RG) may continue to use guidance the NRC found acceptable for complying with the identified regulations as long as their current licensing basis remains unchanged. The acceptable guidance may be from the previous version of this RG. Licensees may use the information in this RG for actions which do not require NRC review and approval. Licensees may also use the information in this RG to resolve regulatory or inspection issues.

Use by NRC Staff

The NRC staff does not intend or approve any imposition or backfitting of the guidance in this RG. The NRC staff does not expect any current licensee to use or commit to using the guidance in this RG, unless such licensee makes a change to its licensing basis. The NRC staff does not expect or plan to initiate NRC regulatory action that would require the use of this RG. Examples of such regulatory actions include the issuance of an order or generic communication, or the promulgation of a rule, requiring the use of this RG without further backfit consideration.

During regulatory discussions on licensee-specific operational issues, the NRC staff may discuss with licensees various actions consistent with staff positions in this RG, as one acceptable means of meeting the underlying NRC regulatory requirements. Such discussions would not ordinarily be considered backfitting, even if prior versions of this RG are part of the licensee's licensing basis. However, unless this RG is part of the licensee's licensing basis, the staff may not represent to the licensee that the licensee's failure to comply with the positions in this RG constitutes a violation.

If a current licensee voluntarily seeks a license amendment or change and (1) the NRC staff's consideration of the request involves a regulatory issue directly relevant to this RG and (2) the specific subject matter of this RG is an essential consideration in the staff's determination of the acceptability of the licensee's request, then the staff may request that the licensee either follow the guidance in this regulatory guide or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory requirements. Such a request by the NRC staff is not considered backfitting as defined in 10 CFR 70.76(a)(1) or 10 CFR 76.76(a)(1).

If a licensee believes that the NRC is either using this RG or requesting or requiring the licensee to implement the methods or processes in this RG in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfit appeal with the NRC in accordance with the guidance in NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection" (Ref. 19) and NUREG-1409, "Backfitting Guidelines" (Ref. 20).

REFERENCES¹

1. Title 10 of the *Code of Federal Regulations*, (10 CFR), part 70, “Domestic Licensing of Special Nuclear Material.” U.S. Nuclear Regulatory Commission (NRC), Washington, DC.
2. 10 CFR part 76, “Certification of Gaseous Diffusion Plants.” NRC, Washington, DC.
3. 10 CFR part 20, “Standards for Protection against Radiation.” NRC, Washington, DC.
4. ASME Standard NQA-1-1994, “Quality Assurance Program Requirements for Nuclear Facilities (with Addenda),” American Society of Mechanical Engineers, New York, NY²
5. NRC, Regulatory Guide (RG) 8.9, “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program.” NRC, Washington, DC.
6. NRC, RG 8.22, “Bioassay at Uranium Mills.” NRC, Washington, DC.
7. NRC, RG 8.25, “Air Sampling in the Workplace.” NRC, Washington, DC.
8. NRC, RG 8.30, “Health Physics Surveys in Uranium Recovery Facilities.” NRC, Washington, DC.
9. NRC, RG 4.15, “Quality Assurance for Radiological Monitoring Programs (Inception through Normal Operations to License Termination) - Effluent Streams and the Environment.” NRC, Washington, DC.
10. NCRP Report 161, “Management of Persons Contaminated with Radionuclides.” National Council on Radiation Protection and Measurements, Bethesda, MD, 2008.³
11. NUREG/CR-4884, “Interpretation of Bioassay Measurement.” NRC, Washington, DC.
12. ANSI/HPS Standard, N13.22-2013, “Bioassay Programs for Uranium.” American National Standards Institute: Health Physics Society, McLean, VA.⁴
13. ICRP Publication 30, “Limits for Intakes of Radionuclides by Workers: Part 1.” International Commission on Radiological Protection, Pergamon Press, Oxford, England, 1979.⁵

¹ Publicly available NRC-published documents are available online through the NRC Library on the NRC’s public Web site at <http://www.nrc.gov/reading-rm/doc-collections/>. The documents can also be viewed online or printed for a fee in the NRC’s Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is USNRC PDR, Washington, DC 20555; telephone 301-415-4737 or (800) 397-4209; fax (301) 415-3548; and e-mail pdr.resource@nrc.gov.

² Copies of American Society of Mechanical Engineers (ASME) documents may be purchased through their Web site at: <http://www.techstreet.com/products/957095>

³ Copies of the National Council on Radiation Protection and Measurements (NCRP) documents may be obtained through the organization’s Web site: <http://www.ncrponline.org/Publications/Publications.html>] or by writing to NCRP at 7910 Woodmont Avenue, Suite 400, Bethesda, MD 20814-3095, telephone 301-657-2652, fax: 301-907-8768.

⁴ Copies of American National Standards Institute (ANSI) documents may be purchased through their Web site at: <http://webstore.ansi.org/>.

14. ICRP Publication 60, "Recommendations of the International Commission on Radiological Protection." ICRP, Pergamon Press, Oxford, England, 1991.
15. ICRP Publication 68, "Dose Coefficients for Intakes of Radionuclides by Workers." ICRP, Pergamon Press, Oxford, England, 1994.
16. ICRP Publication 71, "Age-Dependent Doses to Members of the Public from Intake of Radionuclides—Part 4 Inhalation Dose Coefficients." ICRP, Pergamon Press, Oxford, England, 1995.
17. National Radiological Protection Board, Stradling, N., Hodgson, A., Ansoberlo, E., Bérard, P., Etherington, G., Fell, T., Rance, E., and Le Guen, B., "Industrial Uranium Compounds: Exposure Limits, Assessment of Intake and Toxicity after Inhalation." Report W22, National Radiological Protection Board, Chilton, England: October 2002.⁶
18. IAEA, Safety Guide No. RS-G-1.2, "Assessment of Occupational Exposure due to Intake of Radionuclides." International Atomic Energy Agency, Safety Standards Series, Vienna.1999.⁷
19. NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection." NRC, Washington, DC.
20. NUREG-1409, "Backfitting Guidelines." NRC, Washington, DC.

⁵ Copies of the International Commission on Radiological Protection (ICRP) documents may be obtained through the organization's Web site: <http://www.icrp.org/> or by writing to ICRP at 280 Slater Street, Ottawa, Ontario K1P 5S9, CANADA, telephone +1(613) 947-9750, fax: +1(613) 944-1920.

⁶ The NRPB-W22 report may be obtained at the National Radiological Protection Board and is available online at: <http://www.hpa.org.uk/Publications/Radiation/NPRBArchive/NRPBWSeriesReports/2002nrpbw022/>

⁷ Copies of International Atomic Energy Agency (IAEA) documents may be obtained through their Web site at: <http://www.iaea.org> or by writing the International Atomic Energy Agency P.O. Box 100 Wagramer Strasse 5, A-1400 Vienna, Austria. Telephone (+431) 2600-0, Fax (+431) 2600-7, or E-Mail at Official.Mail@IAEA.Org