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DRAFT REGULATORY GUIDE

Contact: C. Sun
(301) 251-7912

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APPLICATIONS OF BIOASSAY FOR I-125 and I-131

A. INTRODUCTION

Title 10, Section 20.1204(a) of the *Code of Federal Regulations* (10 CFR 20.1204(a)) (Ref. 1) states that each licensee must, "when required…take suitable and timely measurements of—(1) Concentrations of radioactive materials in air in work areas; or (2) Quantities of radionuclides in the body; or (3) Quantities of radionuclides excreted from the body; or (4) Combinations of these measurements."

This regulatory guide provides criteria and methods acceptable to the staff of the U.S. Nuclear Regulatory Commission (NRC) for the development and implementation of personnel monitoring and bioassay programs for any licensee handling or processing unsealed materials containing iodine-125 (^{125}I), iodine-131 (^{131}I), or a combination of the two. It also provides guidance on the selection of workers who should participate in such a bioassay program to detect and measure possible exposure. The guide does not address measurement techniques and procedures.

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, explain techniques that the staff uses in evaluating specific problems or postulated accidents, and provide guidance to applicants. Regulatory guides are not substitutes for regulations, and compliance with them is not required.

This regulatory guide contains information collection requirements covered by 10 CFR Part 20, "Standards for Protection against Radiation," that the Office of Management and Budget (OMB) approved under OMB control number 3150-0014. NRC may neither conduct nor sponsor, and a person is not required to respond to, and information collection request or requirement unless the requesting document displays a currently valid OMB control number. This regulatory guide is a rule as designated in the Congressional Review Act (5 U.S.C. 801-808). However, OMB has not found it to be a major rule as designated in the Congressional Review Act.

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 (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; submitted through the NRC's interactive rulemaking Web page at http://www.nrc.gov; or faxed to (301) 492-3446. Copies of comments received may be examined at the NRC's Public Document Room, 11555 Rockville Pike, Rockville, MD. Comments will be most helpful if received by November 22, 2011.

Electronic copies of this draft regulatory guide are available through the NRC's interactive rulemaking Web page (see above); the NRC's public Web site under Draft Regulatory Guides in the Regulatory Guides document collection of the NRC's Electronic Reading Room at http://www.nrc.gov/reading-rm/doc-collections/; and the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html, under Accession No. ML102800439. The regulatory analysis may be found in ADAMS under Accession No. ML102800457.

B. DISCUSSION

Background

The purpose of this revision is to update the guide to align with (1) current 10 CFR Part 20 regulations; (2) with the dose assessment and bioassay interpretation method recommended by International Commission on Radiological Protection (ICRP) Publication 30 (Ref. 2) for the radioiodine model: and (3) with the method of interpretation of radiobioassay measurement recommended by ICRP Publication 54 (Ref. 3). Thyroid content due to an intake (either inhalation or ingestion pathways) can be derived from methods described in NUREG/CR-4884, "Interpretation of Bioassay Measurements," (Ref. 4). Additionally, National Council on Radiological Protection and Measurements (NCRP) Report 161, "Management of Persons Contaminated with Radionuclides: Handbook," (Ref.5), contains the latest medical interventions, available methods and treatment for radiological events, including radioiodine intakes.

The topics discussed in this guide include determinations of (1) whether bioassay should be performed, (2) frequencies of bioassay, (3) who should participate, (4) the actions to take based on bioassay results, and (5) the specific results that should initiate such actions.

Bioassay program determinations—considering who should participate, frequency of sampling, and so on—are prospective except in cases of intake assessments. This means that these decisions must be based on conservative estimates of what type and quantity of intakes may occur given the kinds of activities expected to take place at the licensee's facility during the monitoring year. The program is also confirmatory in that low or zero results may indicate that the measures in place to control radioiodine materials are effective and that no unexpected intakes have occurred. An unchanging process stream and adequate experience with the process may justify adjustments in the bioassay program (e.g., a reduction or increase in bioassay frequency or inclusion of fewer or more workers in the program).

The guide does not specifically address using other isotopes of radioiodine such as iodine-123 (^{123}I) and iodine-129 (^{129}I). Given that accelerator produced isotopes such as ^{123}I with its 13.2 hour half-life is used frequently and that the annual limit on intake (ALI) and DAC listed in 10 CFR Part 20, Appendix B is substantially different from that of ^{125}I or ^{131}I, it would require specific considerations that are not detailed in this guide. However, the same concepts endorsed in the guide may be used to support applications using other isotopes of iodine if proper consideration is given to the isotope's unique characteristics and adjustments to procedures and practices are made as appropriate. For example, due to the short radiological half-life of ^{123}I, and its unique radiological signature, follow-up bioassays should be performed no longer than 24 hours following its use and action levels should be developed to assure a equivalent level of response as those identified in this guide.

C. STAFF REGULATORY GUIDANCE

1. Conditions under Which Bioassay Is Necessary

a. Routine[1] bioassay is necessary when an individual handles unsealed quantities of radioactive iodine in open form that exceed those shown in Table 1 of this guide.[2] Table

[1] "Routine" here means that an individual is assigned on a scheduled and repeatable basis to submit specimens for bioassay or to report for in vivo measurements. Either radiochemical bioassay of the urine or in vivo counting is acceptable to the NRC staff for estimating internal radioiodine burden or intakes. In some cases, however, a licensee may wish to corroborate estimates from urinalysis data with in vivo determinations or vice-versa. Measurement techniques and analytical procedures are available to devise bioassay applications in other commonly used references.

1 applies to both the quantity handled at any one time or integrated as the total amount of activity introduced into a process by an employee over any 3-month period (i.e., 90 days).

b. When quantities handled in unsealed form are greater than 10 percent of Table 1 values, routine bioassay may be necessary under certain circumstances. A written justification for not performing such bioassay measurements should be prepared and documented for subsequent review during NRC inspections whenever bioassay is not performed and the quantities handled exceed 10 percent of Table 1 values.

Table 1: Activity Levels above Which Bioassay for Radioiodine Is Necessary

Types of Operation	**Total Activity (mCi) over a 3-Months Period Handled in Unsealed Form Making Bioassay Necessary***	
	Volatile or Dispersible	**Bound to Nonvolatile Agent and the Concentration < 0.1 Ci/g**
Processes in open room or bench, with possible escape of iodine from process vessels	1	10
Processes with possible escape of iodine carried out within a fume hood of adequate design, face velocity, and performance reliability	10	100
Processes carried out within gloveboxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box and box leakage	100	1,000

* Quantities may be considered as a cumulative amount in process handled by a worker during a 3-month period (e.g., the total quantity introduced into a chemical or physical process over a 3-month period or on one or more occasions in that period). Quantities in the right-hand column may be used when it can be shown that activity in process is always chemically bound and processed in such a manner that ^{125}I or ^{131}I will remain in nonvolatile form and diluted to concentrations less than 0.1 curie per gram (i.e., 3.7×10^3 Bq/g) of nonvolatile agent. Capsules (such as gelatin capsules given to patients for diagnostic tests) may be considered to contain the radioiodine in non-free form, and bioassay would not be necessary unless a capsule were inadvertently opened (e.g., dropped and crushed). However, certain compounds where radioiodine is normally bound are known to release radioiodine when the material is in process, and the left-hand column may then be applicable. In those laboratories working only with ^{125}I in radio-immunoassay kits, the quantities of ^{125}I are very small and in less volatile forms; thus, bioassay requirements may be judged from the right-hand column. In field operations, where reagent containers are opened outdoors for simple operations such as pouring liquid solutions, the above table does not apply; bioassay should be performed whenever an individual employee handles in open form (e.g., an open bottle or container) more than 50 mCi (1.8×10^9 Bq) at any one time.

Operations involving the routine use of ^{125}I and ^{131}I in an open room or bench are discouraged. Whenever practicable, sealed bottles or containers holding more than 0.1 mCi (3.7×10^6 Bq) of radioiodine substances should be opened at least initially within hoods having adequate face velocities of 0.5 meters per second or more.

c. Except as noted above, bioassay is not required when process quantities handled by a worker are less than 10 percent of those values in columns 1 and 2 of Table 1.

d. In nuclear reactor installations, employees should undergo an in vivo count or urine bioassay within 30 days after the end of exposure in work locations where airborne concentrations of radioiodine exceeded, or might have exceeded a time-integrated concentration of 40 Derived Air Concentration (DAC)-hours[3] over any consecutive 40-

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This guide does not cover those elements of a bioassay program. Each installation should develop programs or obtain services that are best suited to its own needs.

[2] See discussion in the footnote to Table 1 of this guide.

[3] The DAC value of 2×10^{-8} µCi/mL for ^{131}I provided in Table 1, Column 2, Appendix B to the Part 20 is calculated based on the deterministic, non-stochastic, annual limit on intake (ALI) of 50 µCi divided by 2.4×10^9 mL of air breathed by Reference Man (Ref. 5).

hour period. Column 3 of Table 1 and Regulatory Position 4 regarding frequency of bioassays are not applicable to reactor licensees.

e. Measurements shall be performed to determine airborne concentrations, as needed, to meet the requirements of §20.1204(b) and §20.1703(c) for determination of internal exposure, to verify the effectiveness of respiratory protection devices used, and to determine the actual intake with the respirator devices.

f. The first bioassay sample should be obtained between 6 and 72 hours after respiratory protective devices were used to ascertain the effectiveness of the respiratory protection and to reduce the uncertainty when an intake occurred.

2. Participation

All workers who handle radioiodine substances or are sufficiently close to the process so that intake is possible (e.g., within a few meters and in the same room as the worker handling the material) should participate in the bioassay programs described in Regulatory Position 1.

3. Type of Bioassay That Should Be Performed

a. Baseline Bioassay (preemployment or preoperational). Before beginning work with radioiodine materials in sufficient quantity as specified in Regulatory Position 1 above.

b. Routine Bioassay. At the frequency as specified in Regulatory Position 4 below.

c. Special Bioassay. As soon as possible after any incident that might cause radioiodine uptake to exceed thyroid burdens given in Regulatory Position 5a(2) so that actions recommended in Regulatory Position 5a(2)(b) could be applied.

d. Postoperational and Termination. Within 2 weeks of the last possible exposure to ^{125}I or/and ^{131}I when operations are being discontinued or terminated.

e. Diagnostic. Follow up bioassay within 2 weeks of any measurements exceeding activities given as action levels in Regulatory Position 5 to confirm the initial results and, in the case of a single acute intake, to allow an estimate of the effective half-life of radioiodine in the thyroid or the body.

4. Frequency

a. Initial Routine. Except in situations where thyroid contents may exceed quantities specified in Regulatory Position 5a(2), a bioassay sample or monitoring measurement should be obtained within 72 hours (3 days) following entry of an individual into an area where bioassay is performed in accordance with Regulatory Positions 1 and 2 and every 2 weeks, or more frequently, thereafter as long as the conditions described in Regulatory Positions 1 and 2 exist. When work with radioiodine is on an infrequent basis (less frequently than every 2 weeks), bioassay could be performed within 10 days of the end of the work period during which radioiodine was handled (but not sooner than 6 hours unless emergency actions to obtain an early prognosis and thyroid blocking treatment are appropriate) (Ref. 4).

b. After 3 Months. When a periodic monitoring measurement frequency has been selected in accordance with Regulatory Position 4a, it may be changed to quarterly monitoring if all the following conditions are met:

(1) Thyroid content for each individual working in a given area is equal or less than 1 μCi (3.7×10^4 Bq) total of ^{125}I and ^{131}I during any 3-month period (i.e., 90 days).

(2) The average concentration of ^{125}I or ^{131}I over the 3-month period (i.e., 500 hours) breathed by any worker (as obtained when monitoring measurements of radioiodine in air are required) does not exceed the DAC value for "soluble"(s) iodine given in Appendix B to 10 CFR Part 20, Table I, Column 3. When a mixture of ^{125}I and ^{131}I is present, The DAC value for the mixture shall be established following the methods stated in §20.1204(e), (f), and (g); and

(3) The working conditions during the 3-month period with respect to the potential for exposure are representative of working conditions during the period in which the quarterly bioassay frequency will be employed, and there is no reasonable expectation that the criteria in Regulatory Positions 4b(1) and 4b(2) above will be exceeded.

5. Action Levels and the Associated Actions

a. Biweekly or More Frequent Measurements

(1) Whenever the thyroid content of ^{125}I and ^{131}I measurement exceeds 1 μCi (3.7×10^4 Bq), the following protective actions should be taken:

A. Investigate the radioiodine operations involved, including air and other in-plant surveys, as soon as possible to determine the causes of intake and to prevent further unwanted spread and exposures.

B. A repeat bioassay should be performed within 2 weeks of the previous one to monitor the intake and verify the dose assessment.

C. Use engineering controls to reduce exposure as low as reasonably achievable (ALARA).

(2) Whenever the thyroid content of ^{125}I and ^{131}I measurement exceeds 5 μCi (1.8×10^5 Bq), the following actions should be immediately taken:

A. Carry out all steps described in Regulatory Position 5a(1) above.

B. Carry out repeated measurements weekly until the thyroid content is equal or less than 1 μCi (3.7×10^4 Bq) of ^{125}I and ^{131}I. If a possibility exists of longer-term retention of ^{125}I and ^{131}I that requires evaluation, continue bioassay monitoring and measurements as long as necessary to ensure the appreciable thyroid content does not go undetected.

For all severe uptake incidences, refer the case to appropriate medical consultation as soon as possible for decorporation therapy evaluation and recommendations. To provide a beneficial and effective method for

reducing thyroid contents, chelation or decorporation drugs should be applied within 3 or 4 hours post-intake (see Section 12.4.3 in Ref. 4).

(3) If an overexposure occurs, immediate notification and subsequent reporting shall be made as required by 10 CFR 20.2202(a).

b. Quarterly Measurements

When monitoring measurements and surveys indicate an appreciable likelihood that a worker will receive further exposures exceeding the criteria of Regulatory Positions 4b(1) or 4b(2), biweekly or more frequent bioassays should be reinstituted appropriately.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC's plans for using this regulatory guide. The NRC does not intend or approve any imposition or backfit in connection with its issuance.

NRC has issued this draft guide to encourage public participation in its development. NRC will consider all public comments received in the development of the final guidance document. In some cases, applicants or licensees may propose or use a previously established acceptable alternative method for complying with specified portions of the NRC's regulations. Otherwise, the methods described in this guide will be used in evaluating compliance with the applicable regulations for license applications, license amendment applications, and amendment requests."

GLOSSARY

annual limit on intake (ALI)—The derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 5 rem (0.05 sievert [Sv]) or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue. (Notice that the deterministic ALI of iodine-131 [^{131}I] is 50 μCi to the thyroid; in this case, one could assume that 1 rem [0.01 Sv] of committed dose equivalent to the thyroid could be assessed from each intake of 1-μCi of ^{131}I by inhalation.)

bioassay—The determination of kinds, quantities, or concentrations and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body (in vitro analysis).

decorporation—The therapeutic processes by which radioactive materials are mobilized from tissues and organs and removed from the body by enhanced material excretion.

derived air concentration (DAC)—The concentration of a given radionuclide in air which, if breathed by reference man for a working year of 2,000 hours under conditions of light work (inhalation rate of 1.2 cubic meters of air per hour) results in an intake of 1 ALI.

derived air concentration-hour (DAC-hour)—The product of the average concentration of radioactive material in air during a specified period of time (expressed as a fraction or multiple of the derived air concentration) and the duration of exposure to that radionuclide in hours. The DAC-hour expresses an exposure, and 2,000 DAC-hours represent an intake of one ALI, equivalent to a committed effective dose equivalent of 5 rem (0.05 Sv).

direct bioassay (in vivo)—Measurement of gamma or x-radiation emitted from radioactive material located within the body for the purpose of detecting or estimating the quantity (and sometimes the location) of radioactive material present.

indirect bioassay (in vitro)—Measurement of radioactivity in samples of material (usually urine and feces) excreted or removed from the human body.

intake—Activity that enters the body through the respiratory tract or the gastrointestinal tract or the skin. Intake may be acute, meaning a single intake occurring over a very short time period, usually taken to be instantaneous, or chronic, occurring over a specified time period. Common units used in this guide for intake are the microcurie (μCi) and becquerel (Bq).

overexposure—Individual doses received in excess of the annual limits that are listed in §20.1201(a).

uptake—The quantity of material that enters the body fluids from the respiratory tract, the gastrointestinal tract, or through the skin. The term also is sometimes used to indicate material taken into a tissue or organ from circulation. Common units used in this guide for intake are μCi and Bq.

REFERENCES[4]

1. 10 CFR Part 20, "Standards for Protection against Radiation," U.S. Nuclear Regulatory Commission, Washington, DC. 56 FR 23391-23465, May 21, 1991.

2. ICRP Publication 30, "Limits for Intakes of Radionuclides by Worker: Part 1," International Commission on Radiation Protection, Pergamon Press, Oxford, 1979.[5]

3. ICRP Publication 54, "Individual Monitoring for Intakes of Radionuclides by Workers: Design and Interpretation," International Commission on Radiation Protection, Pergamon Press, Oxford, 1988.

4. NUREG/CR-4884, "Interpretation of Bioassay Measurements," U.S. Nuclear Regulatory Commission, Washington, DC 20555. BNL-NUREG-52063, July, 1987.

5. NCRP Report 161, "Management of Persons Contaminated with Radionuclides: Handbook," National Council on Radiological Protection and Measurements, Bethesda, MD, 2008.

[4] Publicly available NRC-published documents are available electronically through the NRC Library on NRC's public Web site at: http://www.nrc.gov/reading-rm/doc-collections/. The documents also can be viewed online or printed for a fee in 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.

[5] Copies of the non-NRC documents included in these references may be obtained directly from the publishing organizations at the link provided.