U.S. NUCLEAR REGULATORY COMMISSION

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# REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

## REGULATORY GUIDE 8.20
## APPLICATIONS OF BIOASSAY FOR I-125 AND I-131

### A. INTRODUCTION

Section 20.108, "Orders Requiring Furnishing of Bioassay Services," of 10 CFR Part 20, "Standards for Protection Against Radiation," indicates that the Nuclear Regulatory Commission (NRC) may incorporate into a license provisions requiring a specific program of bioassay measurements as necessary or desirable to aid in determining the extent of an individual's exposure to concentrations of radioactive material. In certain cases, the requirement for bioassay may also be included in the license by reference to procedures specifying in vivo measurements, measurements of radioactive material in excreta, or both.

This guide provides criteria acceptable to the NRC staff for the development and implementation of a bioassay program for any licensee handling or processing I-125 or I-131. It further provides guidance to such licensees regarding the selection of workers who should participate in a program to detect and/or measure possible internal radiation exposure. The guide is programmatic in nature and does not deal with measurement techniques and procedures.

### B. DISCUSSION

The topics treated 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 particular results that should initiate such actions.

For the user's convenience, the following terms are presented with their definitions as used in this guide:

*Bioassay*—The determination of the kind, quantity or concentration, and location of radioactive material in the human body by direct (in vivo) measurement or by analysis in vitro of materials excreted or removed from the body.

*Intake*—The total quantity of radioactive material entering the body.

*In vivo measurements*—Measurement of gamma- or x-radiation emitted from radioactive material located within the body for the purpose of detecting or estimating the quantity of radioactive material present.

*In vitro measurements*—Measurement of radioactivity in samples of material excreted from the human body.

### C. REGULATORY POSITION

#### 1. Conditions Under Which Bioassay Is Necessary

a. Routine[1] bioassay is necessary when an individual handles, at any one time, unsealed[2] quantities of radioactive iodine that exceed those shown in Table 1 of this guide.

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

c. Except as stated in regulatory position 1.d, bioassay is not required when process quantities handled by a worker are less than 10% of those in Table 1.

d. Special bioassay measurements should be performed to verify the effectiveness of respiratory protection devices and other protective clothing. If an

[1] *Routine* means here 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 urine or in vivo counting is acceptable to the NRC staff for estimating internal radioactivity burdens or intakes. In some cases, however, a licensee may wish to corroborate estimates from urinalysis data with in vivo determinations.

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

## Table 1
## ACTIVITY LEVELS ABOVE WHICH BIOASSAY FOR I-125 OR I-131 IS NECESSARY

| Types of Operation | Activity Handled at Any One Time in Unsealed Form Making Bioassay Necessary* | |
|---|---|---|
| | Volatile or Dispersible* | Bound to Nonvolatile Agent* |
| Processes in open room or bench, with possible escape of iodine from process vessels | 0.1 mCi | 1 mCi |
| Processes with possible escape of iodine carried out within a fume hood of adequate design, face velocity, and performance reliability | 1 mCi | 10 mCi |
| Processes carried out within gloveboxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box and box leakage | 10 mCi | 100 mCi |

* Quantities present may be considered the amount in process by a worker at one time. 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 I-125 or I-131 will remain in nonvolatile form and diluted to concentrations less than 0.1 μCi/mg of nonvolatile agent. Capsules (such as gelatin capsules given to patients for diagnostic tests) may be considered to contain the radioiodine in nonfree form, and bioassay would not be necessary unless a capsule were inadvertently opened (e.g., dropped and crushed). On the other hand, 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 I-125 in radioimmunassay (RIA) kits, the quantities of I-125 are very small and in less volatile forms; thus, bioassay requirements may be judged from the right-hand column.

individual wearing a respiratory protective device or protective clothing is subjected to a concentration of I-125 or I-131 (in any form) in air such that his or her intake with no protection would have exceeded the limits specified in paragraph 20.103(a)(1) of 10 CFR Part 20.[3] bioassays should be performed to determine the resulting actual I-125 or I-131 intake. These special bioassay procedures should also be conducted for personnel wearing respirators if for any reason the I-125 or I-131 concentration in air and the duration of exposure are unknown.

### 2. Participation

All workers handling radioactive iodine or sufficiently close to the process that intake is possible (e.g., within a few meters and in the same room as the worker handling the material) should participate in bioassay programs described in regulatory position 1.

### 3. Types of Bioassays That Should Be Performed

a. *Baseline (preemployment or preoperational).* Within 2 weeks prior to beginning work with radioactive iodine in sufficient quantity that bioassay is specified in regulatory position 1.

b. *Routine.* At the frequencies specified in regulatory position 4.

c. *Postoperational and with Separation Physical.* A bioassay should be performed within 2 weeks of the last possible exposure to I-125 or I-131 when operations are being discontinued or when the worker is terminating activities with potential exposure to these radionuclides.

d. *Diagnostic.* Followup bioassay should be performed within 2 weeks of any measurement exceeding levels given as action points in regulatory position 5 in order to confirm the initial result and, in the case of a single intake, to allow an estimate of the effective half-life of radioiodine in the thyroid.

### 4. Frequency

a. *Initial Routine.* Within 72 hours following entry of an individual into an area where bioassay is speci-

[3] Multiplying the concentrations given in Appendix B, Table I, Column I, 10 CFR Part 20, $5 \times 10^{-8}$ μCi/ml for I-125 (soluble) and $9 \times 10^{-8}$ μCi/ml for I-131 (soluble), by $6.3 \times 10^{6}$ ml gives the corresponding quarterly intake of the respective iodines by inhalation. These quarterly intakes would be about 3.2 μCi for I-125 and 5.7 μCi for I-131, which would give a thyroid dose commitment of about 7.5 rems to a 20-gram thyroid integrated over all future time, using effective half-lives of 41.8 days for I-125 and 7.6 days for I-131 and using a quality factor (QF) of 1.7 to calculate effective disintegration energy in the case of I-125. (This QF of 1.7 is used for conservatism, even though the International Commission on Radiological Protection (1969) and the National Council on Radiation Protection (1971) have published a QF of 1, because some calculations in more recent scientific literature have suggested the use of QF values higher than 1 for electron or beta energies of 0.03 MeV or less.)

U.S. ATOMIC ENERGY COMMISSION

# REGULATORY GUIDE

DIRECTORATE OF REGULATORY STANDARDS

2/16/73

## REGULATORY GUIDE 8.5

## IMMEDIATE EVACUATION SIGNAL

### A. INTRODUCTION

Section 70.24 of 10 CFR Part 70 requires criticality detection and alarm systems in any area containing special nuclear material when the licensee is authorized to possess more than 500 grams of U-235, 300 grams of Pu, or 300 grams of U-233. This guide defines the characteristics of an acceptable audible alarm for use in this and other instances where prompt, complete evacuation is required to prevent serious injury from radiation exposure.

### B. DISCUSSION

United States of America Standards Institute Subcommittee N2.1, Ionizing Radiation Symbols, Color Codes and other Identifying or Warning Devices, prepared standard N2.3-1967[1] which was approved by the United States of America Standards Institute on October 3, 1967. The standard defines the characteristics of an immediate evacuation alarm system.

### C. REGULATORY POSITION

The characteristics of an immediate evacuation signal described in ANSI N2.3-1967, "Immediate Evacuation Signal for Use in Industrial Installations Where Radiation Exposure May Occur," are generally acceptable for use wherever such a system may be needed or required, subject to the following:

1. The minimum duration of the signal should be sufficient to ensure evacuation and permit implementation of access control.

2. Within a given facility or plant, the unique signal described in N2.3-1967 should be consistent if used in more than one location.

3. In some cases, plant design features or operating conditions may require alarms different from that described in the standard. This determination will be made on an individual basis.

[1] The United States of America Standards Institute became the American National Standards Institute, Inc., in 1969. Copies of ANSI N2.3-1967 may be obtained from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018.

fied in accordance with regulatory positions 1 and 2 (but waiting at least 6 hours for distribution of a major part of the iodine to the thyroid[4]) and every 2 weeks or more frequently thereafter as long as the conditions described in regulatory positions 1 and 2 exist. When work with radioactive iodine is on an infrequent basis (less frequently than every 2 weeks), bioassay should be performed within 72 hours of the end of the work period during which radioactive iodine was handled (but not sooner than 6 hours).

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

(1) The average thyroid burden for each individual working in a given area was less than 0.12 $\mu$Ci of I-125, less than 0.04 $\mu$Ci of I-131, and less than the corresponding proportionate amount[5] of a mixture of these nuclides during the initial 3-month period;

(2) The quarterly average radioiodine concentration ($\mu$Ci/ml) in air breathed by any worker (as obtained when measurements of radioiodine concentrations in air are required) does not exceed 25% of the concentration values for "soluble" (s) iodine given in Appendix B, Table I, Column 1, 10 CFR Part 20 ($5 \times 10^{-9}$ $\mu$Ci/ml for I-125 and $9 \times 10^{-9}$ $\mu$Ci/ml for I-131), i.e., 25% of these concentrations multiplied by the total air breathed by an employee at work during one calendar quarter, $6.3 \times 10^{8}$ ml, does not exceed 0.8 $\mu$Ci of I-125 or 1.4 $\mu$Ci of I-131. The appropriate proportionate amount[5] of a mixture of these nuclides should be used as a guide when both I-125 and I-131 are present; 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 4.b(1) and 4.b(2) above will be exceeded.

c. Between 10 and 48 hours after respiratory protective devices, suits, hoods, or gloves are used to limit exposure as stated in regulatory position 1.d.

### 5. Action Points and Corresponding Actions

a. *Biweekly or More Frequent Measurements*

(1) Whenever the thyroid burden at the time of measurement exceeds 0.12 $\mu$Ci of I-125 or 0.04 $\mu$Ci of I-131, the following actions should be taken:

(a) An investigation of the operations involved, including air and other in-plant surveys, should be carried out to determine the causes of exposure and to evaluate the potential for further exposures.

(b) If the investigation indicates that further work in the area might result in exposure of a worker to concentrations that would cause the limiting intakes established in §20.103 of 10 CFR Part 20 to be exceeded, the licensee should restrict the worker from further exposure until the source of exposure is discovered and corrected.

(c) Corrective actions should be implemented that will eliminate or lower the potential for further exposures.

(d) A repeat bioassay should be taken within 2 weeks of the previous measurement and should be evaluated within 24 hours after measurement in order to confirm the presence of internal radioiodine and to obtain an estimate of its effective half-life for use in estimating dose commitment.

(e) Reports or notification must be provided as required by §§20.405, 20.408, and 20.409 of 10 CFR Part 20 or as required by conditions of the license pursuant to §20.108 of 10 CFR Part 20.

(2) If the thyroid burden at any time exceeds 0.5 $\mu$Ci of I-125 or 0.14 $\mu$Ci of I-131, the following actions should be taken:

(a) Carry out all steps described in regulatory position 5.a(1).

(b) Refer the case to appropriate medical/health physics consultation for recommendations regarding therapeutic procedures that may be carried out to accelerate removal of radioactive iodine from the body.

(c) Carry out repeated measurements at approximately 1-week intervals at least until the thyroid burden is less than 0.12 $\mu$Ci of I-125 or 0.04 $\mu$Ci of I-131. If there is a possibility of longer-term compartments containing I-125 or I-131 that require evaluation, continue measurements as long as necessary to ensure that appreciable exposures to these other compartments do not go undetected.

b. *Quarterly Measurements.* Carry out actions at levels as indicated under regulatory position 5.a(1). If measurements and surveys indicate an appreciable likelihood that a worker will receive further exposures exceeding the criteria of regulatory positions 4.b(1) and 4.b(2), reinstitute biweekly or more frequent bioassays.

## D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for using this regulatory guide.

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[4] NCRP Report No. 55, "Protection of the Thyroid Gland in the Event of Releases of Radioiodine," National Council on Radiation Protection and Measurements, Washington, D.C., August 1, 1977, p. 21.

[5] See the appendix for a description and example of using this condition for mixtures.

Except in those cases in which the applicant or licensee proposes an acceptable alternative method, the staff will use the methods described herein after December 15, 1978, in evaluating the radiation protection programs of licensees who have bioassay requirements incorporated in their licenses in accordance with §20.108 of 10 CFR Part 20.

If an applicant or licensee wishes to use the method described in this regulatory guide on or before December 15, 1978, the pertinent portions of the application or the licensee's performance will be evaluated on the basis of this guide.

## Appendix
## CALCULATION OF ACTION LEVELS FOR MIXTURES OF I-125 AND I-131

### A.1 Controlling Instantaneous Thyroid Burdens

Regulatory position 4.b(1) is based on controlling the instantaneous amount in the thyroid and is taken as 25% of the maximum permissible organ burden (MPOB) of I-125 or I-131, respectively, that would give a dose rate of 0.6 rem/week if continuously present in the thyroid. If a mixture of both nuclides is present in the thyroid and X is the fractional activity that is I-125, a 3-month interval may be resumed when the total activity of I-125 and I-131 is below

$$0.12X + 0.04(1 - X)$$

*Example*

If the measurements of I-125 and I-131 in a worker's thyroid are 0.10 $\mu$Ci of I-125 and 0.05 $\mu$Ci of I-131, the fractional I-125 activity is:

$$X = 0.10/(0.10 + 0.05)$$
$$= 0.667$$

Then

$$0.12X + 0.04(1 - X) = 0.12(0.667) + 0.04(0.33)$$
$$= 0.0932$$

$$\text{Total} = 0.10 + 0.05 = 0.15\ \mu\text{Ci}$$

Thus, in this case, the worker involved should remain on the biweekly (or more frequent) schedule and should not be put on the quarterly frequency.

### A.2 Controlling Total Intakes

Regulatory position 4.b(2) is based on controlling total intakes[6] during a quarterly period when air concentration data are available to assess the potential exposure of the worker, either to random single intakes or to variable or constant continuous exposures. The quantities of 0.8 $\mu$Ci of I-125 and 1.4 $\mu$Ci of I-131 were obtained by calculating 25% of the respective total quarterly intakes of 3.2 $\mu$Ci of I-125 or 5.7 $\mu$Ci of I-131 (see footnote 3) that would be inhaled when breathing a total of $6.3 \times 10^8$ ml per quarter working at the standard man breathing rate for 40 hours per week for 13 weeks.

*Example*

Should the average quarterly concentrations estimated from air sampled in a worker's breathing zone be $3 \times 10^{-9}$ $\mu$Ci/ml for I-125 and $5 \times 10^{-9}$ $\mu$Ci/ml for I-131, the total quarterly intakes are:

$$3 \times 10^{-9} \times 6.3 \times 10^8 = 1.89\ \mu\text{Ci I-125}$$
$$5 \times 10^{-9} \times 6.3 \times 10^8 = 3.15\ \mu\text{Ci I-131}$$
$$\text{Total} = 5.04\ \mu\text{Ci}$$

Also, X, the proportion of I-125, is 1.89/5.04 = 0.375

Thus the control level for maintaining biweekly or more frequent bioassay checks would be:

$$0.8X + 1.4(1 - X) = 0.8(0.375) + 1.4(1 - 0.375)$$
$$\text{Total} = 1.18\ \mu\text{Ci for this mixture.}$$

Since the intake of 5.04 $\mu$Ci is greater than 1.18, this employee should stay on the more frequent bioassay schedule.

Note: The numbers of significant digits carried in the above calculations do not imply any given degree of accuracy of measurement. Enough digits are carried to allow following the arithmetic for purposes of the examples.

[6] The limiting total quarterly intakes are in different proportions for I-125 and I-131 than are the MPOBs. This difference is a result of the fact that permissible concentrations are inversely proportional to effective half-lives; whereas an MPOB is calculated assuming a constant burden in the organ of concern, which is maintained by continuous intake of activity balanced by an equal rate of elimination from the organ.