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REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 8.32
(Task OP 713-4)

CRITERIA FOR ESTABLISHING A TRITIUM BIOASSAY PROGRAM

A. INTRODUCTION

Section 20.108, "Orders Requiring Furnishing of Bioassay Services," of 10 CFR Part 20, "Standards for Protection Against Radiation," states 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.

This guide provides NRC staff guidance on:

1. The conditions under which the NRC staff will consider the need for license conditions related to tritium bioassays under § 20.108 of 10 CFR Part 20.

2. The scope, types, and frequency of tritium bioassay programs conducted by licensees for the purpose of demonstrating compliance with applicable provisions of 10 CFR Part 20 or for satisfying license conditions imposed under § 20.108. However, if this guide differs from the requirements of any existing license condition, the licensee should conform to such requirements until the license is amended in accordance with the Commission's regulations.

This guide provides criteria acceptable to the NRC staff for developing and implementing a bioassay program for any licensee handling or processing tritium[1] either as pure gas or in various chemical compounds. It further provides guidance to such licensees on selecting workers who should participate in a program to detect and measure possible internal radiation exposure. This guide is programmatic in nature and does not deal with measurement techniques and procedures.[2]

Any information collection activities mentioned in this regulatory guide are contained as requirements in 10 CFR Part 20, which provides the regulatory basis for this guide. The information collection requirements in 10 CFR Part 20 have been cleared under OMB Clearance No. 3150-0014.

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 activity levels that should initiate such actions.

The information and references that were used in developing this guidance are summarized in NUREG-0938, "Information for Establishing Bioassay Measurements and Evaluations of Tritium Exposure."[3] NUREG-0938 also contains information that may be useful to applicants and licensees in planning and conducting bioassay programs for tritium.

The triggering concentrations given in Table 1 of this guide notwithstanding, licensees are not exempt from the air sampling and bioassay requirements of 10 CFR Part 20; particular attention should be given to paragraphs 20.103(a)(3) and 20.103(c)(2). Paragraph 20.103(a)(3) requires licensees to measure radioactivity concentrations in the air and, as appropriate, to use bioassay measurements for the timely detection and assessment of individual intakes of radioactivity. Paragraph 20.103(c)(2) requires licensees to provide bioassays as appropriate to evaluate actual exposures when the licensee wishes to make allowance for the use of respiratory protection equipment in estimating exposures of individuals to airborne radioactive material. The "appropriateness" of conducting bioassays to comply with paragraphs 20.103(a)(3) and (c)(2) must be judged on a case-by-case basis. For example, if the Table 1 concentration criteria are routinely met, but there are unexpectedly high air sampling results, bioassays may be "appropriate" in order to verify and assure that regulatory intake limits have not been exceeded.

[1]Tritium, an isotope of hydrogen, has a mass number of 3 (2 neutrons, 1 proton). Tritium may be symbolized or represented in the literature by the standard scientific symbol ^3H or by other symbols adopted for convenience in publication such as hydrogen-3, H-3, or T.

[2]Sections 8 through 11 of ANSI N13.14-1983, "American National Standard for Dosimetry—Internal Dosimetry Programs for Tritium Exposure—Minimum Requirements," contain some useful information on procedural aspects of bioassay programs. ANSI N13.14-1983 is available from the American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018.

[3]NUREG-0938 is available from The Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082; or from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

Table 1

ACTIVITY LEVELS OR CONCENTRATIONS ABOVE WHICH TRITIUM BIOASSAY PROGRAMS SHOULD BE PROVIDED

Types of Operation[a]	HTO[b] and Other Tritiated Compounds (Including Nucleotide Precursors)	Tritium (HT or T_2)[c] Gas in Sealed Process Vessels[d]	HTO Mixed with More Than 10 kg of Inert H_2O (e.g., in Reactor Coolant)[e]
Processes in open room or bench with possible escape of tritium from process vessels	0.1 Ci	100 Ci	0.01 Ci/kg
Processes with possible escape of tritium carried out within a fume hood of adequate design, face velocity, and performance reliability	1 Ci	1,000 Ci	0.1 Ci/kg
Processes carried out within gloveboxes that are ordinarily closed but with possible release of tritium from process vessels and occasional exposure to contaminated box and leakage	10 Ci	10,000 Ci	1 Ci/kg

[a]Quantities (< 10 kg) of substances containing tritium that are present during operations may be considered to be either the amount processed by an individual at any one time (when accidental intake is more likely) or the amount of activity that entered into the process (throughput) during any one month (when routine handling of repeated batches is the more likely source of exposure).

[b]HTO is a symbol for a water molecule in which a tritium atom (T) is present in place of a normal hydrogen atom (H).

[c]A molecule of hydrogen gas contains two hydrogen atoms. Either one of these atoms may be replaced with T to form HT, or two T atoms may combine to form T_2 gas.

[d]This assumes that adequate air monitoring has established that there is no tritium leakage or that no significant amount of tritium gas can be converted to HTO before intake.

[e]This column is applicable in place of the previous two columns in cases where tritium can be identified at measurable concentrations in large amounts of water or other substances, such as at nuclear power plants.

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. Only in vitro analysis of urine (or, if more convenient, another representative body fluid) is applicable to tritium or its compounds.

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

Uptake—The total quantity of radioactive material retained in the body (i.e., not immediately exhaled) after an intake.

C. REGULATORY POSITION

1. CONDITIONS UNDER WHICH BIOASSAY IS NECESSARY

1.1. Routine bioassay is necessary when quantities of tritium processed by an individual at any one time or the total amounts processed per month exceed those shown in Table 1 for each form of tritium.

1.2. For workers in nuclear reactor facilities, urine bioassay should be performed when the concentrations of tritium in the reactor coolant water exceed those shown in the right-hand column of Table 1. The lowest value in Table 1, 0.01 Ci/kg of coolant, should be used to initiate a bioassay program whenever employees are exposed to the air in a room or area where more than 10 kg of water containing this or greater concentration or a total of more than 0.1 Ci of tritium is in contact with the air (such as a storage pool). If exposure to water containing a concentration of tritium greater than or equal to 1 Ci/kg is expected, such as when leakages occur, a bioassay program should be initiated because significant intakes, both by inhalation and by absorption of water vapor through the skin, can occur when individuals are exposed to tritium at these concentrations.

1.3. Bioassays should also be performed when an employee can come into skin contact with, ingest, or absorb into the body through cuts, abrasions, or accidental (hypodermic) injection, water or any other substance with concentrations of tritium greater than or equal to 0.01 mCi/kg (0.01 μCi/cc) such as may be common in laboratory applications.

2. PARTICIPATION

All workers involved in the processing of tritium under conditions specified in Regulatory Position 1 or in the environs of the process should participate in the bioassay program.

3. TYPES OF BIOASSAY THAT SHOULD BE PERFORMED

3.1 Baseline (Preemployment or Preoperational)

A baseline bioassay of each worker should be conducted before that worker begins working with tritium in amounts that would require initiation of a bioassay program as specified in Regulatory Position 1.

3.2 Routine

Regular bioassays should be conducted to monitor routine operations at frequencies specified in Regulatory Position 4.

3.3 Postoperational and with Termination Physical Examination

A bioassay should be performed within one month after the last possible exposure to tritium, when operations are being discontinued, or when the worker is terminating activities with potential exposure as indicated by the criteria in Table 1.

3.4 Diagnostic

A followup bioassay should be performed as soon as possible but not later than one week after any sample exceeding levels given as action points in Regulatory Position 5 in order to confirm the initial results and, in the case of a single intake, to allow an estimate of the effective half-life of the tritium in the body. If the initial sample or other data indicates a possible exposure high enough to warrant immediate medical attention, complete and immediate followup should be conducted as described in Regulatory Position 5.1.3.

4. FREQUENCY OF SAMPLING

4.1 Initial Routine

A bioassay sample should be taken within 24 hours, if possible, but not later than 72 hours following entry of an individual into an area where operations require bioassay according to Regulatory Position 1. Samples should then be taken every two weeks or more frequently as long as the individual is working with tritium. When work with tritium is on an infrequent basis (less frequently than every two weeks), bioassay should be performed within ten days of the end of the work period during which tritium was handled. Samples should not be collected until two hours after termination of the potential exposure in order that bladder contents will have had time to equilibrate with other body water.

4.2 After Three Months

A sampling frequency selected in accordance with Regulatory Position 4.1 may be changed to quarterly if, after three months, the following three conditions are met:

4.2.1 The average urinary tritium concentration in specimens obtained from the worker during the three-month period does not exceed 3 μCi/L,

4.2.2. If measurements of the concentration of tritium in air are required as a condition of the license, the quarterly average concentration (μCi/mL) to which workers are exposed multiplied by the factor 6.3×10^8 mL does not exceed 0.8 mCi, and

4.2.3. The working conditions during the three-month period, with respect to the potential for tritium exposure, are representative of working conditions during the period in which a quarterly urinalysis frequency is employed, and there is no reasonable expectation that the criteria given in items 4.2.1 and 4.2.2 above will be exceeded.

5. ACTION POINTS AND CORRESPONDING ACTIONS

5.1 Biweekly or More Frequent Sampling

5.1.1. Whenever the intake of tritium within any 40-hour work period exceeds the amount that would be taken into the body from uniform exposure for 40 hours at the air concentration (5×10^{-6} μCi/mL) specified in Table 1, Column 1, of Appendix B to 10 CFR Part 20,[4] the licensee is required to make evaluations, take necessary corrective actions, and maintain records as specified in paragraph 20.103(b)(2) of 10 CFR Part 20.

5.1.2. If urinary excretion concentrations exceed 5 μCi/L but are less than 50 μCi/L, the following course of action should be taken:

1. An investigation of the operations involved, including surveys and monitoring of air and surface contamination, should be carried out to determine the causes of the intake, and an evaluation of the potential for further larger intakes or of the possible involvement of other employees should be performed.

2. Any reasonable corrective actions that the investigation indicates may lower the potential for further exposures should be implemented.

3. A repeat urine sample should be taken within one week of the previous sample and should be evaluated within a

[4]Multiplying the concentration given in Appendix B, 5×10^{-6} μCi/mL, by 6.3×10^8 mL gives the corresponding quarterly intake limit of tritium by inhalation. In the case of inhaled HTO, which mixes instantly with other water molecules after entering body fluids, the intake may be assumed equal to uptake. The uptake of tritium (as HTO) by absorption through the skin is assumed equal to the uptake by inhalation unless the form of tritium in the air can be demonstrated to have lower uptakes. The total uptake, including skin absorption, would be assumed to be about 6.3 mCi, which delivers a dose commitment of about 1.25 rems to standard man (using the quality factor Q=1.7). A 40-hour occupational exposure at a concentration of 5×10^{-6} μCi/mL would thus result in an intake of 6.3/13=0.48 mCi and a dose commitment of about 0.1 rem. An acute intake (in less than one day) of 0.48 mCi would result in an initial body water concentration of about 11 μCi/L. (The use of Q=1.7 in this example follows the practice used in developing concentration limits for the current 10 CFR Part 20. Changes in recommendations of various committees and a review of quality factor determinations reported in the literature are presented in NUREG-0938.)

week after collection. Internal dose commitments should be estimated using at least these two urine sample evaluations and other survey data, including the probable times of the intake of tritium.

4. Any evidence indicating that further work in the area might result in an employee receiving a dose commitment in excess of the limits established in § 20.101 should serve as cause to remove the employee from work in this operation until the source of exposure is discovered and corrected.

5. Reports or notifications 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.

5.1.3. If urinary excretion concentrations exceed 50 μCi/L, the following course of action should be taken:

1. Carry out all steps in Regulatory Position 5.1.2.

2. If the projected dose commitment exceeds levels for the whole body as provided in § 20.403 of 10 CFR Part 20, notify the NRC as appropriate.

3. Refer the case to appropriate medical and health physics consultants for recommendations regarding the need for immediate therapeutic procedures that may be carried out to accelerate removal of tritium from the body.

4. Carry out repeated sampling at approximately one-week intervals at least until urine samples show concentrations less than 5 μCi/L. If there is a possibility of long-term organic compartments of tritium that require evaluation (see NUREG-0938), continue sampling as long as necessary to ensure that appreciable exposures to these other compartments do not go undetected and to provide estimates of total dose commitments.

5.2 Quarterly Sampling

Carry out the actions called for when any of the action levels indicated in Regulatory Position 5.1 are exceeded. In addition, institute biweekly (or more frequent) sampling for at least the next six-month period, even when urinary concentrations fall below 5 μCi/L.

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.

Except in those cases in which an applicant or licensee proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, or cases in which different requirements are imposed by any existing license condition, the methods described in this guide will be used in evaluating the need for license conditions related to tritium bioassay programs and in evaluating the radiation protection programs of licensees that have bioassay requirements incorporated in their licenses in accordance with § 20.108 of 10 CFR Part 20. This guide will also be used in evaluating changes to existing bioassay programs that may be requested by licensees.

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[1]Copies of ANSI standards may be purchased from The American National Standards Institute, 1430 Broadway, New York, NY 10018.

[2]Copies may be purchased from the U.S. Government Printing Office, Post Office Box 37082, Washington, DC 20013-7082.

[3]Copies may be purchased from Pergamon Press, Inc., Maxwell House, Elmsford, NY 10523.

[4]Copies may be obtained from the Minister of National Health and Welfare of Canada, Radiation Protection Bureau, Brookfield Road, Ottawa, Ontario K1A IC1, Canada.

VALUE/IMPACT STATEMENT

A draft value/impact statement was published with Draft Regulatory Guide OP 713-4 when the draft guide was published for public comment in June 1983. No changes were necessary, so a separate value/impact statement for the final guide has not been prepared. A copy of the draft value/impact statement is available for inspection and copying for a fee at the Commission's Public Document Room at 1717 H Street NW., Washington, DC, under Task OP 713-4.

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