BIOASSAY PROCEDURES

I. Introduction

Bioassay requirements are based on section 64E-5.1304, Florida Administrative Code (FAC) and U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide 8.32.

A radiobioassay is an assessment of radioactive materials that may be present inside a person's body, through analysis of their blood, urine, feces, sweat, or in the case of radioiodine, in-vivo testing of the thyroid gland. In accordance with state regulations, FSU has radiobioassay procedures for radioiodine and tritium, with action levels for organ uptakes, corresponding actions taken if the levels are exceeded, frequency of measurement, and maintenance of records. It is the Principal Investigator's responsibility to ensure that radioiodine users, of quantities listed above, have their thyroids checked accordingly. Bioassay analysis is performed in-house by Radiation Safety Office staff or by qualified vendors.

Bioassay records are maintained for at least 3 years and include the bioassay date, the subject's name, and the results (thyroid burden or urinary tritium concentration) at the time of measurement.

II. Thyroid Radioiodine Bioassays

The thyroid bioassay is a procedure for determining the amount of radioiodine body burden by in-vivo measurements of the thyroid gland. Routine thyroid bioassay is required for anyone who will handle in open form unsealed quantities of radioactive iodine that exceed those shown in the below table. The quantities shown apply to both the quantity handled at any one time, or integrated as the total amount of activity introduced into a process over any 3-month period.

I-125 or I-131 Activity Handled in Unsealed Form Requiring Bioassay

Type of Radioiodine Operation	Volatile or Dispersible	Bound to Non-volatile Agent
Processes in open room or bench, with possible iodine escape from process vessels	1 mCi (37 MBq)	1 mCi (37 MBq)
Processes with possible escape of iodine carried out in a fume hood of adequate design, face velocity, and performance	1 mCi (37 MBq)	10 mCi (370 MBq)
Processed carried out in glove boxes, ordinarily closed, but with possible release from process & exposure to contaminated box and box leakage	10 mCi (370 MBq)	100 mCi (3700 MBq)

A bioassay must be taken within 72 hours of initial use of radioiodine and every 2 weeks thereafter. When use is on an infrequent basis (less than every 2 weeks), a bioassay must be taken within 10 days of the last day of use. If the thyroid burden at the time of measurement exceeds 0.12 uCi of I-125 or 0.04 uCi of I-131, the following actions will be taken.

- An investigation of the operations, including air and other surveys, to determine the cause(s), and corrective actions that will be taken to eliminate or lower the potential for further exposures.
- A repeat bioassay shall be taken within 2 weeks of the previous measurement and will be evaluated within 24 hours after the measurement.
- Notification reports will be provided per sections 64E-5.345, and 64E-5.347, FAC.

II. Thyroid Radioiodine Bioassays (continued)

If the calculated concentration of the subject's thyroid is > 0.121 uCi of I-125 or 0.04 uCi of I-131, action will be taken to reduce the subject's uptake: investigating the cause and the potential for further dose and restricting further exposure until a new procedure is in place. Follow-up bioassays will be performed to confirm that the thyroid burden is decreasing. If excessive levels persist, medical advice will be sought.

III. Tritium Bioassays

State regulations and NRC Regulatory Guide 8.32 specify that tritium bioassays be performed on persons working with 10 mCi (37 MBq) or more of tritium in a 3-month period (on an open laboratory bench top). The bioassay is a procedure for determining the amount of tritium body burden by in-vitro measurements of a urine sample. It is the responsibility of the PI to assure that tritium users, of quantities listed above, submit urine specimens to the RSO. If the calculated concentration of tritium exceeds the calculated minimum detectable concentration determined prior to sample analysis, the corrective action described below will be taken.

Routine bioassay is required when an individual handles in open form unsealed quantities of **tritium** that exceed those shown in Table 2. The quantities shown apply to both the quantity handled at any one time or when integrated as the total amount of activity introduced into a process by an employee over a 1-month period.

Table 2 Tritium Activity Handled in Levels or Concentrations Requiring Bioassay

Type of Operation	HTO & Other Tritiated Compounds	Tritium Gas in Sealed Process Vessels
Processes in open room or bench, with possible escape from process vessels	0.1 Ci (3.70 GBq)	100 Ci (3.7 TBq)
Processes with possible escape of tritium carried out in a fume hood of adequate design, face velocity, & performance reliability	1 Ci (37 GBq)	1,000 Ci (37 TBq)
Processes carried out within glove boxes, ordinarily closed, but with possible release of tritium from process & occasional exposure to contaminated box & box leakage	10 Ci (370 GBq)	10,000 Ci (370 TBq)

A bioassay shall be taken within 72 hrs of initial use of tritium and every 2 weeks thereafter. When tritium work is on an infrequent basis (less frequent than every 2 weeks), a bioassay shall be taken within 10 days of the last day of use. If the urinary tritium concentration exceeds 5 uCi/L at the time of the measurement these actions shall be taken:

- An investigation of the operations involved, including air and other facility surveys, shall be carried out to determine the cause(s);
- Corrective actions to prevent further exposures shall be implemented;
- A repeat bioassay shall be taken within 1 week of the previous measurement and shall be evaluated within 1 week after the measurement. Internal dose commitments shall be estimated using at least two bioassays and other survey data, including the probable times of intake of tritium; and
- Notification reports must be provided as required by 64E-5.345, and 64E-5.347, or as required by conditions of the license; and

III. Tritium Bioassays (continued)

Bioassay records are maintained for 3 years and include the date of the bioassay, the subject name, and the urinary tritium concentration at the time of the measurement.

IV. Tritium Bioassay Requirements

Tritium bioassays will be performed on anyone who processes tritium in quantities exceeding the limits shown in the below table, either at one time or in total for any 30-day period.

Tritium Activity Handled in Levels or Concentrations Requiring Bioassay

Type of Operation	HTO (Tritium Oxide) & Other Tritiated Compounds	HT (Tritium Gas) in Sealed Process Vessels
Processes in open room or bench	0.1 Ci (3.70 GBq)	100 Ci (3.7 TBq)
Processes carried out in a fume hood	1 Ci (37 GBq)	1,000 Ci (37 TBq)
Processes carried out within glove boxes	10 Ci (370 GBq)	10,000 Ci (370 TBq)

In addition, bioassays will be performed when an individual has come into skin contact, ingested, or absorbed (through cuts, abrasions or accidental injections) any substance with tritium concentrations > 0.01 uCi/cc.

A bioassay must be taken within 72 hrs of initial use of tritium and every 2 weeks thereafter. When tritium work is on an infrequent basis (< every 2 weeks), a bioassay must be taken within 10 days of the last day of use.

If the urinary tritium concentration is > 5 uCi/L at the time of the measurement, these actions must be taken:

- An investigation of the operations, including air and other surveys, to determine the cause;
- Corrective actions to prevent recurrence will be implemented;
- A repeat bioassay must be taken a week of the previous measurement and will be evaluated within 1 week after the measurement. Internal dose commitments must be estimated using at least two bioassays and other survey data, including the probable intake times; and
- Notification reports must be provided as required by sections 64E-5.345, and 64E-5.347, FAC.

V. Bioassay Frequency

Baseline Bioassay

- Baseline bioassays are typically be performed for any individual requiring monitoring. However, since baseline values are not likely to yield any existing body burden for most subjects and since the likelihood of exceeding 10 % of the Annual Limit for Intake (80 mCi x 0.10 = 8 mCi) through skin contact, ingestion, or absorption is very improbable, baseline bioassays do not need to be routinely performed.
- When baseline bioassays are required, samples will be collected before any tritium work.

V. Bioassay Frequency (continued)

Initial Bioassay

For every individual that requires tritium bioassay, the initial sample should be taken within 72 hours of the initial exposure. However, unless all urine will be collected for the emergency bioassay criteria, the initial void after completion of the work involving tritium should be discarded.

Follow-up Bioassay

Additional samples should be collected about every two weeks following the initial bioassay, during the duration of projects that require frequent handling of tritium. If the frequency of tritium exposure is less often than every two weeks, then samples only need be collected within ten days of completion of each experiment.

Emergency Bioassay

If an individual has had or suspects that they had an accidental exposure to, they should have initial samples collected of the first few voids. Enough follow-up bioassays shall be performed to allow for dose reconstruction if any tritium is detected by the initial bioassay(s).

Ideally, all voids done within the first 24 hours following the exposure should be collected. The individual being monitored should be provided with collection apparatus and a log sheet to keep track of collection dates and times. If any urine is not collected during this time, that should be noted as well and NRC Regulatory Guide 8.9 should be consulted regarding any total activity correction factors that may have to be applied. Additionally, analyses of the collected urine may have to be done to determine specific gravity or creatine concentration.

VI. Analysis Procedure and Equipment

All urine samples are analyzed by placing 2.0 ml of the urine to be assayed in a vial containing at least 10 milliliters of scintillation cocktail. The sample should then be counted for at least 10 minutes in accordance with the instructions for liquid scintillation counting in Appendix D.

VII. Sample Processing and Disposal

Urine samples should be handled in accordance with “Universal Precautions” as outlined in 29 CFR 1910.1030 (bloodborne pathogens standard). After the samples have been analyzed, all remaining fluid and rinsates should be discarded into the sanitary sewer system. Gloves and other solid waste material can be discarded as ordinary trash; however, all potentially radioactively contaminated material should be disposed of as radioactive waste.

VIII. Records

Bioassay records are maintained for 3 years and shall include the date of the bioassay, the name of the patient, and the urinary tritium concentration at the time of the measurement. Records of all analyzed samples should be kept on file.

IX. Action Levels

If the calculated concentration of tritium exceeds the following criteria, notify the monitored individual and take the corrective actions outlined in the appropriate section.

IX. Action Levels (continued)

A. Detectable levels > the MDC value for the counting instrument and < 5 uCi/L:

- Review the handling procedures performed by the subject and ensure that they are in keeping with good health physics and ALARA practices and principles.
- Document the findings and any necessary actions in the comments section of the bioassay log that corresponds to the initial sample meeting this criterion.

B. If the concentration is between 5 uCi/L and 50 uCi/L:

- Investigate the operations involved and perform surveys and air samples as required to help evaluate the potential for intake by the subject and other personnel in and around the work area, during and following these operations.
- Take reasonable corrective actions to limit the potential for future exposures
- Determine dose commitments to affected individuals utilizing the survey and other collected data, including taking follow-up urine samples within one week of the exposure and analyzing these samples within one week of collection. Additional samples must be taken as necessary to aid in the determination of the dose commitment.
- Ensure that no dose limit resulting from further work in the area will be exceeded, by taking steps to improve work practices, procedures, and/or environmental controls as necessary. If this can't be done, ensure that the individual is removed from all duties that would allow any further tritium exposure.

C. If the concentration exceeds 50 uCi/L:

- Carry out the actions described above and notify the FDOH Bureau of Radiation Control if projected dose limits will exceed any limit as specified in Chapter 64E-5, FAC.
- Take actions to accelerate the removal of tritium from the body, seeking medical advice or referring the person to medical specialists, as necessary.
- Perform follow-up bioassays at approximately 1-week intervals, until the concentrations are < 5 uCi/L. If there is a possibility of long-term compartments of organic tritium remaining in the exposed individual, consult NRC Reg. Guide 8.32 and the RSO for more instructions.