1.0 Purpose and Scope

This procedure provides the method for thyroid bioassay and dose assessment of personnel that work with I-125 and are required to participate in this program.

2.0 Roles and Responsibilities

2.1 Environmental, Health and Safety (EH&S) Office
- Maintain, oversee and implement of this procedure.

2.2 Radioiodine Users
- Minimize the potential for intakes of I-125 by implementing proper radiation safety controls.
- As required by this procedure or the Radiation Safety Officer (RSO), the I-125 users will comply with this procedure.

3.0 Definitions

- **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 the intake of a given radionuclide in the year that would result in a committed effective dose equivalent of 5 rem or a committed dose equivalent of 50 rem to any individual organ or tissue. For I-125 the stochastic ALI is 200 micro curies (uCi) and the non-stochastic ALI is 60 uCi, therefore, the non-stochastic is the controlling limit. These ALI values were obtained from US Nuclear Regulatory Commission’s Regulatory Guide 8.20. Because of the “as low as reasonably achievable (ALARA)” requirement, radioactive material intakes must be prevented.

- **Bioassay:** the determination of radioactive material in the human body, whether by direct measurements or by analysis of materials excreted from the human body. For I-125, direct counting of the thyroid is the preferred bioassay method.

- **Dose conversion factor (DCF):** is the committed effective dose equivalent (CEDE) per unit intake or the committed dose equivalent (CDE) per unit intake. The CEDE DCF is calculated by dividing 5 rem by the stochastic ALI (5 rem/200 uCi = 0.025 rem/uCi = 25 mrem/uCi). The CDE DCF is calculated by dividing 50 rem by the non-stochastic ALI (50 rem/60 uCi = 0.833 rem/uCi = 833 mrem/uCi) and is used for calculating the CDE to the thyroid.

- **Intake:** radioactivity that enters the body through the respiratory, the gastrointestinal tract, or the skin. Intake may be acute, meaning a single intake occurring over a short time, or chronic that occurs over a specified time. Common units used in this procedure are microcuries (uCi).

- **Intake Retention Fraction (IRF):** the fraction of an acute inhalation intake expected to be present in the thyroid at various times post intake that are derived from ICRP 30 metabolic models. Attachment 1 provides a table of IRF values for stable iodine and I-125. The IRF values for I-125 are obtained by multiplying the stable iodine IRF values by the appropriate radioactive decay factor.

- **Investigation Level (IL):** an activity of I-125 taken into the body (intake) which must be investigated by the RSO. The IL can be multiplied by the appropriate IRF to obtain the corresponding activity in the thyroid representing an intake that must be investigated by the RSO. The IL corresponds to an intake that would
cause 100 mrem committed dose equivalent (CDE) to the thyroid. For quarterly thyroid bioassay measurements this corresponds to an intake of 0.12 µCi (2.66E5 dpm) and an activity in the thyroid of 0.004 µCi (8880 dpm). The thyroid activity is calculated by multiplying the IL of 0.12 µCi by the I-125 IRF for 90 days (see Attachment 1).

• **Medical Intervention Level (MIL):** whenever the thyroid content at the time of bioassay measurement exceeds 5 µCi the RSO will refer the case to appropriate medical consultation for recommendations regarding therapeutic procedures that may be carried out to accelerate removal of radioiodine from the body. This should be done within 2–3 hours after exposure so that any prescribed thyroid blocking agent (e.g., potassium iodide) may be effective. This MIL is from the U.S. Nuclear Regulatory Commission’s Regulatory Guide 8.20.

• **Minimum Detectable Activity (MDA):** The smallest quantity of a radioisotope which can be detected with 95% confidence. The equation is provided below.

• **Recording Level (RL):** dose from an intake of radioactive material (e.g., I-125) above which it is recorded and entered into the radiation worker’s dose record. The RL is equal to 10 mrem committed dose equivalent to the thyroid. For quarterly thyroid bioassay measurements this corresponds to an intake of 0.012 µCi (2.66E4 dpm) and an activity in the thyroid of 0.0004 µCi (888 dpm). The thyroid activity is calculated by multiplying the RL of 0.012 µCi by the I-125 IRF for 90 days (see Attachment 1).

4.0 References
• Massachusetts Department of Public Health, Standards for protection against radiation, 105 CMR 120.200, 2018.

5.0 Detection System and Quality Control
• The thyroid counting system is composed of the following: Ludlum model 44-3 sodium iodide detector and Ludlum model 2200 scaler rate meter. The end of the sodium iodide detector is wrapped with 3 mm lead shielding.
• Thyroid counting system was tested and peaked by the manufacturer (Ludlum Instruments) for I-125 to ensure maximum counts are obtained when measuring I-125, which must be completed annually.
• A quality control test was established with the I-129 calibration source (4.437E5 dpm, SRS Number 114493, Eckert & Ziegler Analytics). 10 counts were obtained with calibration source that was placed in the thyroid neck phantom for a counting interval sufficiently long to obtain at least 10,000 counts (1% counting statistics). The source was removed and replaced in the neck phantom before each count. This was achieved with three-minute accounts. The mean and +/- 3 standard deviation values were calculated. If the quality control test counts are within this range the detector is deemed to be properly functioning. If the test counts fall outside of this range the RSO must evaluate the detector system. This quality control test must be performed before calibrating this detector and before thyroid bioassay measurements are performed. See Attachment 2 for an image of the quality control counting geometry.
• These measurements shall be documented in the counting log and plotted with MS Excel file. File name: I-125 QC chart. File location: W:\dept\ehso\shared\ehso\RADCON\Instrumentation\I-125.

6.0 Recording Level and Minimum Detectable Activity
• The thyroid bioassay counting system must be sufficiently sensitive to detect intakes equal to or above the Recording Level (RL).
• For radiation workers handling I-125 in quantities greater than 100 µCi, the routine thyroid bioassay counting frequency is expected to be quarterly (refer to Regulatory Guide 8.20 section C(1)(b)). Based on this counting frequency the RL corresponds to an I-125 activity in the thyroid of 0.0004 µCi (888 dpm). The minimum detectable activity (MDA) for the thyroid bioassay counting system must be below 888 dpm.

• The MDA must be calculated and documented in the counting log after the thyroid bioassay counting system is calibrated.

• The MDA is calculated as follows:

\[
MDA = \frac{4.66\sqrt{B} + 3}{(E)(T)}
\]

Where,

\( B = \) background counts in 3 minute,
\( E = \) I-125 thyroid counting efficiency, and
\( T = \) background counting time.

• The values for B, E, and T were determined in 2020 when the thyroid bioassay counting system was initially set up and were recorded as 51 counts, 0.033 c/d, and three minutes, respectively. From this equation the MDA was calculated to be less than 50% of the RL for I-125 activity in the thyroid.

• The values for B, E, T, and MDA will need to be determined annually or after the counting system is serviced and recorded in the counting log.

7.0 Thyroid Counting Efficiency for I-125

• Initially and annually thereafter the thyroid bioassay counting system must be calibrated using the following steps:
  
  o Move other radioactive sources away from the thyroid bioassay counting system.
  o Position the neck phantom in the calibration geometry (see Attachment 2).
  o Place the I-129 calibration standard into the neck phantom and count for three minutes. Repeat this process 10 times by removing and replacing calibration standard each time. Calculate the average of the 10 counts.
  o Remove the standard from the neck phantom and collect three-minute background count.
  Calculate the average net counts by subtracting the background counts.
  o Efficiency is calculated by dividing the net average counts by the activity of the I-129 calibration standard (4.437E5 dpm, SRS Number 114493, Eckert & Ziegler Analytics) and multiplying this quotient by 1.86. The 1.86 factor is from Ludlum Measurements, Inc. (available at ludlums.com website) and accounts for differences in the gamma emission rates of I-125 and I-129.
  o These measurements shall be documented in the counting log.

• Thyroid bioassay counting system must be calibrated if detection instrument is repaired, serviced or replaced.

8.0 Thyroid Bioassay Measurements

• There are four categories of bioassay measurements: baseline, routine, special, and termination.

  Baseline bioassay measurement are made before a radiation worker starts working with radiiodine.

  Routine bioassay measurements are made to verify that radiation safety controls are adequate and that intakes of radiiodine are not occurring.
• Special bioassay measurements are made after a suspected intake of radioiodine.
• Termination bioassay measurements are performed after radioiodine work terminates.
• Move all radioactive sources away from the thyroid bioassay counting system.
• The thyroid bioassay measurements for I-125 consist of a 3-minute count with the radiation worker in the thyroid counting geometry (see Attachment 3) and a 3-minute background count without the radiation worker present. The black foam spacer that is taped to end of NaI detector probe should press against the top of the sternum.
• The net counts are calculated by subtracting the background counts from the thyroid bioassay counts.
• The activity in the thyroid is calculated by dividing the net counts by the I-125 thyroid counting efficiency.
• All thyroid bioassay counts that are above the RL must receive a dose assessment and the committed dose equivalent (CDE) and committed effective dose equivalent (CEDE) must be recorded. This will require multiple thyroid bioassay measurements on different days and preferably several counts within one week of the intake.
• All thyroid bioassay counts that are above the IL must be investigated to identify the cause of the intake and to prevent reoccurrence.
• All thyroid bioassay counts that are above the MIL must be immediately referred by the RSO for medical consultation.
• These measurements shall be documented in the counting log.

9.0 Intake and Dose Assessment
• The intake of radioactive material is calculated by dividing the thyroid activity by the appropriate IRF. Whenever possible the intake should be estimated from multiple thyroid bioassay measurement results. For multiple bioassay measurement results a least-squares fitting should be used with both a weighted and unweighted fit. From these fits the highest intake estimate should be selected for the dose assessment.
• The unweighted fit is calculated as follows:

\[
I = \frac{\sum_{i=1}^{n} A_i IRF_i}{\sum_{i=1}^{n} IRF_i^2}
\]

Where,
\(A_i\) = bioassay measurement result for thyroid,
\(IRF_i\) = intake retention fraction corresponding to bioassay measurement result.

• A weighted fit is calculated as follows:

\[
I = \frac{\sum_{i=1}^{n} A_i}{\sum_{i=1}^{n} IRF_i}
\]

Where,
\(A_i\) = bioassay measurement result,
\(IRF_i\) = intake retention fraction corresponding to bioassay measurement result.

• If the date of the intake is known the appropriate IRF can be obtained from the table in Attachment 1. Linear interpolation can be used to obtain IRF values that are not provided in this table. If the intake date is not known, the RSO will investigate with the user to determine the most likely date of intake.
• From the intake the CDE and CEDE can be calculated.
• The CDE is calculated by multiplying the intake by the CDE conversion factor (50,000 mrem/60 uCi).
• The CEDE is calculated by multiplying the intake by the CEDE conversion factor (5,000 mrem/200 uCi).
• The CDE and CEDE must be included in the annual dose report for the radiation worker.
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Attachment 2