APPENDIX U

Iodine-131 or I-125 In-Vivo Thyroid Bioassay Program

Facilities involved in operations which exceed 1 mCi of unsealed radioiodine, must establish a thyroid bioassay program. This program shall be in compliance with section 64E-5.1320, F.A.C.

SENSITIVITY

Determine the minimum sample counting time needed to distinguish 0.04 μCi of I-131 in the thyroid from the background for the instrument. List instrumentation in Appendix B.

Measure the background count rate (Rb) in counts per minute (cpm) and record.

Measure a correction factor (CF) using an I-131 standard and record.

$$CF = \frac{Rst - Rb}{A(\mu Ci)}$$ Rst = count rate of standard (cpm)

Example: Background is 30 cpm and a 100 μCi standard measures 40,030 cpm on the instrument.

$$CF = \frac{40{,}030 - 30}{100\ \mu Ci} = 400\ cpm/\mu Ci$$

Calculate minimum sample counting time (t_{ms}) in minutes for the instrument.

$$\text{Lower Limit of Detection (LLD)} = \frac{4.66}{CF}\sqrt{\frac{Rb}{t_{ms}}}$$

$$t_{ms} = \left(\frac{4.66}{CF(.04)}\right)^2 Rb$$

$$t_{ms} = \frac{13{,}572 \times Rb}{CF \times CF} \quad \text{(minutes)}$$

RESULTS

Count the thyroid for at least t_{ms}.

The quantity of radioactive material (Q) deposited in the thyroid is:

$$Q = \frac{\text{Net Thyroid cpm}}{CF} \text{ or } \frac{(\text{neck cpm - bkg cpm})\ (\mu Ci\ \text{capsule})}{\text{capsule cpm - bkg cpm}}$$

Example

Background is 150 counts in 5 minutes or $\frac{150}{5} = 30$ cpm

100 μCi I-131 standard measures 40,030 cpm

$CF = \frac{40{,}030-30}{100\ \mu Ci} = 400\ cpm/\mu Ci$

$CF = 400\ cpm/\mu Ci \quad Rb = 30\ cpm$

$t_{ms} = \frac{13{,}572 \times 30}{(400)(400)} = 2.54\ minutes$

Must count at least 2.54 minutes.

Have chosen to count 5 minutes.

Thyroid Count Rate (Rt) - 175 counts in 5 minutes.

$$Rt = \frac{175}{5} = 35\ cpm$$

$$Q = \frac{35-30}{400} = 0.0125\ \mu Ci$$

Result is < 0.04 microcurie.

BIOASSAY FREQUENCY AND CORRESPONDING ACTIONS.

1. A baseline (pre-employment or pre-operational) bioassay will be performed.
2. A bioassay will be taken within 72 hours of initial use of radioiodine and every two weeks thereafter. When work with radioiodine is on an infrequent basis (less frequent than every two weeks), a bioassay will be taken within ten days of the last day of use.
3. The corresponding actions will be taken if the thyroid burden at the time of measurement exceeds 0.04 microcurie of I-131:
   - A. An investigation of the operations involved, including air and other facility surveys, shall 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 64E-5.304, 64E-5.310 or 64E-5.311, Florida Administrative Code, (F.A.C.), to be exceeded, the licensee shall restrict the worker from further exposure until the source of exposure is discovered and corrected.
   - C. Corrective actions that will eliminate or lower the potential for further exposures shall be implemented.
   - D. A repeat bioassay shall be taken within two weeks of the previous measurement and shall be evaluated within 24 hours after the 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. Notification reports must be provided as required by 64E-5.345 and 64E-5.347, or as required by conditions of the license and pursuant to subsection 64E-5.625(8), F.A.C.

4. If the thyroid burden at any time exceeds 0.14 microcurie of I-131, the following actions shall be taken:

   A. Carry out all steps as described in 3. a. - e. above.

   B. As soon as possible, refer the case to an appropriate medical consultant 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 one week intervals at least until the thyroid burden is less than 0.04 microcurie of iodine 131.

5. Bioassays may be performed quarterly, if the following conditions are satisfied:

   A. The average thyroid burden for each individual working in a given area for which bioassays were performed pursuant to Item 2., above, was less than 0.04 microcurie of iodine 131.

   B. If measurements of the concentration of radioiodine in air are required as a condition of the license, the quarterly average concentration does not exceed 25 percent of the value for I-131 specified in Table I, Column I, of State of Florida Bureau of Radiation Control, ALIs, DACs, and Effluent Concentrations July 1993.

   C. The working conditions during the three month period with respect to the potential for exposure are representative of working conditions during the period in which the quarterly bioassay frequency is employed, and there is no reasonable expectation that the criteria given in 5. A. and B. will be exceeded.

   D. Bioassays shall be randomly distributed over the quarter and will be done within one week after a procedure involving the handling of I-131 to provide a representative assessment of exposure conditions.

6. If the thyroid burden performed during quarterly bioassays exceed 0.04 microcurie of I-131, the following actions shall be taken:

   A. Carry out all steps as described in Items 3 and 4 above.

   B. Reinstitute bioassays every two weeks for at least the next three months before reestablishing quarterly bioassays.

RECORDS

Records of thyroid bioassay measurements will be maintained until termination of the radioactive materials license. The records will contain the thyroid burden measurement, the date of the measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

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