APPENDIX G

APPLICATION OF BIOASSAY FOR I-125 AND I-131

A. CONDITIONS UNDER WHICH BIOASSAY IS NECESSARY

1. Routine bioassay is necessary when an individual handles in open form, unsealed quantities of radioactive iodine that exceed those shown in Table 1. The quantities shown in Table 1 apply to both the quantity handled at any one time or integrated as the total amount of activity handled by an individual over a one month period.

2. Bioassay is not required, but recommended, when process quantities handled by an individual are less than those in Table 1.

B. PARTICIPATION

All individuals handling radioactive iodine or sufficiently close to the process so that intake is possible (i.e., within a few meters and in the same room as the individual handling the material), should participate in bioassay programs.

C. TYPES OF BIOASSAY THAT SHOULD BE PERFORMED

1. Baseline

   A baseline bioassay should be conducted prior to beginning work with radioactive iodine in amounts that would require participation in the bioassay program.

2. Routine

   Regular bioassay should be conducted to monitor routine operations at the frequency specified in Section D.

3. Emergency

   A bioassay should be performed as soon as possible after any incident that might cause thyroid uptakes to exceed burdens given in Section E.1.b so that actions recommended in Section E.1.b.(3) can be most effective.

4. Post-Operational and Termination of Usage

   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 individual is terminating activities with potential exposure to these radionuclides.

5. Diagnostic

   Follow-up bioassay should be performed within 2 weeks of any measurements exceeding levels given as action points in Section E. 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 radioiodine in the thyroid.

D. FREQUENCY

Initial Routine

A bioassay sample or measurement should be obtained within 72 hours following entry of an individual into an area where bioassay is performed in accordance with Sections A and B and every 4 weeks or more frequently thereafter, as long as the conditions described in Sections A and B exist. When work with radioactive iodine is on an infrequent basis, (less frequently than every 4 weeks), bioassay should be performed within 10 days of the end of the work period during which radioactive iodine was handled, unless emergency action is appropriate.

E. ACTION POINTS AND CORRESPONDING ACTIONS

1. Monthly and Other Measurements

   a. Whenever the thyroid burden at the time of measurement exceeds 0.12 μCi (4.4 kBq) of I-125 or 0.04 μCi (1.5 kBq) of I-131, the following actions will be taken:

      (1) An investigation of the operations involved, including air and other in-house surveys, will be carried out to determine the causes of exposure and to evaluate the potential for further exposures or for the possible involvement of other individuals.

      (2) Any evidence indicating that further work in the area might result in an individual receiving a dose commitment in excess of the limits established in 64E-5.304, should serve as cause to remove the individual from work in this operation until the sources of exposure is discovered and corrected.

      (3) Reports or notification must be provided as required by 64E-5.344 and 64E-5.345 of Chapter 64E-5 or as required by conditions of the license.

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

      (5) 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 effective half-life for use in estimating dose commitment.

   b. If the thyroid burden at any time exceeds 0.5 μCi (18.5 kBq) of I-125 or 0.14 μCi (5.2 kBq) of I-131, the following actions will be taken:

      (1) Carry out all steps in item a of this regulatory position.

(2) If the projected dose commitment exceeds levels for whole body as provided in 64E-5.304 of Chapter 64E-5, provide appropriate notification to DOH.

(3) As soon as possible, the case will be referred 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 when the time of exposure is known so that any prescribed thyroid blocking agent would be effective.

(4) Carry out repeated measurements at approximately 1 week intervals at least until the thyroid burden is less than 0.12 μCi (4.4 kBq) of I-125 or 0.04 μCi (1.5 kBq) of I-131.

TABLE 1

ACTIVITY LEVELS ABOVE WHICH BIOASSAY FOR I-125 OR I-131 IS REQUIRED

	Activity Handled in Unsealed Form Making Bioassay Necessary*	
Type of Operation	Volatile or Dispersible*	Bound to Nonvolatile Agent
Processes in open room or bench, with possible escape of iodine from process vessels	1.0 mCi (37 MBq)	1.0 mCi (37 MBq)
Processes with possible escape of iodine carried out within a fume hood of adequate design, face velocity, and performance reliability	1.0 mCi (37 MBq)	10.0 mCi (370 MBq)
Processed carried out within gloveboxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box and box leakage	10.0 mCi (370 MBq)	100.0 mCi (3700 MBq)

*Quantities may be considered the cumulative amount in process handled by a individual during a 1-month period; e.g., the total quantity introduced into a chemical or physical process over a 1 month period, or on one or more occasions in that period, by opening stock reagent containers from which radioactive iodine may escape. 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 and I-131 will remain in nonvolatile form and diluted to concentrations less than 0.1 mCi/mg (3.7 MBq/mg) of nonvolatile agent. Capsules (such as gelatin capsules given to patients for diagnostic test), may be considered to contain the radioiodine in non-free form, and bioassay would not be necessary unless a capsule were inadvertently opened (e.g., dropped and crushed). However, 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. In field operations, where reagent containers are opened outdoors for simple operations such as pouring liquid solutions, the above table does not apply; bioassay should be performed whenever an individual handles in open form (e.g., an open bottle or container) more than 50 mCi (1850 MBq) at any one time.

Operations involving the routine use of I-125 or I-131 in an open room or bench are discouraged. Whenever practicable, sealed bottles or containers holding more than 0.1

mCi (3.7 MBq) of I-125 or I-131 should be opened at least initially within hoods having adequate face velocities of 150 lf/min or more.