

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8, Rev. 1, Date: 1980

7. MEDICAL ISOTOPES COMMITTEE		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check One)	
<input type="checkbox"/>	Names and Specialties Attached; and	<input type="checkbox"/>	Appendix G Rules Followed; or
<input type="checkbox"/>	Duties as in Appendix B; or _____ (Check One)	<input type="checkbox"/>	Equivalent Rules Attached
<input type="checkbox"/>	Equivalent Duties Attached	16. EMERGENCY PROCEDURES (Check One)	
8. TRAINING AND EXPERIENCE		<input type="checkbox"/>	Appendix H Procedures Followed; or
<input type="checkbox"/>	Supplements A & B Attached for Each Individual User; and	<input checked="" type="checkbox"/>	XXXXXXXXXXXXXXXXXXXX See 23 Below
<input type="checkbox"/>	Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES (Check One)	
9. INSTRUMENTATION (Check One)		<input type="checkbox"/>	Appendix I Procedures Followed; or
<input type="checkbox"/>	Appendix C Form Attached; or	<input checked="" type="checkbox"/>	Equivalent Procedures Attached
<input checked="" type="checkbox"/>	List by Name and Model Number	18. WASTE DISPOSAL (Check One)	
10. CALIBRATION OF INSTRUMENTS		<input type="checkbox"/>	Appendix J Form Attached; or
<input type="checkbox"/>	Appendix D Procedures Followed for Survey Instruments; or _____ (Check One)	<input checked="" type="checkbox"/>	Equivalent Information Attached
<input type="checkbox"/>	Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One)	
<input type="checkbox"/>	Appendix D Procedures Followed for Dose Calibrator; or _____ (Check One)	<input type="checkbox"/>	Appendix K Procedures Followed; or
<input type="checkbox"/>	Equivalent Procedures Attached	<input type="checkbox"/>	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES	
<input checked="" type="checkbox"/>	Description and Diagram Attached	<input type="checkbox"/>	Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM		<input type="checkbox"/>	Appendix L Procedures Followed; or _____ (Check One)
<input checked="" type="checkbox"/>	Description of Training Attached	<input type="checkbox"/>	Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon - 133)	
<input checked="" type="checkbox"/>	Detailed Information Attached	<input checked="" type="checkbox"/>	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS (Check One)		22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
<input type="checkbox"/>	Appendix F Procedures Followed; or	<input type="checkbox"/>	Detailed Information Attached
<input type="checkbox"/>	Equivalent Procedures Attached	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
<input checked="" type="checkbox"/>	Appendix F Procedures Followed; or	<input checked="" type="checkbox"/>	Detailed Information Attached
<input type="checkbox"/>	Equivalent Procedures Attached	<input checked="" type="checkbox"/>	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE <i>(Check appropriate box)</i>		SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	FILM		
	TLD		
	OTHER <i>(Specify)</i>		
b. FINGER	FILM		
	TLD		
	OTHER <i>(Specify)</i>		
c. WRIST	FILM		
	TLD		
	OTHER <i>(Specify)</i>		

d. OTHER *(Specify)*

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY

STATE

ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED
(See Section 170.31, 10 CFR 170)

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type of Print)*

Robert E. Wise, M.D.

(2) TITLE

Chief Executive Officer

(1) LICENSE FEE CATEGORY:

7C Amendment

(2) LICENSE FEE ENCLOSED: \$ 120.00

c. DATE

5/1/85

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).
2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.
3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.
5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

INSTRUMENTATION

Instrumentation used for the Iodine-125 labelling consists of the following:

1. Electrometer/Geiger counter: Eberline E-120 electrometer and Eberline HP-260 low energy hand probe.
2. Gamma counters: Micromedic 4-200 or isoData 20-20.
3. Radioiodine mini-hood.
4. Air filter to sample the hood effluent transported to a roof exhaust fan.

RADIOIODINE MINI-HOOD

The hood within a hood
that offers **EXTRA PROTECTION**
in radioiodine control.

for
labelling
hood



Self-contained Mini-Hood has an activated charcoal air filtering cartridge to efficiently trap up to 90% radioiodine. Used inside a regular operating hood, it provides additional working protection and reduces radioiodine discharge to well within permissible limits. Eliminates the need for expensive in-line filter systems. Reduces hood maintenance costs.

Constructed of sturdy, shatterproof Lucite®. Mini-Hood has an integral blower capable of pulling 100 linear feet per minute; minimum of 100 linear feet per minute face velocity. One cubic foot of working volume offers adequate working area. Lightweight, portable... easily set up for radioiodine work and stored away when not in use. On-Off switch is located directly on blower. Comes with 5 feet of 3-line cord and grounding connector. 115V, 60/60 Hz.

112-035 Radioiodine Mini-Hood..... \$495.00 ✓
112-036 Replacement Charcoal Air
Filtering Cartridge 12"x12"x1".... 90.00 ✓
087-112 220V Converter 55.00



TOTAL POWER CORP.
MEDICAL DIVISION

6 New York Ave.
Framingham, Mass. 01701
Phone (617) 237-2024 or 879-2066

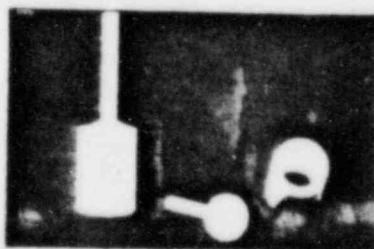
PLANCHETS

Atomlab Planchettes are available in several variations:

Aluminum with Flat Bottoms = AL Flat
Aluminum with Raised Concentric Rings = AL Con
Stainless Steel with Flat Bottoms = SS Flat
Stainless Steel with Raised concentric
Rings = SS Con
Copper with Flat Bottoms = COP Flat
Copper with Raised Concentric Rings = COP Con

SIZE	#	PRICE PER C
1" x 5/16"		
AL Flat	129-001	\$ 10.00
AL Con	129-002	\$ 10.00
SS Flat	129-003	\$ 10.00
SS Con	129-004	\$ 12.00
1-1/4" x 3/32"		
AL Flat	129-005	\$ 9.00
AL Con	129-006	\$ 9.00
SS Flat	129-007	\$ 10.00
SS Con	129-008	\$ 10.00
COP Flat	129-025	\$ 15.00
COP Con	129-026	\$ 15.00
1-1/4" x 5/16"		
AL Flat	129-009	\$ 9.00
AL Con	129-010	\$ 9.00
SS Con	129-012	\$ 11.00
1-1/2" x 1/4"		
AL Flat	129-013	\$ 10.00
AL Con	129-014	\$ 10.00
SS Flat	129-015	\$ 11.00
SS Con	129-016	\$ 11.00
2" x 1/8"		
AL Flat	129-017	\$ 11.00
AL Con	129-022	\$ 12.00
SS Flat	129-018	\$ 18.00
SS Con	129-019	\$ 18.00
2" x 1/4"		
AL Flat	129-023	\$ 13.00
AL Con	129-024	\$ 13.00
SS Flat	129-020	\$ 19.00
SS Con	129-021	\$ 19.00

ATOMLAB TEFLON PRECIPITATION APPARATUS



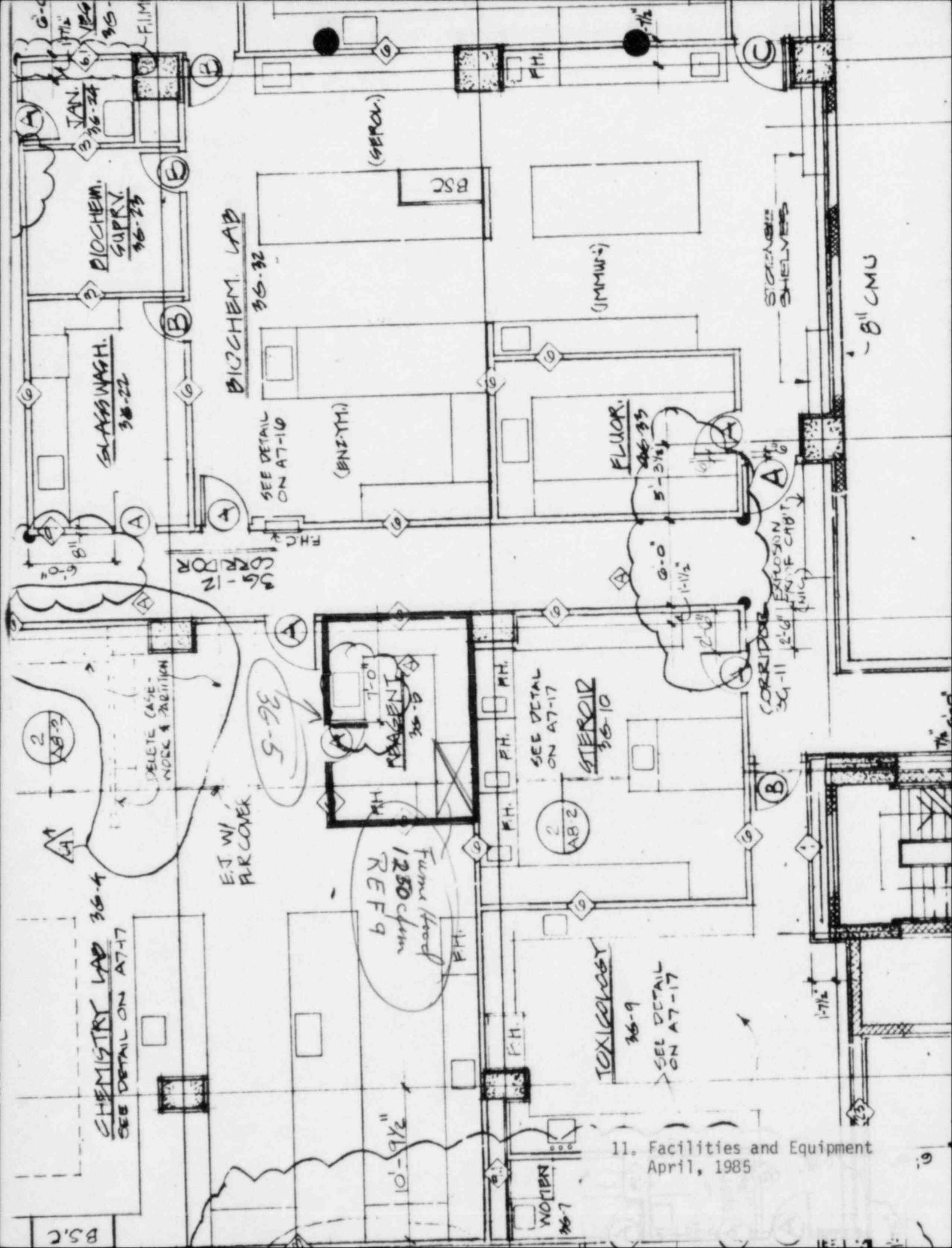
Made of tough rigid white Teflon which, being chemically inert, having an absolute non-adhesive surface and zero moisture absorption, is easily cleaned and decontaminated. The slotted disc accommodates 1-1/8" dia. filter paper for mounting on the very inexpensive, dual purpose nylon cupped-disc and ring device.

015-003 Precipitation Instrumentation
April, 1985

FACILITIES AND EQUIPMENT

The following layout diagram shows room 3G-5, which is an enclosed room with a built-in fume hood exhausting air to a roof vent at 1250 cubic feet per minute. The heavy line on the layout plan shows the limits of the restricted area.

An activated charcoal trap in the exhaust stream filters out any radioactive iodine which escapes from a small hood placed within the permanent hood. A filter trap placed upstream of the activated charcoal in the laboratory fume hood samples the exhaust air for contamination.



CHEMISTRY LAB 36-4
SEE DETAIL ON A7-17

GLASS WASH. 36-22

BIOCHEM. SUPPLY 36-23

BIOCHEM. LAB 36-32

TOXICOLOGY 36-9

STEROID 36-10

FLUOR. 36-33

Fume Hood
1250 cfm
REFP

REAGENT 36-5

CORRIDOR 36-12

CORRIDOR 36-11

WOMEN 36-7

PERSONNEL TRAINING PROGRAM

This Iodine labelling will be done by one or two workers well experienced in this laboratory procedure. The Radiation Safety Officer will meet with them at least once a year to discuss good radiation safety practice.

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

Each purchase of Iodine-125 will be made in quantities of 10 mCi or less per order. Shipments of less than 10 mCi per order will be sent directly to the clinical labs.

WIPE TEST PROTOCOL

The following is a protocol for wipe-testing areas to assess levels of removable radioactive contamination. Two different types of detectors are available for detection of low level gamma radiation. An electrometer with a thin-window proportional chamber is used as a quick check for gross contamination. Lower levels of activity must be detected with the gamma counter.

A calibration standard is used to determine the response of the radiation detector. A known amount of radioisotope, usually 0.001 microcurie, is deposited on a wipe as a standard. When counted with the appropriate detector this will serve as a calibration standard.

All measurements are to be recorded in a laboratory radiation survey log.

Wipe Test Procedure:

1. Rub 100 cm square with a dry wipe. If a larger area is surveyed the results should be expressed as DPM/100 cm².
2. Count the wipe for removable contamination using the appropriate radiation detection instrument.
3. Convert the wipe result in CPM to DPM utilizing the standard mentioned earlier.
4. Convert removable contamination as DPM/100 cm² and enter in the radiation survey log.

Interpretation of the results. If the measured contamination is less than 200 DPM/100 cm² no additional clean-up is required; if the measured contamination is greater than 200 DPM/100 cm² additional clean up is required until the measured activity is less than 200 DPM/100 cm².

WASTE DISPOSAL

Radioactive solid wastes resulting from the use of Iodine 125 will be held for decay, as measured in a low background area with a low-level survey meter, until the measured activity reaches background levels.

If appropriate these wastes will be disposed by Interex Corporation, Natick, Massachusetts, NRC license #20-14082.

PROCEDURES FOR THE USE OF RADIOACTIVE GASES

A maximum of approximately 2 millicuries of iodine 125 will be used for any week for labelling.

The labelling will be done in a fixed hood in Room 3G-5. The exhaust rate to a roof exhaust vent is 1250 cubic feet per minute. The iodination will be done in a hood within the permanent hood. The inner hood has an activated charcoal filter to absorb any iodine released during this study; in addition the permanent hood has an activated charcoal filter in the exhaust stack. Potential release of iodine up the stack will be monitored with an air filter which samples the exhaust plume.

To calculate the worst case release of iodine to an unrestricted area, that is the roof of the building, assume that 5% of the activity (100 microcuries) is released into an unrestricted area.

The concentration of iodine at this release point averaged over a 24 hour period is:

$$C = 100 \text{ } \mu\text{Ci} \times 24 \text{ hr} / (1.25 \times 10^3 \text{ CFM} \times (1.66 \times 10^6 \text{ ml/hr} - \text{CFM})) \\ = 2.0 \times 10^{-9} \text{ } \mu\text{Ci/ml}$$

The concentration is less than the maximum permissible concentration of soluble iodine (5×10^{-9} microcuries/ml).

EMERGENCY PROCEDURES FOR SPILLS OF RADIOACTIVE IODINE 125 IN THE
CLINICAL LABORATORY

If a spill of radioactive iodine 125 occurs during use:

1. Leave the fume hood "on."
2. Notify all persons not involved in the spill to vacate the area and close the door of the room.
3. Monitor personnel for contamination; individuals not contaminated must vacate the area. Any activity on the skin should be flushed with soap and water.
4. Remove lab coats or other outer garments which may be contaminated.
5. Notify the Radiation Safety Officer and the person in charge of the laboratory.
6. Post a "Radioactive Spill, No Entry" sign on the door of the room.
7. Enter the room again only after the hood has vented the room for one hour.
8. Survey the room with a Geiger counter to determine if there is any residual activity.
9. Perform wipe tests in the area around the spill to determine whether further cleanup is necessary.

Laboratory Supervisor:	Phone:	Home Phone:
Radiation Safety Officer:	Phone:	Home Phone:

PROCEDURES AND PRECAUTIONS FOR USE OF IODINE 125

These special precautions shall be observed in handling soluble iodine 125:

1. A lab coat and 2 pair of disposable gloves must be worn when handling iodine 125. The gloves should be changed frequently.
2. After handling iodine wash hands and monitor them with a Geiger counter to detect any contamination.
3. A Geiger counter should be near the hood and switched to the most sensitive range while handling soluble iodine.
4. Those handling soluble iodine must have a thyroid scan taken as a baseline measurement, and thereafter within 24 hours after each procedure.



IODINE-125

CATALOG NUMBER

NEZ 033H

HIGH CONCENTRATION

in ~ 0.1M NaOH (reductant free) solution

QUALITY CONTROL RESULTS

Radiochemical Purity:

Measured by thin layer chromatography using the upper phase of the solvent system n:butanol, pyridine, water, conc. ammonium hydroxide, (8:4:8:1) on alumina to contain > 99% as iodide on the analysis date.

Radionuclidic Purity:

Determined by Ge(Li) gamma spectrometry to be > 99.9% 125I; 9.0 x 10^-5% 126I on the analysis date. No other radionuclidic impurities were found.

Specific Activity:

MEETS SPECIFICATIONS

Iodination Incorporation:

MEETS SPECIFICATIONS

Concentration:

469 mCi/ml 17353 (MBq/ml) at the analysis date

pH: 13

LOT NO. 4852H

Calibration Date: 04-23-85

Analysis Date: 03-29-85

DuPont/NEN Products offers a wide range of Iodinated compounds. Call us if you need a custom Iodination or assistance with one that is not working. This information is available upon request from technical service.

Complete recovery of microliter quantities of solution is difficult because small droplets may cling to the septum or walls of the container. To maximize volume recovery we suggest the following:

- Shake the container downward to concentrate the solution at the bottom of the vial.
• Using a remote tool, remove the vial from its container and tap vial down against a hard surface in a ventilated hood.

We recommend that your Radiation Safety Office review any change in your existing procedure.

The above suggestions will not insure 100% volume recovery but will maximize recovery and minimize the risk of contamination.

FRESH LOT DATES

1985

Calendar grid for 1985 showing months JANUARY through DECEMBER with days of the week and dates.

I-125 is available every day from stock. O: alternating Wednesdays a fresh lot is stocked. Calibrated for 20 days hence.

125I Decay Table Physical Half-Life 60 Days

Table with 11 columns (Days Before/After Calibration Date 0-9) and 4 rows of decay factor data.

Multiply this factor times the nominal amount in the vial to get the amount on any given day.

CAUTION: NOT FOR USE IN HUMAN OR CLINICAL DIAGNOSIS

This product is intended for research or manufacturing use only. It is pharmacologically untried and verification of its suitability for use in humans or as a clinical diagnostic reagent and the compliance with all Federal and State laws regarding such applications are the sole responsibility of the purchaser.

LIMITED WARRANTY

E.I. du Pont de Nemours and Company warrants that, at the time of shipment, the products sold by it are free from defects in material and workmanship and conform to specifications which accompany the product. Du Pont makes no other warranty, express or implied, with respect to the products, including any warranty of merchantability or fitness for any particular purpose.

¹²⁵I

60d

EC

γ 0.035

E 0.177

IODINE-125: HANDLING PRECAUTIONS

NEN Products has developed the following suggestions for handling ¹²⁵I after years of experience working with this low energy gamma and X-ray emitter.

PHYSICAL DATA

Principle radiation emissions (1)

Gamma 0.035 MeV (6.5%)

K α X-rays 0.027 MeV (112.7%)

K β X-rays 0.031 MeV (25.4%)

Unshielded exposure rate at 1 cm from 1 mCi point source = 1.4 R h⁻¹ (2)

Half value layer for lead shielding = 0.02 mm (2)

OCCUPATIONAL LIMITS

Maximum permissible air concentration based on a 40 hour working week = 5×10^{-9} μ Ci ml⁻¹(3)

Maximum permissible body burden = 4.0 μ Ci (5)

Maximum permissible thyroid burden = 1.2 μ Ci (5)

DOSIMETRY

The thyroid is the critical organ for ¹²⁵I uptake. Individual uptake and metabolism vary over a wide range. The thyroid may be assumed to accumulate 30% of soluble radioiodine intake to the body and retain iodine with a 138 day biological half-life.(4) All radioiodine in the body can be assumed to be eliminated via the urine.(6)

SERVICES AVAILABLE:

Dupont NEN Products has gained considerable experience with trapping and monitoring the volatile species of iodine. This data is available upon request from customer service.

CALL OUR TOLL-FREE
NUMBER 800-225-1572

The following iodination publications could be helpful in designing or improving incorporations.

W. M. Hunter, F. C. Greenwood, Nature, 194, p. 495 (1962)

R. H. Seevers, R. E. Counsell, Chem. Rev., 82, 575 (1982)

J. C. Travis, Fundamentals of RIA and Other Ligand Assays, Scientific Newsletters, 1977, p. 56.

SPECIAL PRECAUTIONS:

Store Na ¹²⁵I solutions at room temperature because freezing results in subsequent volatilization of radioiodine. Avoid acidic solutions to minimize volatile species of radioactivity. Some radioiodine compounds may penetrate gloves. When handling these compounds use remote tools, wear two pairs of gloves and change the outer pair frequently or whenever suspected to be contaminated.

PRECAUTIONS

1. Designate area for handling ¹²⁵I and clearly label all containers.
2. Store mCi quantities of ¹²⁵I in containers surrounded by 1/8" thick lead.
3. Use tools to prevent direct handling of potentially contaminated vessels and unshielded multi mCi sources.
4. Prohibit smoking, eating and drinking in the laboratory where ¹²⁵I is handled.
5. Use transfer pipets, spill trays and absorbent coverings to confine contamination.
6. Handle quantities greater than 10 μ Ci in a ventilated hood.
7. Handle mCi quantities in closed systems vented through activated charcoal traps.
8. Sample exhausted effluent by continuously drawing a known quantity of air through cartridges containing activated charcoal.
9. Use disposable lab coat, gloves and wrist guards for secondary precaution.
10. Select gloves appropriate for chemicals handled.
11. Regularly monitor and promptly decontaminate gloves and surfaces to maintain contamination control.
12. Use NaI (TI) detector or liquid scintillation counter to detect ¹²⁵I.
13. Submit urine samples for bioassay from 2 to 12 hours after handling ¹²⁵I to indicate personal uptake.
14. Conduct periodic thyroid counts to determine dose.
15. Isolate waste in sealed labeled containers.
16. Establish surface contamination, air concentration, urinalysis, and thyroid burden action levels below maximum limits and investigate any causes which threaten these levels to be exceeded.

REFERENCES:

- (1) Kocher, David C., Radioactive Decay Data Tables, Springfield: National Technical Information Service, 1981 DOE/TIC-11026
- (2) Calculated with Computer Code 'Gamma' Utilizing Decay Scheme Data from Kocher and Mass Attenuation Coefficients for Lead and Mass Energy Absorption Coefficients for Air from the Radiological Health Handbook, Washington: Bureau of Radiological Health, 1970. The HVL reported here is the initial HVL for narrow beam geometry.
- (3) 10 CFR 20—Standards for Protection Against Radiation.
- (4) Recommendations of the International Commission on Radiological Protection, ICRP Publication 2, Pergamon Press, London, 1959.
- (5) Calculation using ICRP2 methods with a quality factor of 1.
- (6) Estimation of Radiation Doses to Body Tissues from Intermittent Contamination Due to Occupational Exposure, ICRP Publication 10, Pergamon Press, 1968.



NEN Products

CALL OUR TOLL-FREE

23. Procedures and Precautions
for Use of Radioactive
Material
April, 1985