

NRC FORM 313M

(9-81)

10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

## APPLICATION FOR MATERIALS LICENSE - MEDICAL

Approved by OMB

3150-0041

Expires 9-30-83

**INSTRUCTIONS** - Complete items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.

1.a. NAME AND MAILING ADDRESS OF APPLICANT (institution, firm, clinic, physician, etc.) INCLUDE ZIP CODE

HILO HOSPITAL  
1190 Waiianuenue Avenue  
Hilo, Hawaii 96720

TELEPHONE NO.: AREA CODE 808) 969 4111

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED (if different from 1.a.) INCLUDE ZIP CODE

Same

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Don Tolbert, Ph.D.

TELEPHONE NO.: AREA CODE 808) 536-2774

3. THIS IS AN APPLICATION FOR: (Check appropriate item)

a. ☐ NEW LICENSE

b. ☒ AMENDMENT TO LICENSE NO. 53-03506-1

c. ☐ RENEWAL OF LICENSE NO. \_\_\_\_\_

4. INDIVIDUAL USERS (Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)

James T. Lambeth, M.D.  
William E. Spies, M.D.  
R. S. Matsubara, M.D.  
James Williams, M.D.

5. RADIATION SAFETY OFFICER (RSO) (Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)

James T. Lambeth, M.D.

## 6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES			IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	As needed
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED	PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	As needed
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED	PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	As needed
10 CFR 35.100, SCHEDULE A, GROUP III	X	2000 each	GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	As needed
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	As needed
10 CFR 35.100, SCHEDULE A, GROUP V	X	AS NEEDED	XENON-133 AS GAS OR GAS + SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	X	300
10 CFR 35.100, SCHEDULE A, GROUP VI	X	1000			

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. (Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
NONE	8512020290 851104 REG 5 LIC 30 53-03506-01 PDR		

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(9-81)

70267

## INSTRUMENTATION

### Survey Meters

1. Manufacturer: Eberline Instrument Corporation  
Model No.: E-530  
Probe: HP-177C  
Min. Range: 0 - 0.2 mR/hr; 0 - 240 cpm  
Max. Range: 0 - 200 mR/hr; 0 - 240,000 cpm
2. Manufacturer: Eberline Instrument Corporation  
Model No.: E-520  
Probe: HP-260  
Min. Range: 0 - 0.2 mR/hr; 0 - 240 cpm  
Max. Range: 0 - 200 mR/hr; 0 - 240,000 cpm
3. Manufacturer: Eberline Instrument Corporation  
Model No.: E-120G  
Probe: Enclosed GM  
Min. Range: 0 - 10 mR/hr.  
Max. Range: 0 - 1000 mR/hr.

See attached calibration procedures.

### Pocket Dosimeters

A total of eight; manufactured by Victoreen; exposure range 0 - 200 mR. Model No.'s 862(2) and 541R(6). The charger is also manufactured by Victoreen. See attached calibration procedures.

### Dose Calibrator

1. Manufacturer: Nuclear Associates  
Model No.: 34-061  
No of Instruments: One  
Serial No.: 6130

See attached calibration procedures.

Item 9-1

Date: 9-20-85

70267

Diagnostic Instruments

Type	Manufacturer	Model No.
1. Camera	Searle Radiographic Inc.	Pho/Gamma IV
2. Dual Scintillation Probe	Picker	1376-A
3. Scintillation Probe	Picker	2806-B
4. Spectroscaler	Picker	628-436

Item 9-2  
Date: 9-20-85

70267

## CALIBRATION PROCEDURES

### Survey Instruments and Pocket Dosimeters

Survey instruments and pocket dosimeters will be calibrated annually by Mid-Pacific Medical Physics according to procedures outlined in NRC License No. 53-23207-01. Survey meters will be checked for consistency using a built-in sealed source, or other sealed source, prior to each use. Readings differing greater than 20% will be cause for investigation and recalibration, if necessary.

### Dose Calibrator

The geometrical variation of the instrument was checked following installation. The procedures used for daily constancy checks, quarterly linearity checks, and annual accuracy checks are attached.

### Instruments Used For Diagnostic Purposes

These instruments will be calibrated, quality control procedures performed and maintained in accordance with accepted standards and manufacturer's recommendations. These procedures will be the responsibility of Hilo Hospital staff.

Item 10-1  
Date: 9-20-85

70267

DOSE CALIBRATOR CONSTANCY, LINEARITY, AND  
ACCURACY CHECK PROCEDURES

Constancy: Daily constancy checks will be performed using at least two long-lived references. One standard will be Cs-137 (198  $\mu$ Ci on 1/11/78) and the other will be Co-57 (5.1 mCi on 8/23/83) and/or Ba-133 (263  $\mu$ Ci on 1/4/78). The accuracy of all three standards is within  $\pm 5\%$ .

A background level measurement will be recorded on the window setting used before each measurement with a standard. The net activity will then be computed and recorded. Limits of  $\pm 5\%$  will be determined and used as the limit beyond which repair or adjustment is required.

In addition to the Cs-137 standard being assayed using the Cs-137 window, one or both of the other standards mentioned above will be used on the commonly used window settings.

Linearity: Tests for the instruments linearity will be performed quarterly or after repair. The method used is outlined on the attached. Errors greater than  $\pm 5\%$  will indicate the need for adjustment or repair. If the non-linearity cannot be corrected, it will be necessary to use either (a) an aliquot of the elute that can be accurately measured, or (b) a graph will be constructed to correct for the error.

Accuracy: Accuracy checks will be performed annually or after repair, using the above standards. The calibration of these standards are provided by New England Nuclear and are traceable to the NBS. These sources are in vial type E containers. The accuracy check procedures include the following:

1. Each of the above standards will be assayed at the appropriate setting. Background activity will be subtracted to yield net activity. An average of at least three readings will be determined.
2. If the average activity determined in the first step does not agree with the decay corrected activity of the standards to within  $\pm 5\%$ , the instrument should be repaired or adjusted. If this is not possible, a calibration factor will be provided for use during routine assays of radionuclides.
3. At the time the above measurements are being made, the standards used in the daily constancy checks will be assayed using the window settings for these checks. These readings will be background corrected.

Item 10-8  
Date: 9-20-85

70267

## FACILITIES AND EQUIPMENT

### Floor Plan Information

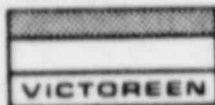
Attached is a floor plan of the Nuclear Medicine area. This area is located on the first floor of the hospital. A low-level radioactive waste storage area is located on the ground floor and the walls contain the equivalent of at least 5 mm of lead. The latter is a dedicated space which will be secured as per 10 CFR 20.207. The area will be labeled as per the requirements of 10 CFR 20.203 and radiation levels surrounding the area will be maintained according to the requirements of 10 CFR 20.105 (b).

No Xenon-133 will be used. A self-contained fume hood will be used. This fume hood is made by Victoreen. The specifications and associated diagram are shown on the attached. Air flow measurements will be made initially to assure that the minimum linear flow speed is 100 ft./min. and checked semi-annually thereafter. The fume hood will be used for opening I-131 activities of 0.1 mCi or more. The use of this system, based on present usage, will be less than six (6) times per month. Therapeutic doses of I-131 greater than 30 mCi are not expected to number more than one (1) per month. The filter system will be monitored using the uptake probe in order to determine the procedures necessary to maintain ALARA.

Tc-99m generators will be stored in the Hot Lab and doses will be drawn from behind a L-Block shield. One-inch thick lead bricks will be used to keep exposure levels in the Hot Lab ALARA around the generators and temporary waste storage. Radiation levels adjacent to the Nuclear Medicine area, including the Hot Lab, will be determined initially to ensure that levels are compliant with 10 CFR 20.105 (b). Signs will be used as per the requirements of 10 CFR 20.203.

Item 11-1  
Date: 9-20-85

## VICTOREEN NUCLEAR ASSOCIATES



100 Voice Road  
Carle Place, NY 11514-1593  
(516) 741-6360  
A Sherrill-Globe Corporation Subsidiary **SG**



### Radioiodine Fume Hood

*Designed specifically for iodination procedures*

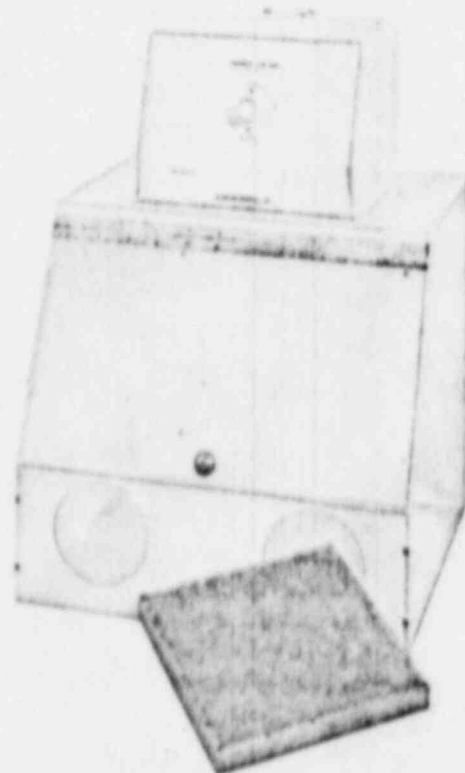
- Made of easy-to-decontaminate plexiglass.
- Occupies only 24" of bench space

The Radioiodine Fume Hood is ideal for preparing, handling and containing the materials used in iodination procedures. Utilizing only 24" of bench space, it enables the technician to perform hazardous operations with comfort and relative safety.

The rugged unit is made of 3/4" clear plexiglass, offering maximum visibility. A large internal work area and spacious arm ports allow uninhibited manipulation of materials within the hood. The 24" x 18" swing-away front door permits easy placement and retrieval of items. An air baffle assures an even air flow out of the hood. Negative air-flow speed can be adjusted from 0-180 CFM.

UL-approved induction-type motor, 1/2 hp, 110 VAC, 50-60 Hz. Disposable charcoal filter traps 98% of radioiodine produced. Can accommodate up to two filters (one included with hood). Measures 24" wide x 20" deep x 36" high. Gross 125 lbs.

11-201 Radioiodine Fume Hood ..... \$1,225.00  
11-202 Replacement Charcoal Filter ..... 90.00

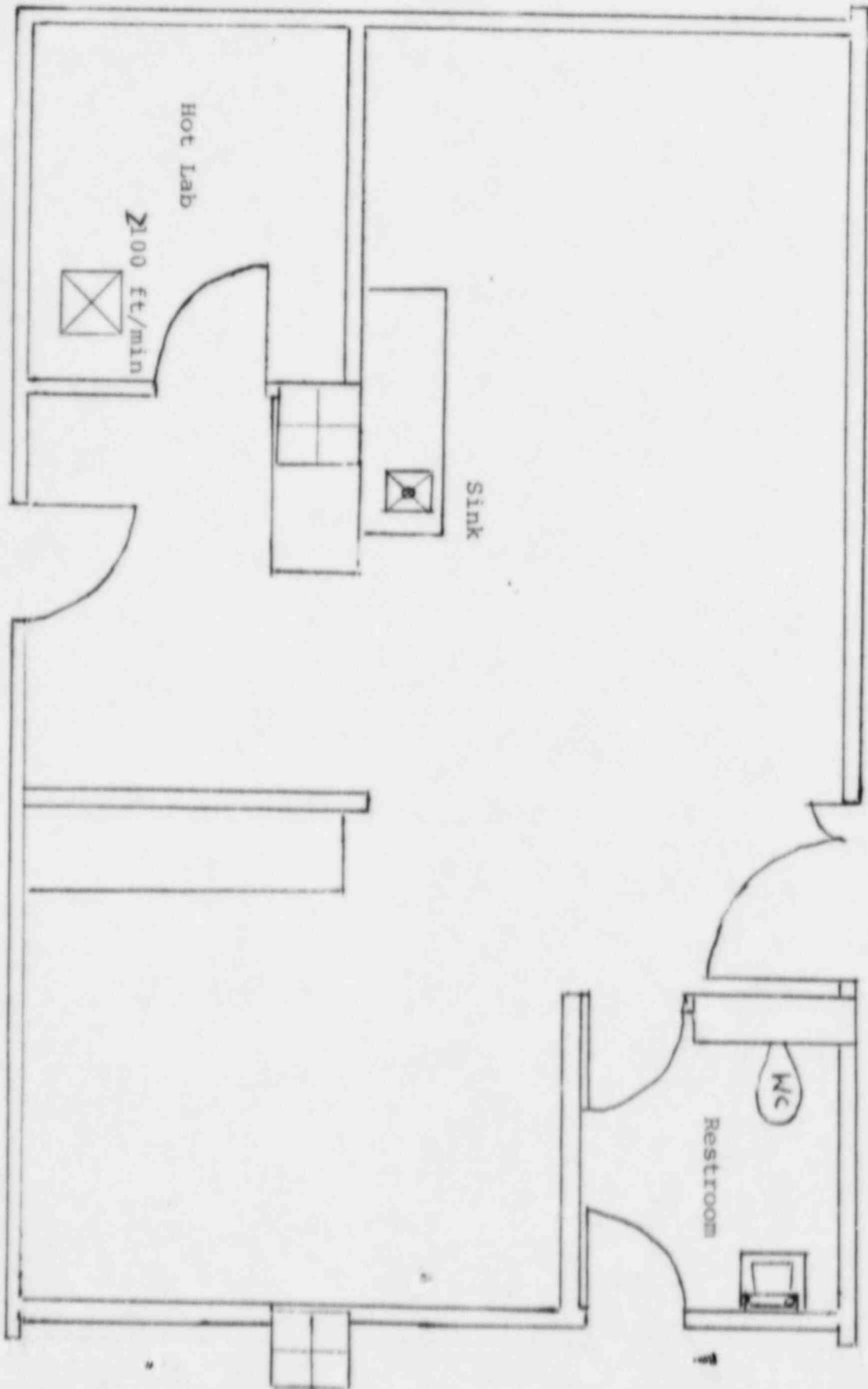


Item 11-2  
Date: 9-20-85

70267



NUCLEAR MEDICINE AREA



Item 11-3

Date: 9-20-85

70267



11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

13. Always transport radioactive material in shielded containers.

14. When opening vials of I-131 containing activities greater than 0.1 mCi, wear gloves and open under a fume hood.

Item 15-2

Date: 9-20-85

70267

## AREA SURVEY PROCEDURES

1. All elution, preparation, and injection areas will be surveyed daily with a GM survey meter equipped with a pancake probe and decontaminated if necessary. For daily surveys where no abnormal exposures are found, only the date, the identification of the person performing the survey, and the survey results will be recorded.
2. Laboratory areas where only small quantities of radioactive material are used (less than 200  $\mu$ Ci) now operate under a General License as provided for under 10 CFR 31.11.
3. The waste storage area will be surveyed weekly.
4. The weekly and monthly surveys will consist of:
  - a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.
  - b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 100 cpm per 100 cm<sup>2</sup> for the contaminant involved. Wipes of elution and preparation areas or other "high background" areas will be removed to a low background area for measurement.
5. A permanent record will be kept of all survey results, including negative results. The record will include:
  - a. Name of person conducting the survey.
  - b. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.
  - c. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).
  - d. Detected contamination levels, keyed to locations on drawing.
  - e. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.
  - f. The equipment used for the survey.
  - g. The date of the survey.
6. Area will be cleaned if the contamination level exceeds three times the background reading.

Item 17-1

Date: 9-20-85

70247