

L+L= 20847
030-21260

FORM NRC-313 I (1-79) 10 CFR 30		U.S. NUCLEAR REGULATORY COMMISSION		1. APPLICATION FOR: (Check and/or complete as appropriate)	
APPLICATION FOR BYPRODUCT MATERIAL LICENSE INDUSTRIAL				03330	
				<input checked="" type="checkbox"/> a. NEW LICENSE	
				<input type="checkbox"/> b. AMENDMENT TO: LICENSE NUMBER	
See attached instructions for details. Completed applications are filed in duplicate with the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety, and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 or applications may be filed in person at the Commission's office at 1717 H Street, NW, Washington, D. C. or 7915 Eastern Avenue, Silver Spring, Maryland.				<input type="checkbox"/> c. RENEWAL OF: LICENSE NUMBER	
2. APPLICANT'S NAME (Institution, firm, person, etc.) ECOGEN INC.			3. NAME OF PERSON TO BE CONTACTED REGARDING THIS APPLICATION BARRY LEVINSON, RSO		
TELEPHONE NUMBER: AREA CODE - NUMBER EXTENSION (609) 799-4020			TELEPHONE NUMBER: AREA CODE - NUMBER EXTENSION (609) 799-4020		
4. APPLICANT'S MAILING ADDRESS (Include Zip Code) P.O. BOX 6818 Lawrenceville, NJ 08648			5. STREET ADDRESS WHERE LICENSED MATERIAL WILL BE USED (Include Zip Code) 4100 Quakerbridge Rd. Lawrenceville, NJ 08648 (until 1/86) (See Attachment V.)		
(IF MORE SPACE IS NEEDED FOR ANY ITEM, USE ADDITIONAL PROPERLY KEYED PAGES.)					
6. INDIVIDUAL(S) WHO WILL USE OR DIRECTLY SUPERVISE THE USE OF LICENSED MATERIAL (See Items 16 and 17 for required training and experience of each individual named below)					
FULL NAME			TITLE		
a. SEE ATTACHMENT VI.					
b.					
c.					
7. RADIATION PROTECTION OFFICER			Attach a resume of person's training and experience as outlined in Items 16 and 17 and describe his responsibilities under Item 15.		
8. LICENSED MATERIAL					
L I N E	ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	NAME OF MANUFACTURER AND MODEL NUMBER (If Sealed Source)	MAXIMUM NUMBER OF MILLICURIES AND/OR SEALED SOURCES AND MAXIMUM ACTI- VITY PER SOURCE WHICH WILL BE POSSESSED AT ANY ONE TIME	
NO.	A	B	C	D	
(1)	SEE ATTACHMENT I.				
(2)					
(3)					
(4)					
DESCRIBE USE OF LICENSED MATERIAL E					
(1)					
(2)					
(3)					
(4)					

FORM NRC-313 I (1-79)

License Fee Information
10 7-11
5/8/85
Cover letter

"OFFICIAL RECORD COPY"

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REG1 LIC30
29-20847-01 PDR

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9. STORAGE OF SEALED SOURCES			
LINE NO.	CONTAINER AND/OR DEVICE IN WHICH EACH SEALED SOURCE WILL BE STORED OR USED A.	NAME OF MANUFACTURER B.	MODEL NUMBER C.
(1)	N/A		
(2)			
(3)			
(4)			

10. RADIATION DETECTION INSTRUMENTS						
LINE NO.	TYPE OF INSTRUMENT A.	MANUFACTURER'S NAME B.	MODEL NUMBER C.	NUMBER AVAILABLE D.	RADIATION DETECTED (alpha, beta, gamma, neutron) E.	SENSITIVITY RANGE (milliroentgens/hour or counts/minute) F.
(1)	SEE ATTACHMENT II.					
(2)						
(3)						
(4)						

11. CALIBRATION OF INSTRUMENTS LISTED IN ITEM 10	
<input checked="" type="checkbox"/> a. CALIBRATED BY SERVICE COMPANY NAME, ADDRESS, AND FREQUENCY SEE ATTACHMENT II.	<input type="checkbox"/> b. CALIBRATED BY APPLICANT Attach a separate sheet describing method, frequency and standards used for calibrating instruments.

12. PERSONNEL MONITORING DEVICES		
TYPE — (Check and/or complete as appropriate.) A.	SUPPLIER (Service Company) B.	EXCHANGE FREQUENCY C.
<input type="checkbox"/> (1) FILM BADGE <input checked="" type="checkbox"/> (2) THERMOLUMINESCENCE DOSEMETER (TLD) <input checked="" type="checkbox"/> (3) OTHER (Specify): <u>Bioassay</u> <u>See Attachment III.</u>	R.S. Landauer Jr. and Co. Glenwood Park, IL 60425	<input type="checkbox"/> MONTHLY <input checked="" type="checkbox"/> QUARTERLY <input type="checkbox"/> OTHER (Specify): _____

13. FACILITIES AND EQUIPMENT (Check where appropriate and attach annotated sketch(es) and description(s).)	
<input checked="" type="checkbox"/> a. LABORATORY FACILITIES, PLANT FACILITIES, FUME HOODS (Include filtration, if any), ETC. <input type="checkbox"/> b. STORAGE FACILITIES, CONTAINERS, SPECIAL SHIELDING (fixed and/or temporary), ETC. <input type="checkbox"/> c. REMOTE HANDLING TOOLS OR EQUIPMENT, ETC. SEE ATTACHMENT IV. <input type="checkbox"/> d. RESPIRATORY PROTECTIVE EQUIPMENT, ETC.	

14. WASTE DISPOSAL	
a. NAME OF COMMERCIAL WASTE DISPOSAL SERVICE EMPLOYED <u>Teledyne Isotopes, Westwood, NJ</u>	
b. IF COMMERCIAL WASTE DISPOSAL SERVICE IS NOT EMPLOYED, SUBMIT A DETAILED DESCRIPTION OF METHODS WHICH WILL BE USED FOR DISPOSING OF RADIOACTIVE WASTES AND ESTIMATES OF THE TYPE AND AMOUNT OF ACTIVITY INVOLVED. IF THE APPLICATION IS FOR SEALED SOURCES AND DEVICES AND THEY WILL BE RETURNED TO THE MANUFACTURER, SO STATE	

INFORMATION REQUIRED FOR ITEMS 15, 16 AND 17

Describe in detail the information required for Items 15, 16 and 17. Begin each item on a separate page and key to the application as follows:

15. RADIATION PROTECTION PROGRAM. Describe the radiation protection program as appropriate for the material to be used including the duties and responsibilities of the Radiation Protection Officer, control measures, bioassay procedures (if needed), day-to-day general safety instruction to be followed, etc. If the application is for sealed source's also submit leak testing procedures, or if leak testing will be performed using a leak test kit, specify manufacturer and model number of the leak test kit.

SEE ATTACHMENT V.

16. FORMAL TRAINING IN RADIATION SAFETY. Attach a resume for each individual named in Items 6 and 7. Describe individual's formal training in the following areas where applicable. Include the name of person or institution providing the training, duration of training, when training was received, etc.

SEE ATTACHMENT VI.

- a. Principles and practices of radiation protection.
- b. Radioactivity measurement standardization and monitoring techniques and instruments.
- c. Mathematics and calculations basic to the use and measurement of radioactivity.
- d. Biological effects of radiation.

17. EXPERIENCE. Attach a resume for each individual named in Items 6 and 7. Describe individual's work experience with radiation, including where experience was obtained. Work experience or on-the-job training should be commensurate with the proposed use. Include list of radioisotopes and maximum activity of each used.

SEE ATTACHMENT VI.

18. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 2, certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Part 30, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

WARNING: 18 U.S.C. Section 1001, Act of June 25, 1948; 62 Stat. 749; makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

<p>a. LICENSE FEE REQUIRED (See Section 170.31, 10 CFR 170) \$700.00</p>	<p>b. CERTIFYING OFFICIAL (Signature) <i>Bruce C. Carlton</i></p>
<p>(1) LICENSE FEE CATEGORY Bioproducts - Industrial</p>	<p>c. NAME (Type or print) Bruce C. Carlton</p>
<p>(2) LICENSE FEE ENCLOSED \$ 700.00</p>	<p>d. TITLE Vice President, Research & Development</p>
	<p>e. DATE May 8, 1985</p>

FORM NRC 313 (11-79)

ATTACHMENT I.

Item 8. Licensed Material

<u>Element and Mass No.</u>	<u>Chemical and/or Physical Form</u>	<u>Maximum Activity to be Possessed at Any One Time</u>
1. Phosphorous-32	Organic and inorganic liquids(non-volatile)	50. mCi.
2. Iodine-125	NaI and proteins	5. mCi.
3. Sulfur-35	Organic and inorganic liquids(non-volatile)	15. mCi.
4. Tritium(H-3)	Organic and inorganic liquids(non-volatile)	25. mCi.
5. Carbon-14	Organic and inorganic Liquids(non-volatile)	6. mCi.

Item 8.E Use of Radionuclides

All the radionuclides will be used in microcurie amounts as labelled nucleotides and organic compounds in microbiological and biochemical in vitro studies. The Iodine 125 will be used in RIA, and in low millicurie amounts for labelling molecules. The P-32 will occasionally be used in millicurie amounts for labelling molecules.

ATTACHMENT II

Items 10 and 11. Radiation Detection Equipment and Calibration

ITEM 10.

1. Geiger-Mueller Survey Instruments. One has been purchased. Additional will be purchased as necessary.

Model: Eberline EI20 with HP190 probe or equivalent.

Use: Monitoring the use of I-125 and P-32

Range: 0.1 to 50 mr/hr.

Calibration: to Cs-137; see page II-2 for calibration procedure.

Check: Check source

2. Liquid Scintillation Counting Spectrometer

Model: Beckman LS3801

Use: Experimental analysis and analysis of contamination smears and urine (bioassay) samples.

Range: 100 cpm/sample to 1,000,000 cpm/sample;

Lower limit for Detection:

Tritium: 50 dpm/sample(in Tritium sample)

Carbon 14, I-125, P-32: 100 dpm/sample

Calibration: As required; by use of standardized radionuclide sources, e.g. Beckman cat. no. 566321

ITEM 11.

RADIATION DETECTION INSTRUMENTS

CALIBRATION PROCEDURE

1. Geiger-Mueller Survey meter.

The survey meters will be calibrated by our staff using the source at Rutgers University, New Brunswick, NJ.

The survey instruments are routinely calibrated every six months using a nominal 100 mCi. Cs-137 gamma "instrument calibration" source. The exposure rate has been determined by the vendor, using ionization chambers whose calibration is traceable to the National Bureau of Standards. The procedure is typically as follows:

- a. The instrument is placed in a free air uniform gamma field of the calibrator where the exposure rate corresponds to the mid-scale reading of the meter on a given range setting and calibrated at the mid-point. The exposure rate is determined by a Victoreen R-chamber of an appropriate range.
- b. The instrument is then placed in the gamma field at exposure rates corresponding to one-third the full scale and two-thirds of the full scale reading. If the meter readings at either of these two points differ from the true exposure rate by more than ten percent(10%), the meter is adjusted by repeating steps a. and b. until the meter is within ten percent.
- c. Steps a. and b. are performed for all range settings of the instrument that can be calibrated with this source.
- d. A calibration label is affixed to the instrument, specifying the ranges that have been calibrated and the date of calibration.

2. Liquid Scintillation Counter.

See Item 10. previous page.

ATTACHMENT III.

Item 12. Personnel Monitoring

Personnel badges will be worn by all persons using millicurie amounts of P-32 and Iodine-125 to assure that all exposures are minimized. It is unlikely that anyone will be exposed to levels which will result in doses above the limits of 10CRF20.202 so badges will be worn to establish good health physics practices. Finger dosimeters will be required for P-32 users.

Persons conducting labelling procedures with Iodine 125 or using I-125 labelled compounds with activities above those used for RIA will be required to have urine assays routinely. Persons conducting a labelling procedure will be required to have a urine analysis within one(1) day (but no sooner than four hours) after the procedure has been completed. If the results of the urine analysis is positive the person will have his thyroid monitored at the Rutgers University Department of Radiation and Environmental Health and Safety, Piscataway NJ, 08854.

Urine analysis or other appropriate bioassays will be done in the event of a suspected accidental intake of a radionuclide. The standard procedure for urine analysis is to count a one(1) ml. sample of the individual's urine by Liquid Scintillation. The minimum detectable body burdens for the isotopes of Item 8 are calculated below.

TRITIUM: The MDL is $\frac{50 \text{ dpm/ml}}{2.22 \times 10^6 \text{ dpm/uCi}} = 2.2 \times 10^{-5} \text{ uCi/ml}$

which corresponds to a whole body water burden of approximately 0.095 uCi. This threshold is well below the Maximum Permissible Body Burden of 1000 uCi (ICRP 10). Analysis of other organ burdens of Tritium will be done using the latest reference data, e.g. NCRP or ICRP documents.

CARBON 14: The MDL is $\frac{100 \text{ dpm/ml}}{2.22 \times 10^6 \text{ dpm/uCi}} = 0.050 \times 10^{-3} \text{ uCi/ml}$
SULFUR 35:
P-32:

Which corresponds to whole body burdens in excess of the Maximum Permissible Body Burdens (ICRP 10), 400 uCi for C-14 and S-35, and 30 uCi for P-32. Because of the relatively high threshold of the urine assay for these radionuclides and the small probability that a significant fraction of the Maximum Permissible Body Burdens would be taken into the body of a radiation worker in situations other than accidents, urine assay for these isotopes will be done only if there is a suspicion that accidental intake may have occurred.

Urine Analysis for I-125 will be done by counting a one milliliter aliquot of urine using the Liquid Scintillation system described above. This instrument has a minimum detectability on the order of 0.010 nCi/sample, well below the prescribed limits of intake.

ATTACHMENT IV.

Item 13. Facilities

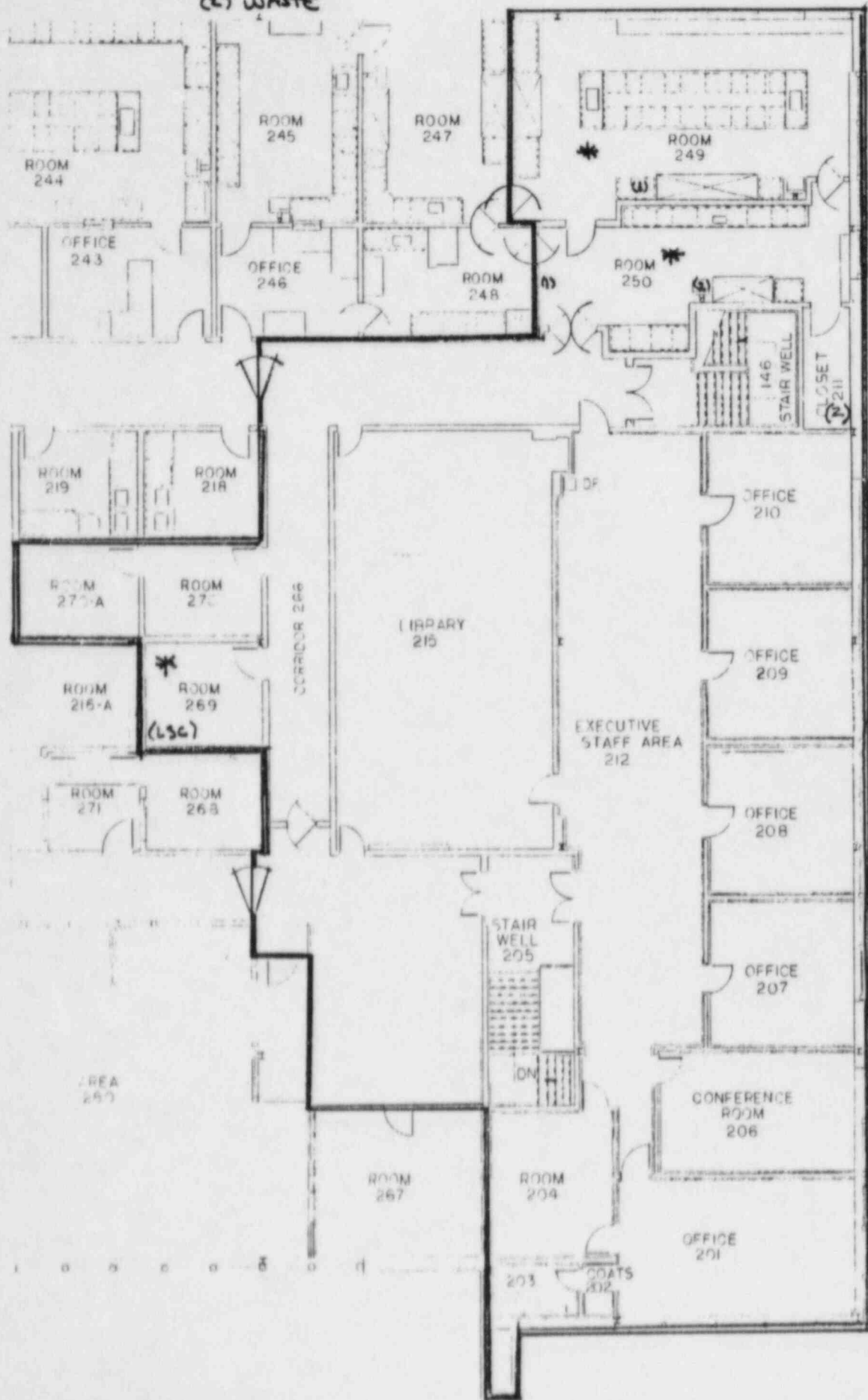
A floor plan of the laboratory is attached. The areas in which radioisotopes will be used are indicated.

Features:

1. Floor covering: Sealed tile or equivalent.
2. Working surfaces: Formica or equivalent; absorbant, plastic backed paper will be used at all times.
3. Hoods: Impervious surfaces; with minimum of 100 linear feet per minute air flow across the front of the hood opening with the windows at normal height.
4. Iodination Facilities: Iodinations will be done in a hood or mini-hood equipped with an adequate activated charcoal filter in the exhaust system.

QUAKERBRIE ROAD SITE

* RAM USED
(1) STORAGE
(2) WASTE



ATTACHMENT V.

Item 15. Radiation Protection Program

See the attached Radiation Safety Guide. The specific items of the program are listed below:

	<u>page no.</u>
a. Survey Program	14,20,22
b. Records keeping	13, 21, 26, 27
c. Sealed source leak test	N/A
d. Instructions to Personnel	7,(Appendix II)