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

Radiology Associates, P.C.
#1 Ajax Dr., Suite 130
Madison Heights, Michigan 48071

TELEPHONE NO. AREA CODE (313) 544 3877

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

2. PERSON TO CONTACT REGARDING THIS APPLICATION

David Close, Consultant
Nuclear Medicine Associates

TELEPHONE NO. AREA CODE (216) 641 5799

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

a. ☐ NEW LICENSE
b. ☒ AMENDMENT TO LICENSE NO. 21-16754-01
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.)*

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.)*

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6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		

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
The purpose of this amendment application is three fold: 1. Please delete the 2665 Elizabeth Lake Rd., Pontiac, Michigan facility from the license. A close out survey is enclosed. 2. Please add 14103 Fenkel, Detroit, Michigan 48227 as an authorized place of use to the license. Items #9, 11 and 21 are enclosed for this facility. 3. Request authorization for the use of Gd-153 (possession limit of 2000mCi) and I-125 (possession limit of 700mCi) as sealed sources for use in bone mineral analyzers as per the enclosed Item #23.			

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21-16754-01

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License Fee Information on Next Page

CONTROL NO. 80263

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. _____ Date: _____

7. MEDICAL ISOTOPES COMMITTEE

- ☐ Names and Specialties Attached; and
- ☐ Duties as in Appendix B; or _____ *(Check One)*
- ☐ Equivalent Duties Attached

8. TRAINING AND EXPERIENCE

- ☐ Supplements A & B Attached for Each Individual User; and
- ☐ Supplement A Attached for RSO.

9. INSTRUMENTATION *(Check One)*

- ☐ Appendix C Form Attached; or
- ☐ List by Name and Model Number

10. CALIBRATION OF INSTRUMENTS

- ☐ Appendix D Procedures Followed for Survey Instruments; or _____ *(Check One)*
- ☐ Equivalent Procedures Attached; and
- ☐ Appendix D Procedures Followed for Dose Calibrator; or _____ *(Check One)*
- ☐ Equivalent Procedures Attached

11. FACILITIES AND EQUIPMENT

- ☐ Description and Diagram Attached

12. PERSONNEL TRAINING PROGRAM

- ☐ Description of Training Attached

13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

- ☐ Detailed Information Attached

14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*

- ☐ Appendix F Procedures Followed; or
- ☐ Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*

- ☐ Appendix G Rules Followed; or
- ☐ Equivalent Rules Attached

16. EMERGENCY PROCEDURES *(Check One)*

- ☐ Appendix H Procedures Followed; or
- ☐ Equivalent Procedures Attached

17. AREA SURVEY PROCEDURES *(Check One)*

- ☐ Appendix I Procedures Followed; or
- ☐ Equivalent Procedures Attached

18. WASTE DISPOSAL *(Check One)*

- ☐ Appendix J Form Attached; or
- ☐ Equivalent Information Attached

19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*

- ☐ Appendix K Procedures Followed; or
- ☐ Equivalent Procedures Attached

20. THERAPEUTIC USE OF SEALED SOURCES

- ☐ Detailed Information Attached; and
- ☐ Appendix L Procedures Followed; or _____ *(Check One)*
- ☐ Equivalent Procedures Attached

21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)

- ☐ Detailed Information Attached

22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS

- ☐ Detailed Information Attached

23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b

- ☐ Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

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

d. OTHER (Specify)

Applicant Rec. 7 III
Check No. 10128
Amount/Fee Category $120 (7C)
Type of Fee AMD
Date Check Rec'd 12/9/85
Received By DSR

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)*

(1) LICENSE FEE CATEGORY: 7C

(2) LICENSE FEE ENCLOSED: $ 120.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

X John Mellen

(1) NAME *(Type or Print)*

X JOHN MELLEN

(2) TITLE

X Radiation Safety Officer

c. DATE

X 10-29-85

NRC FORM 313M (9-81)

CONTROL NO. 80263

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.

Item #23

A bone mineral analyzer will be installed in the camera room of the 2870 E. 14 Mile Rd., Warren, Michigan facility by Lunar Radiation Corporation. The Gd-153 unit would be model #DP-3 containing a source from the GD series. The I-125 unit would be model #SP-2 containing a source approved by the NRC for use with this unit.

Training for the use of these devices will be provided by Lunar Radiation Corporation. The manufacturer's instructions for use will be followed. Source changes will be performed by the manufacturer or by a nuclear medicine technologist trained in the procedure by the manufacturer. Service will be performed by a manufacturer authorized service engineer.

Authorization is also requested to periodically transport the device to one of the other facilities listed on the license. The source will be kept in the analyzer during transport. Transportation of the device shall be as described in our license renewal application. The device will be used and stored in the camera room of the facility in which it is located.

The above statements concerning use, training and service shall apply at all facilities. Should the vehicle become disabled during transport, the device will be kept locked in the vehicle and the Radiation Safety Officer shall be notified as soon as practical. The driver shall be so instructed.

APPENDIX C

INSTRUMENTATION

14103 Fenkel

1. Survey meters

   a. Manufacturer's name: Atomic Products

      Manufacturer's model number: 069-701

      Number of instruments available: 1

      Minimum range: 0 mR/hr to 0.5 mR/hr

      Maximum range: 0 mR/hr to 50 mR/hr

   b. Manufacturer's name: Victoreen

      Manufacturer's model number: 492

      Number of instruments available: 1

      Minimum range: 0 mR/hr to 10 mR/hr

      Maximum range: 0 mR/hr to 1000 mR/hr

2. Dose Calibrator(s)

   Manufacturer's name: Capintec

   Manufacturer's model number: CRC-4

   Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Scintillation camera	Nuclear Chicago	Pho-gamma IV

4. Other (e.g., liquid scintillation counter, area monitor, velometer)

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Prepared: 10-24-85
Lic. # 21-16754-01

Facilities and Equipment

Diagram

14103 Fenkel

Adjacent Areas

___	Air Supply
___	Air Exhaust
___	Scanner
___	Uptake/Well
1	Camera
2	Lockable Door
3	Receipt Area
4	Generator
4	Kit Preparation
5	Isotope Storage
4	Dose Preparation
5,6	Waste Storage
7	Dose Calibrator
___	Refrigerator
___	Sink
___	Lead Castle

Lead Shielding

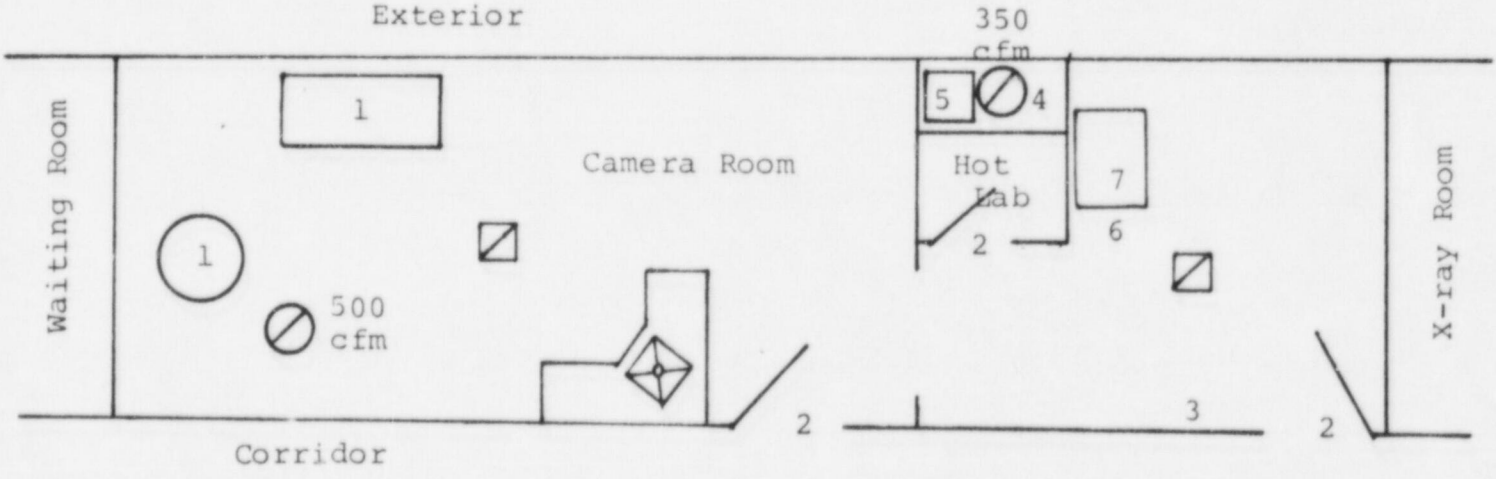
___	_____
___	_____
___	_____
___	_____
___	_____
___	_____
___	_____

4 Moly Shield
9" L x 9" W x 12" H x 3/4" T

5 Lead bricks
12" L x 12" W x 8" H x 2" T

7 L-shield
16" L x 12" W x 15" H x ½" T

___ L x ___ W x ___ H x ___ T



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Prepared 10-24-85
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Item #21

14103 Fenkel

Procedures and Precautions for Use of Radioactive Gases

1. Quantities to be used:

   a. Patient information

      1. 5 studies per week
      2. 15 mCi per study.

   b. Possession limit: 100mCi

2. Use and Storage Areas:

   A. The camera room and hot lab are used for the storage and use of Xenon. Storage of the Xenon is in the hot lab. This hot lab also is used to store tubing, face masks and etc., that have been contaminated until the Xenon has decayed. Satureated charcoal filters will be stored here also.

   B. The xenon exhaust system consists of two exhaust fans, one for the camera room and one for the hot lab. The camera room exhaust operates at 500 cfm and the hot lab exhaust at 350 cfm. Both fans exhaust directly to the outside and will be turned on and off as indicated below. The normal return air is passive via the hallway. The hot lab exhaust will be on at least anytime xenon is in storage or in use.

   C. The camera room and the hot lab are at negative pressure at all times the fans are on. The ventilation will be checked semi-annually with a velometer to assure that no change in exhaust rate has occurred and the rooms are at negative pressure.

3. Procedures for Routine Use:

   A. The dose will be prepared and assayed in the dose calibrator if possible. Shielding of the dose will be maintained at all times up to patient administration, except during identification and assay. Unnecessary personnel will be excluded from the camera room during Xenon use. Patients will be instructed as to the procedure and trial runs will be conducted if at all possible. Finger badges will be worn by all personnel handling Xenon. The camera room exhaust will be activated. The camera room door will be closed. The exhaust systems will be on at least seven hours per study.

   B. Face masks along with a Xenon rebreathing system (Atomic Products #060-133 or equivalent) and charcoal gas trap ("Nonex" #36-023 or equivalent) will be employed. The face mask covers both nose and mouth. Straps will be used to hold the face mask in place. Tubing and valves, etc. will be inspected prior to use to assure continuity.

4. Emergency Procedures:

A. In the event a dose of Xenon is accidentally released into the camera room or hot lab, the rooms will be evacuated until levels have been reduced to 1×10^{-5} uCi/ml. Removal of personnel from these rooms will be effected if the patient's condition permits. The time required for this evacuation is 10 minutes.

$$\text{Room volume} = 2800 \text{ ft}^3 = 7.92 \times 10^7 \text{ ml}$$

$$\text{Initial Concentration (Co)} = \frac{15{,}000}{7.92 \times 10^7 \text{ ml}} = 1.89 \times 10^{-4} \text{ uCi/ml.}$$

$$\text{Clearance Rate } (\lambda) = \frac{850 \text{ cfm}}{2800 \text{ ft}^3} = 0.304 \text{ min}^{-1}$$

$$\text{Concentration} = Coe^{-\lambda t}$$

$$= 1.89 \times 10^{-4} \, e^{-.305 \times 10}$$

$$= 1.89 \times 10^{-4} \, (.0474)$$

$$= 8.95 \times 10^{-6} \text{ uCi/ml}$$

Prior to re-entry, a measurement will be made using a low level G-M near the floor. A reading equivalent to background shall be considered as evidence that the ventilation has cleared the room of Xenon as calculated.

5. Air Concentrations in Restricted Areas:

The exhaust runs at a total of 850 cfm and is on for seven hours per study. It is assumed that 20% of the used Xenon escapes due to leakage, trap pass-through and patient associated losses.

$$\text{Activity (A)} = 15{,}000 \text{ uCi} \times 0.2 = 3000 \text{uCi}$$

$$\text{Volume (V)} = 850 \text{ cfm} \times 420 \text{ min} \times 2.83 \times 10^4 \text{ ml/ft}^3$$

$$= 1.01 \times 10^{10} \text{ ml}$$

$$\text{Concentration} = \frac{A}{V} = \frac{3000 \text{ uCi}}{1.01 \times 10^{10}} = 2.97 \times 10^{-7} \text{ uCi/ml}$$

This value is significantly less than the 1×10^{-5} uCi/ml limit.

6. Air concentrations in unrestricted areas:

A. By identical calculation to that above, it would be shown that the average concentration in unrestricted areas is 2.97×10^{-7} uCi/ml which is less than the 3×10^{-7} uCi/ml limit.

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B. After every 20 procedures, the trapping efficiency of the charcoal trap will be evaluated by holding a low level G-M on contact with the inlet tube to the trap during the "evacuate" mode. When the maximum reading is reached, the probe will be placed on the exhaust tube. If the maximum exhaust reading exceeds 10% of the inlet reading, taking background into consideration, the trap will be considered to be saturated and the cartridge will be replaced.

C. Saturated charcoal traps will be stored in the hot lab for decay. After decay, a survey will be performed using a low level G-M on contact with the unshielded column. If the reading is equivalent to background, the column may be disposed.

Survey Meter Model E520

Serial # 1089

Calibrated Due 5-2-86

Calibration = 5.5 mR/hr Using 137Cs Source

65 ELIZABETH LAKE RD.
PONTIAC, MICHIGAN

FACILITIES AND EQUIPMENT DIAGRAM

FINAL

Close-Out Survey

DATE 10-23-85

TECHNOLOGIST [illegible]

SURVEYS

1.	0.01 mR/hr	5.	0.01 mR/hr
2.	0.01 mR/hr	6.	0.01 mR/hr
3.	0.01 mR/hr	7.	0.01 mR/hr
4.	0.01 mR/hr	8.	0.01 mR/hr

BKG. 0.01 mR/hr ✓ = BKG. READING.

WIPE TEST

1.	✓	5.	✓
2.	✓	6.	✓
3.	✓	7.	✓
4.	✓	8.	✓

TOTAL WIPE COUNT 0.01 mR/hr

ROOM BACKGROUND 0.01 mR/hr

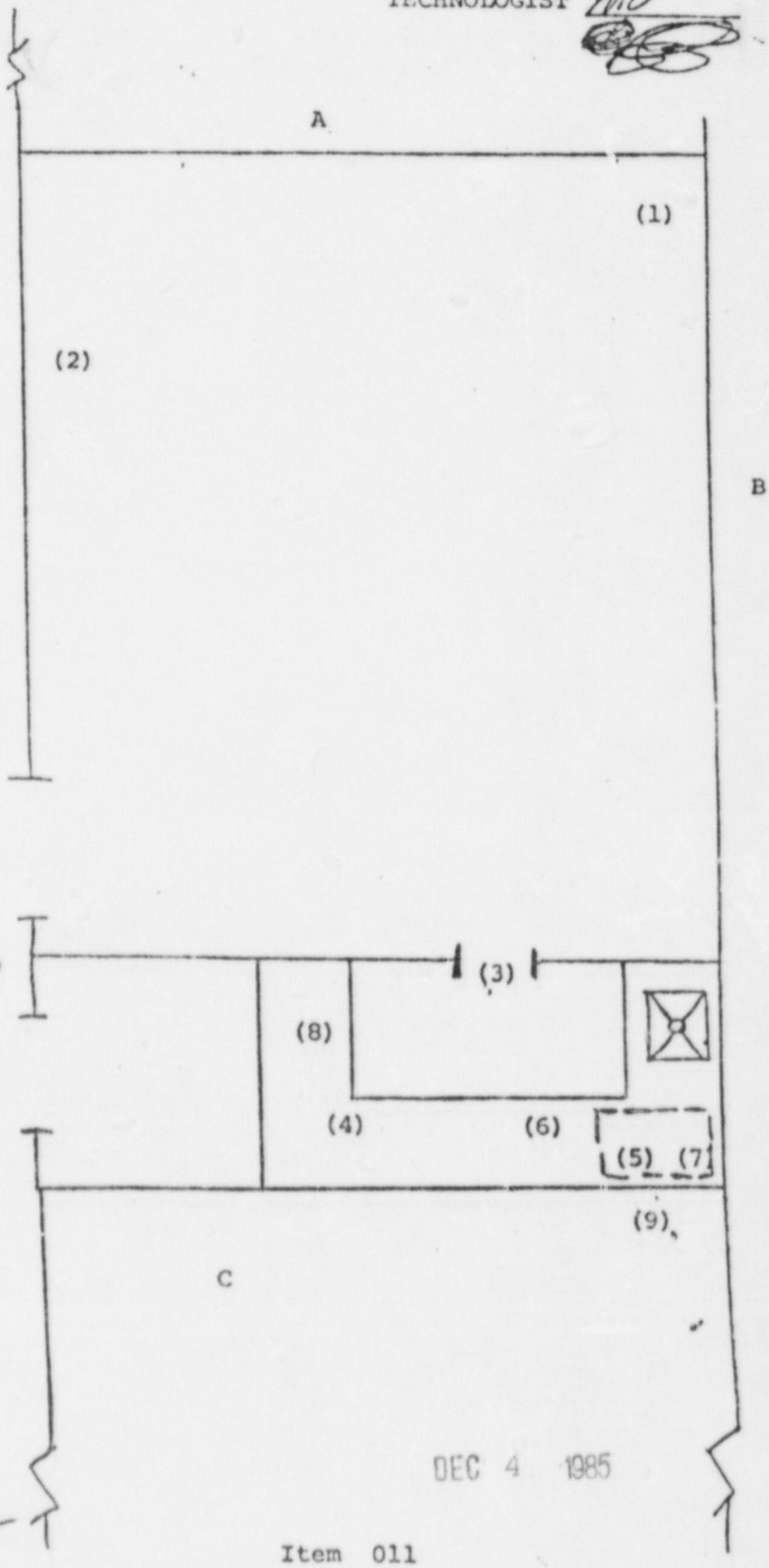
ACTION LEVEL === ANY READING > BACKGROUND.

TOTAL WIPE TEST PERFORMED IS SINGLE WIPE ON ALL AREAS

BKG = 0.01 mR/hr

TOTAL WIPE TEST = 0.01 mR/hr

Negative Wipe Test



DEC 4 1985

Item 011

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Prepared 12-10-82
License # 21-16754-01

) NEN Co^{57} Ne 8 289 Act. 50 μCi Date 11-7
Serial # 8911794

) NEN Cs^{137} Ne 8 356 Act. 222 μCi Date 5-22-78
Serial # 319-235-06

The Sources listed above were removed from the Pontiac location and transported to TPK for storage. These were transported in a properly labeled and sealed transport container.

The following readings were obtained.

1.) At surface = 2.0 mR/hr
2.) At 3' = 0.03 mR/hr
3.) Wipe Test = 0.01 mR/hr

All ~~trace~~ radioactive trash was removed for storage and eventual disposal at TPK.

LABEL II

There were no Tc products.

Those removed were Se^{75} & ^{131}I

Surface Reading = 0.6 mR/hr

WIPE TEST OF CONTAINER = 0.01 mR/hr

3' READING = 0.02 mR/hr

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