NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION **APPLICATION FOR MATERIALS LICENSE – MEDICAL**	Approved by OMB 3150-0041

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

NUCLEAR DIAGNOSTICS, INC.
29 West 281 Calumet
Warrenville, Illinois 60555

TELEPHONE NO.: AREA CODE (312) 393-2889

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

See supplementary information.

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Ronald D. Edwards, physicist

TELEPHONE NO.: AREA CODE (312) 369-1677

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

a. [X] NEW LICENSE
b. [ ] AMENDMENT TO LICENSE NO. ____
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.)*

See supplementary information.

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.)*

Lynn R. Dale, M.D.
Ronald D. Edwards, physicist

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	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	
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

Applicant ....
Check No. 620
Amount Fee Category $580
Type of Fee K appl
Date Check Rec'd 10/13/84
Received By CG

RECEIVED BY LFMS
Date 10/13/84
Log RC 9/14
By CG
Orig. To R/14
Action Compl CG

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8506110066 850508
REG3 LIC30
12-24416-01 PDR

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: _____

Appendixes referred to in this application from NRC Medical Licensing Guide 10.8, Rev. I, October, 1980.

7. MEDICAL ISOTOPES COMMITTEE	
	Names and Specialties Attached; and
X	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
X	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
X	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
	Equivalent Procedures Attached; and
X	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
X	Appendix F Procedures Followed; or
	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
X	Appendix G Rules Followed; or
	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
X	Appendix H Procedures Followed; or
	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
X	Appendix I Procedures Followed; or
	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
X	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	X	FILM	R. S. Laundauer Co. or any other	Monthly
		TLD	NRC/state-approved supplier.	
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD		Monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

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)

(1) LICENSE FEE CATEGORY:

(2) LICENSE FEE ENCLOSED: $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
Charles G. Burchett

(1) NAME *(Type or Print)*
Charles G. Burchett

(2) TITLE
Secretary/Treasurer

c. DATE
September 15, 1984

NRC FORM 313M (9-81)

CONTROL NO. 77914

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.

SUPPLEMENTORY INFORMATION FOR MATERIALS LICENSE REQUEST
NUCLEAR DIAGNOSTIC INC./29W281 Calumet, Warrenville, Illinois 60555

The following is a request for By-Products Material license to perform diagnostic procedures at the facilities listed in this request. Enclosed please find letters requesting termination of currently existing By-Product Material's licenses. These terminations are to be effective upon issuance of the By-Product Materials license to Nuclear Diagnostic, Inc.
The supplementory information is as follows:

1.b. Facilities where material will be utilized:

(1) Cole Hospital: 809 West Church Street, Champaign, Illinois 61820

(2) Paxton Community Hospital: 651 East Pells Street, Paxton, Illinois 60957

(3) John Warner Hospital: 422 West White Street, Clinton, Illinois 61727

(4) Gibson Community Hospital: 1120 North Melvin, Gibson City, Illinois 60936

(5) Jarmen Memorial Hospital: 704 North Main, Tuscola, Illinois 61953

(6) Shelby Memorial Hospital: South First and Cedar Streets, Shelbyville, Illinois 62565

(7) Central Community Hospital: 355 North Fifth Street, Clifton, Illinois 60927

4. Authorized users and facilities:

a. Cole Hospital - Lynn R. Date, M.D.: reference IL-00348-01

b. Paxon Community Hospital - Frank Lesko, M.D.: reference 22 16328 01

c. John Warner Hospital - Jay Ambrosia, M.D.: reference St. Mary's Hosp.-Decatur
Carlos Capati, M.D.: reference St. Mary's Hosp-Decatur
T. Aiden Ferry, M.D. reference St. Mary's Hosp-Decatur
Robert Roma, M.D. reference St. Mary's Hosp.-Decatur

d. Gibson Community Hospital - Mins Chen, M.D.

e. Jarmen Memorial Hospital - Frank Lesko, M.D.: reference 22 16328 01

f. Shelby Memorial Hospital - Lynn R. Dale, M.D. reference IL 00348 01

g. Central Community Hospital - Dr. Lindburg, reference Iriquois Hospital Watseka, Illinois

7. Radiation Safety Committee not required.

9. Instrumentation:

Survey instruments:	Low level CDV 700 Victoreen	0-50 mR/hr
	High range CDV 715 Victoreen	0-50 mR/yr
Dose Calibrator:	Nuclear Associates Rad Cal	
Gamma Camera:	Technicare Mobil Imaging System	

10. Calibration of survey instruments: Radiation survey instruments will be calibrated according to the procedures in Appendix D of Regulatory Guide 10.8. The instruments will be calibrated by Radiation Protection Consultants, Ltd., Aurora, Illinois, or any other NRC/State approved firm. The instruments will be calibrated at least annually.

Dose Calibrator calibration: Dose calibrator will be calibrated in accordance with the procedures in Appendix D of Regulatory Guide 10.8. The annual accurach check will be performed by Radiation Protection Consultants, Ltd. or any other NRC/State approved firm. The sources used will be NBS traceable standards of Cobalt 57, Barium 133 and Cesium 137. The minimal activity of the sources will be 1-5 millicuries, 250 microcuries and 200 microcuries, respectively. The sources will be provided by the firm calibrating the source. Daily function checks will be performed, utilizing a 200 microcurie Cesium 137 source. Quarterly linearity tests will be performed utilizing activity equal to the maximum activity measured in the dose calibrator.

11. Facilities and equipment: Diagram of the department is attached.

Available equipment includes long-handled forceps, lead syringe shields, plastic backed absorbent pads, radiation decontamination kit, vinyl disposable gloves and lead bricks.

12. The Personnel Training Program will consist of instruction to Nuclear Diagnostic, Inc. personnel and any other personnel at each facility who might well be included in the instructional program on the advise of the Radiation Safety Officer. Items included in the training program will be pertinent to each individual's situation. The training program will be conducted at least annually and a record will be kept.

13. Radioactive materials will be ordered by the Nuclear Medicine Technologist from Nuclear Diagnostic, Inc. after having checked to see if receipt of this material will not exceed allowable possession limits.

    The material which is received during hours which the nuclear medicine technologist is present will be checked in accordingly by that individual. Any materials received during the hours the technologist is not available, the material will be checked in by personnel who have been specifically instructed and appointed by NBI. The instructions for inspection of the package are as follows:

    a. Visual inspection of the package for obvious damage or leakage.

    b. If the package is not damaged, the package is taken to the Nuclear Medicine Department and secured.

    c. If obvious damage is noted to the package or if leakage is noted, the carrier is asked to remain.

    d. The Radiation Safety Officer or other authorized personnel are notified immediately.

    e. If the determination is made that there is actual contamination, the proper authorities are notified, such as the Nuclear Regulatory Commission and the Illinois Department of Nuclear Safety.

    A copy of the procedures, including the name and telephone number of the Radiation Safety Officer and his designate, will be posted at the receiving area.

17. See additional supplementory information relating to radiation surveys to be performed and procedures to be followed.

OTHER INFORMATION

1. Wipe/leak tests of sealed sources will be performed by Radiation Protection Consultants, Ltd., NRC License No. 12=13370-01 and the leak tests will be performed on the sealed sources as required.

2. The ALARA program as outlined in Appendix O of Regulatory Guide 10.8 will be followed.

SUPPLEMENTORY INFORMATION FOR BY-PRODUCTS MATERIAL LICENSE REQUEST
NUCLEAR DIAGNOSTIC INCORPORATED/WARRENVILLE, ILLINOIS 60555

A. Shipments of radioactive material will be received at Cole Hospital, Champaign, Illinois and placed into a storage area authorized for exclusive use by Nuclear Diagnostics, Inc. Please see the enclosed diagram outlining the storage area. Individuals involved in the receipt of the shipments will receive training as to the proper procedure to be followed. This is explained in the portion of the application relating to training.

The material will be secured in the storage room and access to the storage room will be by Nuclear Diagnostic Inc.'s personnel only. In the event of any emergencies, the following named individuals would be contacted to handle the situation:

1. Tom Buckrucher - Nuclear Medicine Technologist
2. Lynn R. Dale - R.S.O. 217 258 2549
3. Ronald D. Edwards - Consulting Physicist - 312-369 6488

B. Tc 99m eluted from the generator will be checked for Mo 99 and if materials are within acceptable limits, the source will be transported in glass vials to the authorized sites for use. See transport procedure in paragraph D. The Tc 99m will be combined with Sulphur Colloid, etc. at each site requiring such radiopharmaceuticals for specific exams. All materials for mixing the radiopharmaceuticals will be provided by Nuclear Diagnostic, Inc. All material used at each facility, syringes, alcohol wipes, etc. will be removed from the facility by Nuclear Diagnostic Inc.'s technologists when leaving the facility.

Radiopharmaceuticals will be injected by the Nuclear Diagnostic Inc. technologist. The radiologist designated for each facility will be present or within 1½ hour travel time after a telephone call.

The gamma camera used at each facility will be checked for proper function prior to each use at the facility. Tests will consist of checks for analyzer setting for each nuclide to be utilized as well as field flood evaluation. The dose calibrator will be transported to each facility and it will be also checked prior to each use at each facility utilizing the Cs 137 check source. The check of the dose calibrator will consist of a constancy check with a reading obtained for each nuclide setting to be utilized.

The material will be kept in lead shields and also lead syringe shields will be utilized during injections whenever feasible.

C. A radiation survey will be performed at each facility where material is prepared or utilized upon completion of our exams to be performed. The survey will include wipe tests of the injection areas and preparation areas. The procedure for the wipe tests are as follows:

1. The wipe will be held at a 1 cm distance from the probe.
2. The beta shield will be kept open.
3. The wipe to be analyzed will be analyzed in an area of natural background.
4. Each wipe will be checked for a fifteen second duration.
5. Action level for decontamination procedures will be any reading exceeding the background level.

Records of the radiation surveys performed will be kept for each facility.

Other procedures relating to the radiation surveys will be those of Appendix I of Regulatory Guide 10.8, October, 1980, Revision I. The only exception to the procedures listed in Appendix I will be those items contained in 4b and 6. The procedures to be followed in place of these two items is explained in the previous paragraph.

D. The radioactive material will be transported in lead lined boxes with absorbant material to control any contamination which may occur from leakage. Each vial will be cushioned with the absorbant material to protect against breakage. DOT requirements will be followed. The containers will be Type 7A DOT approved.

The lead box will be kept in the transporting vehicle whether by van or auto. The back of the van or the trunk of the auto will be utilized. A currently calibrated, appropriate radiation survey instrument will be available in the vehicle to perform necessary radiation surveys.

The lead box will be properly labeled as to content. The box will be kept secured from unauthorized access in the vehicle when the vehicle is unattended. The vehicle will always be kept locked when unattended.

If material is kept in the vehicle over-night, the vehicle and the storage compartment will be kept locked and the radioactive container will be shielded from view from any unauthorized personnel.

D. Radiation surveys will be performed of the vehicle after all material has been removed at the end of the day. All material removed from the vehicle will be returned to the storage area at Cole Hospital.

E. Driver training consists of:

1. Survey transporting vehicles at the start of each day before material is placed in the vehicle.
2. Secure material contained in the vehicle from unauthorized access.
3. In case of accident, if able:
   a. Check material container for damage or leakage
   b. If no damage or leakage is noted, notify local police department and Radiation Safety Officer or his designate. Explain situation.
   c. If damage or leakage to material container is noted,
      (1) put on vinyl gloves and check container with survey instrument for any excessive readings
      (2) perform wipe tests on any wet areas which may be noted and evaluate for contamination
      (3) if container wipe tests exhibit leakage, put plastic backed absorbant pads over wet areas and mark appropriately. Keep all unauthorized personnel away from the area.
      (4) notify local policy, Radiation Safety Officer, Nuclear Regulatory Commission Regional office and State Department of Radiation Safety.
      (5) Do not leave accident scene until help arrives and material is secured.

Should driver not be in any condition to perform above procedures, instructions are posted on the containers instructing to call the Radiation Safety Officer or his designate for further directions.

Driver/technologists receive retraining in the above instructions at least annually.

APPENDIX J

WASTE DISPOSAL

Note: In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, NRC is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials in the sanitary sewer in accordance with § 20.303 of 10 CFR Part 20.

1. Liquid waste will be disposed of (check as appropriate)

___x___ In the sanitary sewer system in accordance with § 20.303 of 10 CFR Part 20.

___x___ By commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

2. Mo-99/Tc-99m generators will be (check as appropriate)

___x___ Returned to the manufacturer for disposal.

___x___ Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the generators will be disposed of as normal trash.**

___x___ Disposed of by commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

3. Other solid waste will be (check as appropriate)

___x___ Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash.

___x___ Disposed of by commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

4. The commercial waste disposal service used will be
U.S. Ecology-Louisville, Kentucky
ADCO, Tinley Park, Illinois
(Name) (City, State)

NRC/Agreement State License No. _____

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* Be sure that waste storage areas were described in Item 11 and that they are surveyed periodically (Item 17).

** These generators may contain long-lived radioisotopic contaminants. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.