L+L: 20910
030-28896

| NRC FORM 313M (9-81) 10 CFR 35 | U.S. NUCLEAR REGULATORY COMMISSION<br>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

Kenneth I. Scheer, M.D.
1180 Beacon Street
Brookline, MA 02146

TELEPHONE NO.: AREA CODE (617) 232 1115

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

James McVey, Corp. R&SO
Quadrex HPS Inc.

TELEPHONE NO.: AREA CODE (904) 373 6066

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

a. ☒ 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.)*

Kenneth I. Scheer, 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.)*

Kenneth I. Scheer, M.D.

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 of 10 CFR Part 35, and NEED NOT BE LISTED.)*

| ELEMENT AND MASS NUMBER | CHEMICAL AND/OR PHYSICAL FORM | MAXIMUM NUMBER OF MILLICURIES FOR EACH FORM | DESCRIBE PURPOSE OF USE |
|---|---|---|---|
| Gadolinium-153 | Sealed Sources (Gulf Nuclear Model No. GD-1) | 2000 mCi total (1000 mCi per source, one source for source exchange | To be used in NOVO Diagnostics bone densitometry to determine bone density (osteoporosis) on humans. |

License Fee Information on ~~Next~~ Page 3 + Cover ltr.

## 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 N/A |
| | Duties as in Appendix B; or *(Check One)* |
| | Equivalent Duties Attached |

**8. TRAINING AND EXPERIENCE**

| | |
|---|---|
| | Supplements A & B Attached for Each Individual User; and |
| X | Supplement A Attached for RSO. see attached |

**9. INSTRUMENTATION** *(Check One)*

| | |
|---|---|
| | Appendix C Form Attached; or |
| X | List by Name and Model Number see attached |

**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)* |
| X | Equivalent Procedures Attached see attached |

**11. FACILITIES AND EQUIPMENT**

| | |
|---|---|
| X | Description and Diagram Attached see attached |

**12. PERSONNEL TRAINING PROGRAM**

| | |
|---|---|
| X | Description of Training Attached see attached |

**13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL**

| | |
|---|---|
| X | Detailed Information Attached see attached |

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

| | |
|---|---|
| | Appendix F Procedures Followed; or N/A |
| | Equivalent Procedures Attached |

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

| | |
|---|---|
| | Appendix G Rules Followed; or |
| | Equivalent Rules Attached N/A see item 23 |

**16. EMERGENCY PROCEDURES** *(Check One)*

| | |
|---|---|
| | Appendix H Procedures Followed; or |
| X | 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 |
| X | Equivalent Information Attached |

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

| | |
|---|---|
| | Appendix K Procedures Followed; or N/A |
| | Equivalent Procedures Attached |

**20. THERAPEUTIC USE OF SEALED SOURCES** N/A

| | |
|---|---|
| | 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 N/A |

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

| | |
|---|---|
| | Detailed Information Attached N/A |

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

| | |
|---|---|
| X | Detailed Information Attached |

## 24. PERSONNEL MONITORING DEVICES

| | TYPE (Check appropriate box) | | SUPPLIER | EXCHANGE FREQUENCY |
|---|---|---|---|---|
| a. WHOLE BODY | X | FILM | R.S. Landauer or equivalent | Quarterly |
| | | TLD | | |
| | | OTHER (Specify) | | |
| b. FINGER | | FILM | | |
| | | TLD | | |
| | | OTHER (Specify) | | |
| c. WRIST | | FILM | | |
| | | TLD | | |
| | | OTHER (Specify) | | |

d. OTHER (Specify)

Sept-8-I
Applicant.....
Check No. 6.37.....
Amount, Fee Category 580.-3F.....
Type of Fee Application.....
Date Check Rec'd 9/14/85.....
Received By S.L.K.....

## 25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

N/A

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
3F

(2) LICENSE FEE ENCLOSED $ 580

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
Kenneth Schein MD

(1) NAME *(Type or Print)*
KENNETH SCHEIN MD

(2) TITLE
—

c. DATE
8/27/85

NRC FORM 313M (9-81)

## 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 9: NOVO Diagnostic Bone Densitometer System with dual photon detection system.

Item 10: The frequency of calibration for the bone densitometer will be as required to maintain quality images. The unit will be thoroughly checked upon installation and yearly thereafter by a qualified manufacturer's representative. Internal adjustments are performed via computerized programs to produce quality images. Performance checks may be performed daily as indicated.

Item 8: Statement of Training and Experience

According to the standard guide for training and experience, the following description is provided to fulfill this requirement:

A. Medical Training: M.D. degree; licensed to practice in the State of Massachusetts. Verification is attached.

B. Radiation Safety Training: Will be provided to the user by Quadrex HPS Inc. to include those areas recommended by the USNRC as acceptable criteria. The qualifications of the instructors, the training manual and testing will be submitted to your office from Quadrex HPS Inc.

Training for Bone Mineral Analyzer Diagnostic Devices
As Recommended by the USNRC

Group A - Basic Radiation Physics and Instrumentation (3 hours)

1. Atomic Structure
2. Decay Process and Types of Emissions (especially gamma radiation)
3. Radioactivity - Definitions and Units (curies, rems, and sub-units)
4. Interactions of Radiation with Matter
5. Half-Life, Inverse Square Law and Half-Value Layers (time, distance, and shielding)
6. Decay Constant Formula and Use of Decay Tables
7. Inverse Square Law Formula and Examples
8. Calculation of Radiation Dose in Air, Tissue and Bone
9. Radiation Dose - Dose Rate, Time and Average Dose
10. Characteristics of Sealed Sources (compared to radioactive liquids and other physical forms)

Group B - Radiation Biology (3 hours)

1. Acute and Chronic Exposures
2. Somatic and Genetic Effects
3. Basis of Maximum Permissible Dose
4. Typical Somatic Effects at Various Dose Levels
5. Genetic Effects and Genetically Significant Dose
6. Factors Affecting Biological Damage (dose, dose rate, type of radiation, type of tissue, amount of tissue, biological variation and chemical modifiers).

Group C - Radiation Protection (2 hours)

1. Principles of Radiation Safety and ALARA Management Program
2. "Standards for Radiation Protection" 10 CFR Part 20 and "Instructions to Radiation Workers" 10 CFR Part 19,
3. License Conditions for Radiation Safety Program
4. Radioactive Shipment Receiving, Opening, Handling, Storage and Security Procedures
5. Radiation Labels and Required Posting and Documents
6. Routine Proper Use, Inventory and Accountability Procedures for Sealed Sources, or Devices Containing Sealed Sources
7. Leak Test of Sealed Sources and Contamination Control
8. Shipment Returns, DOT Regulations and Supplier Instructions and Forms
9. Radiation Detection Instrumentation
10. NRC Draft Regulatory Guide "Instruction Concerning Radiation Exposure" Dated May, 1980 and NRC Regulatory Guide 8.13 "Instructions Concerning Prenatal Radiation Exposure" Dated November, 1975
11. Title 10 CFR Part 35 "Medical Use of Radionuclides" and NRC Regulatory Guide 10.8 Procedures and License Applications
12. Radiation Safety References, NCRP and ICRP Publications
13. Review and Discussion of the Sealed Source "Device Specific" Manufacturer Literature and Instructions

Item 11. Facilities and Equipment

The Novo Diagnostic System's Dual Photon Bone Densitometer is a fixed unit installed in the office. The unit will not be relocated without prior permission of the NRC. The Gadolinium-153 source is to be installed in the densitometer device by the authorized manufacturer representative. The source will not be removed from the device by the licensee. Source exchange will be performed by an authorized representative of the manufacturer of the device. Attached is additional information from the manufacturer describing the use of the device.

Also attached is a drawing indicating the location of the densitometer in the facilities. The unit shall be under the direct control of the licensee and shall not be used except by the licensed users. It shall be controlled from unauthorized use or tampering during off duty hours.

Item 12: Personnel in the office will be instructed in the proper handling and use of radioactive materials as relevant to their jobs. This can include dosimetry useage, safety and record keeping. Those personnel qualified by the NRC provisions can actively participate in the handling of the licensed materials while those not qualified can only assist in the maintenance of the patients and other non-licensed activities at the direction of the licensed physician. All appropriate female personnel will be instructed about the importance of pre-natal exposure reduction.

Item 13: a. All radioisotopes will be ordered, as licensed, by the authorized user and received by the authorized user. Such receipt will occur only during normal working hours. No provisions are made for off-hour delivery.

b. Any leaking or damaged packages will be cause for the authorized user to detain the carrier and his vehicle until determined that no contamination is present. Proper notifications and further assistance will be made or attained respectively where indicated.

c. Records of receipt will be maintained by the RSO.

d. Gadolinium-153 sealed sources will be installed by a qualified and authorized representative of the manufacturer. These sealed sources will only be inspected for continued package integrity and no leakage and will not be opened by the physician.

Item 16: If it appears the Gadolinium-153 bone density device is stuck in an "open" or exposed position or any malfunction potentially compromising the integrity of the source or device, the patient shall be immediately removed and no person shall be allowed to an area within 10 feet of the device. The user shall contact the manufacturer or his designated representative to identify the problem. The device shall not be used, or the area around the device occupied until the problem is rectified by the manufacturer representative. The area shall be posted to prevent unnecessary entry until the unit is returned to a safe condition.

RADIATION SAFETY OFFICER: Dr. Scheer

OFFICE PHONE: 617-232-1115

HOME PHONE:

Item 17: Leak testing and office surveys will be performed at least yearly or as otherwise indicated.

Item 18: a. The Gadolinium-153 source shall be removed and returned to the manufacturer's representative or to a licensed waste disposal facility for ultimate disposition. The source shall be properly packaged to include shielding, if necessary, and presented for disposal. The disposal broker will be ADCO services of Tinley Park, IL or an equivalent substitute. The source will be buried in an approved burial ground such as Barnwell, SC or an equivalent.

b. Records of all waste disposal will be maintained.

Item 23: Radiation Protection Program for Gadolinium-153 Sealed Source

A. The device is to be operated by the user authorized by a licensed issued by the State of Florida.

B. The users and ancillary support personnel are not to modify, remove or exchange the source or the device in a way that would hamper the effectiveness of its use, compromise the radioactive source containment or unnecessarily expose personnel to radiation.

C. Personnel shall not place their hand or body in the beam of radiation emitted by the device that shall cause it to be unecessarily exposed.

D. The device containing radioactive material shall be secured to prevent unauthorized use, tampering or removal except during actual usage.

E. The device shall be visually inspected prior to each use to assure continued safe functioning. Any abnormal conditions should be reviwed with the manufacturer's representative or a health physics consultant.

F. Persons operating or assisting in the procedures associated with this device shall wear a radiation dosimetry device of either film badge or TLD type. These dosimeters will be changed and presented for analysis on a quarterly frequency. These devices will be furnished and serviced by a company such a R.S. Landauer, Inc. or equivalent.

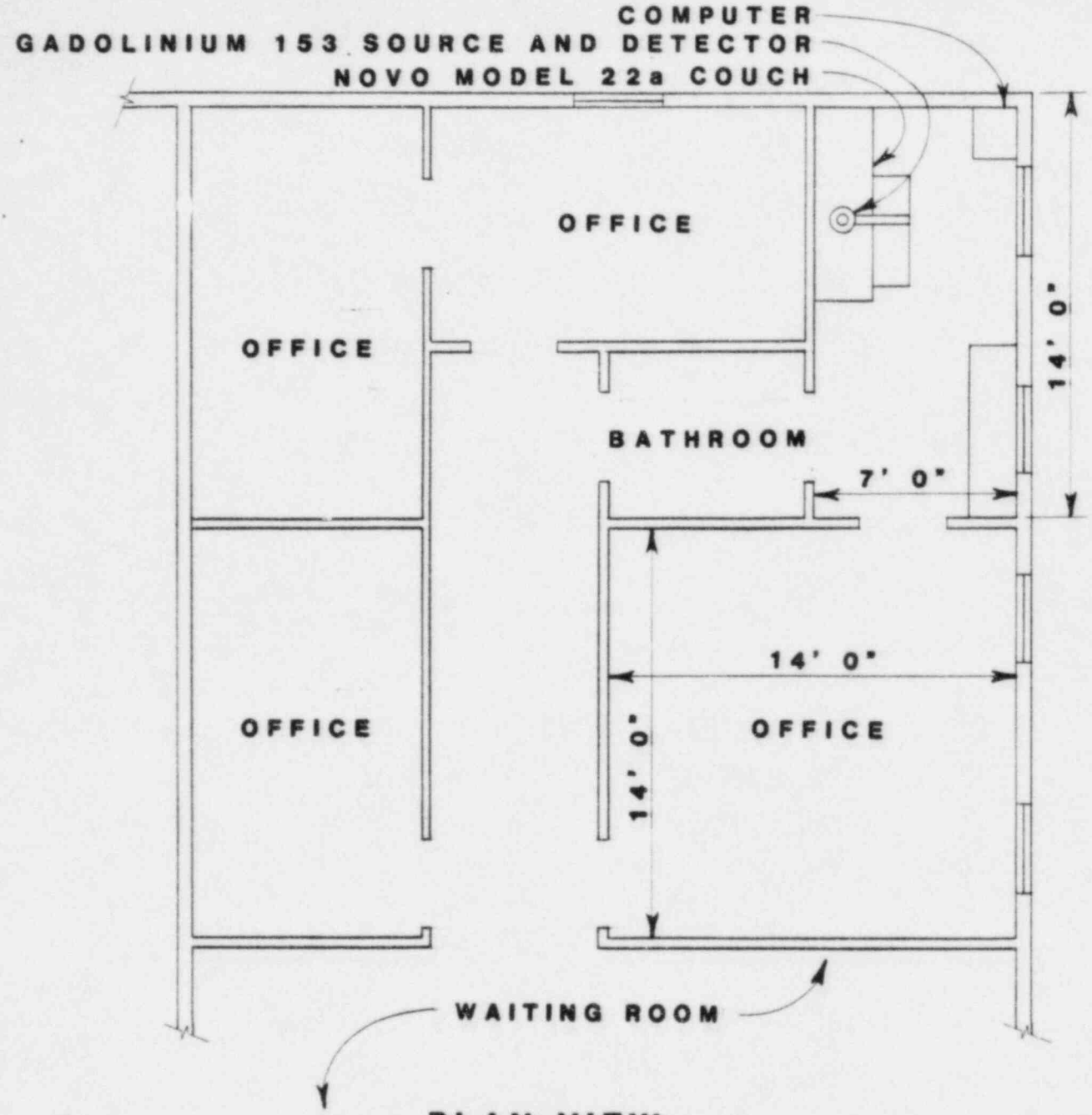
G. Persons frequenting the room housing this device shall not smoke, eat or drink unless for the purposes of medical treatment.

H. Radioactive material shall be used for diagnostic medical uses only.

I. Records will be kept of the receipt and return of the radioactive materials, the use and leak testing of the source and film badge/TLD results.

J. The source shall be installed into the densitometer device by an authorized representative of the manufacturer. During the initial installation or source transfer, a radiation survey shall be conducted by the installer indicating the radiation levels in the "open" and "closed" modes. A copy of the survey shall be provided to the licensee and shall be available for inspection by the State of Florida.

K. The source shall be leak tested at a twelve month interval. Having a half-life of 242 days, the source will be replaced periodically. Leak testing will be performed by the manufacturer of the device, or his licensed representative. The source shall not be removed or leak tested by the licensee.




## PLAN VIEW

**K.I. SCHEER M.D.**
**1180 BEACON STREET**
**BROOKLINE, MA. 02146**
**(NOVO BONE DENSITOMETER)**

| | | | | | | |
|---|---|---|---|---|---|---|
| CHARGE No NOV-0801-8 | | Quadrex HPS Inc. GAINESVILLE, FLORIDA | | | | |
| DESIGNED N/A | DATE | BONE DENSITOMER LICENSE | | | | |
| DRAWN | DATE 8-85 | | | | | |
| APPROVED | DATE 8/85 | SIZE A | DRAWING No 63A0008 | SCALE NONE | SHEET 1 of 1 | |

K & E 10-9155 62111

The Commonwealth of Massachusetts

# BOARD OF REGISTRATION IN MEDICINE

Established A. D. 1894

THIS IS TO CERTIFY

That Kenneth Isaac Scheer of Watertown,

a GRADUATE of New York University in the year 1963,

and a Diplomate of the National Board of Medical Examiners, has been found qualified by this Board and registered as a qualif[illegible]ysician, as provided by the laws of the Commonwealth.

BOSTON, MASS. September 17 1964.

Charles A Cotton M.D.
Chairman

David W Cutter M.D.
Secretary

CERTIFICATE No 28297

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVCE

NO: NR-485-D-101-S DATE: January 5, 1984 PAGE 1 OF 4

DEVICE TYPE: Dual Photon Bone Densitometer

MODEL: BMC LAB 22a

DISTRIBUTOR: Novo Laboratories, Inc.
59 Danbury Road
P.O. Box D
Wilton, CT 06897

MANUFACTURER: Novo Diagnostic Systems
Novo Alle
Dk-2880
Bagsuaerd, Denmark

SEALED SOURCE MODEL DESIGNATION: Gulf Nuclear Model No. GD-1

ISOTOPE: Gadolinium-153 MAXIMUM ACTIVITY: 1 curie

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (V) General Medical Use (Bone Mineral Analyzer)

CUSTOM DEVICE: _____ YES __X__ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: NR-485-D-101-S DATE: January 5, 1984 

DEVICE TYPE: Dual Photon Bone Densitometer

DESCRIPTION:

The BMC LAB 22a is a complete system for the noninvasive determination of bone mineral content (BMC) in the lower spine and the femoral necks. The system is composed of a scanner, dual channel analyzer, dual photon source, and computer software.

The source housing and scintillation detectors are arranged on a C-type frame (called a scanner assembly), rectilinear drive mechanism (stepper motors) move the scanner assembly in a pre-programmed pattern.

The source housing is constructed of brass and is lead filled. The housing contains the source shutter mechanism and shutter opening solenoid. The shutter is held in the "closed" or "store" position by a spring. The entire housing unit is bolted into the unit by the user following the manufacturers instructions. Source exchange is normally accomplished by returning the entire housing to a specific licensee.

In the event of a failure, the shutter will return to the "closed" position mechanicall Additionally, at the completion of a scan, the computer alerts the operator both visually and audibly to shut off the beam. Program execution will not proceed to completion until the beam has been switched off.

LABELING:

The source is engraved with the model number, the isotope and the unique serial number. Labels are affixed to the source holder which contains the statement, "Source Holder for Novo BMC LAB 22a. To Be Operated By Authorized Personnel Only," the device number, the ANSI N538 classification, the manufacturers name, address on logo, serial number, the trefoil radiation symbol, the words, "Caution-Radioactive Material," the isotope and activity and date of assay and the statement "Leak Test Must Be Performed Every Six Months." "Date and Initials" (with space to be filled in). Additionally, the device is labeled in a conspicuous place with the trefoil radiation symbol, the words, "Caution-Radioactive Material," the manufacturers name and logo, serial number, and the statement, "Novo BMC LAB 22a Dual Photon Bone Densitometer."

DIAGRAM:

See Attachments 1 and 2.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: NR-485-D-101-S DATE: January 5, 1984 

DEVICE TYPE: Dual Photon Bone Densitometer

CONDITIONS OF NORMAL USE:

The BMC LAB 22a is intended for the noninvasive determination of bone mineral content in the axial skeleton and the femoral necks. The unit will be used in clinics by personnel who are properly trained in the use of the device and in radiation protection.

PROTOTYPE TESTING:

The source has an ANSI N542 classification of 77C53524 and has received a special form certificate No. USA/0282/S.

Since the source holder assembly is mounted inside the scanner during use, the assembly is well protected against abrasion, corrosion, significant vibration, impact, and compressive loads. Novo reports the device would operate at a high temperature of 120°F, the limitation is due to the electronic component. In the event of a fire, the lead would melt down, due to the construction of the source holder and the majority of shielding would remain around the source. The computer test program was run to varify functions of the unit.

EXTERNAL RADIATION LEVELS:

Novo reported that at 6 centimeters from the source the dose rate is 3 R/hour/curie. Additionally, Novo states that normally scanning a patient in all modes imparts a total bone marrow dose of 5 mrem and a maximum exposure to the skin of 10 mrem.

The exposure rate at the control panel will not exceed 0.3 mrem/hour.

The maximum exposure rate at the surface of the source holder is 100 mrem/hour.

QUALITY ASSURANCE AND CONTROL:

Novo Diagnostic Systems' quality control department test every unit with respect to safety devices and proper functioning of associated electronics. A test report is supplied with every system. The units are installed by a company trained service engineer. Onsite testing is composed of the "on-off" function of the source holder and the running of a special computer test program.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: NR-485-D-101-S DATE: January 5, 1984 PAGE 4 OF 4

DEVICE TYPE: Dual Photon Bone Densitometer

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The device shall be distributed only to persons specifically licensed by the NRC or an Agreement State, pursuant to Section 30.33, 10 CFR 30 and 10 CFR 35 or equivalent regulations of an Agreement State.
- The device shall be leak tested at six month intervals using techniques capable of detecting 0.005 microcurie of removable contamination.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
- This registration sheet and the information contained within the references shall not be changed or transferred without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and test data cited below, the ANSI classification of the source, the condition of use of the device, and that the device will be used by persons trained in radiation safety, we conclude that the Model BMC LAB 22a dual photon bone densitometer design is acceptable for licensing purposes. Furthermore, we conclude that the device would be expected to maintain its containment integrity for normal conditions of use and accident conditions which might occur during uses specified in this certificate.

REFERENCES:

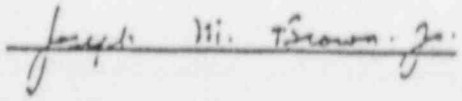
The following supporting documents for the BMC LAB 22a dual photon bone densitometer are hereby incorporated by reference and are made a part of this registry document:

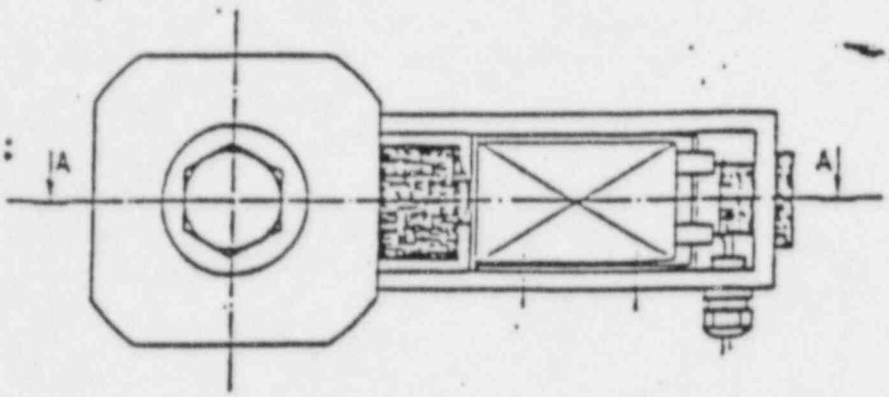
- Novo Laboratories, Inc. letters dated October 7, 1983 and December 9, 1983, with enclosures thereto.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: January 5, 1984 Reviewer: 

Date: January 5, 1984 Concurrence: 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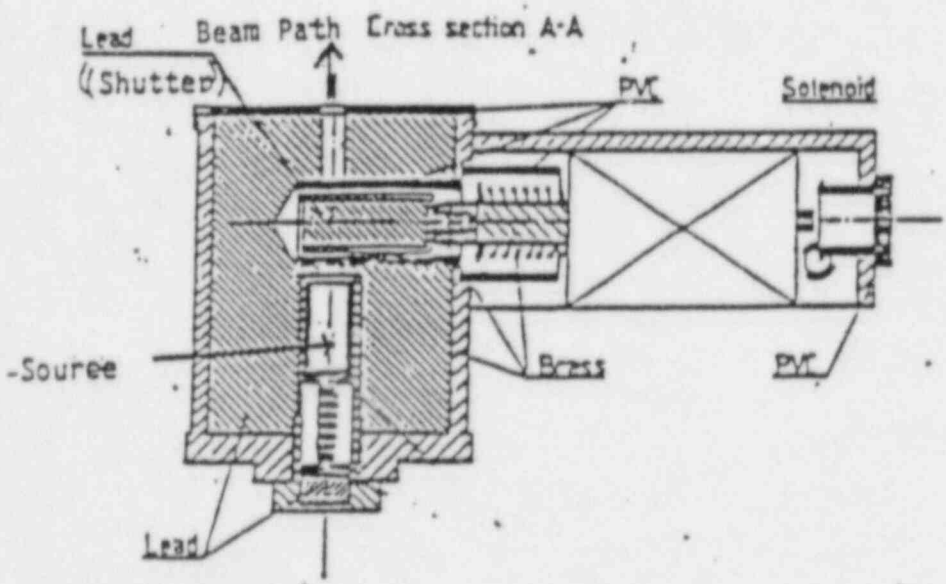
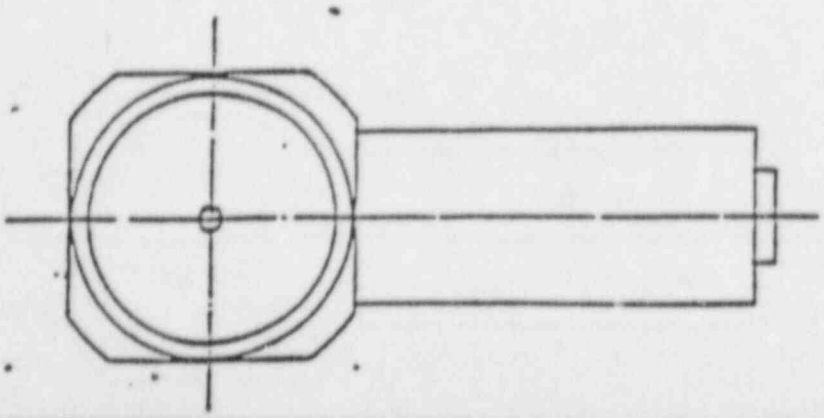
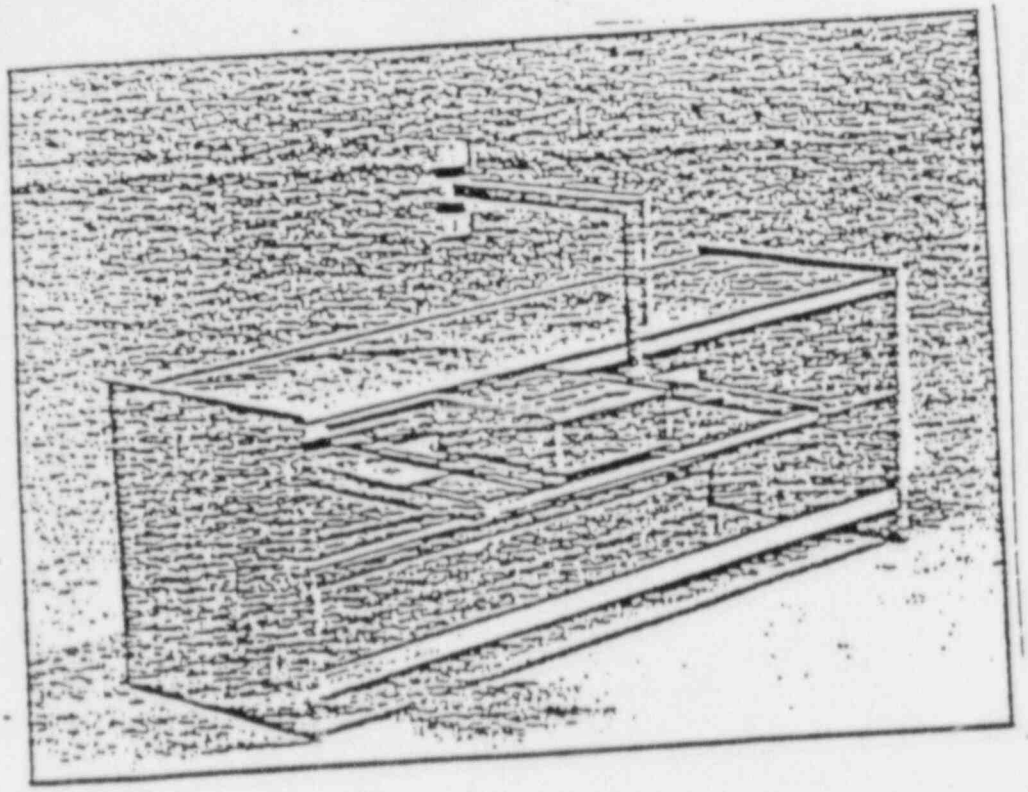
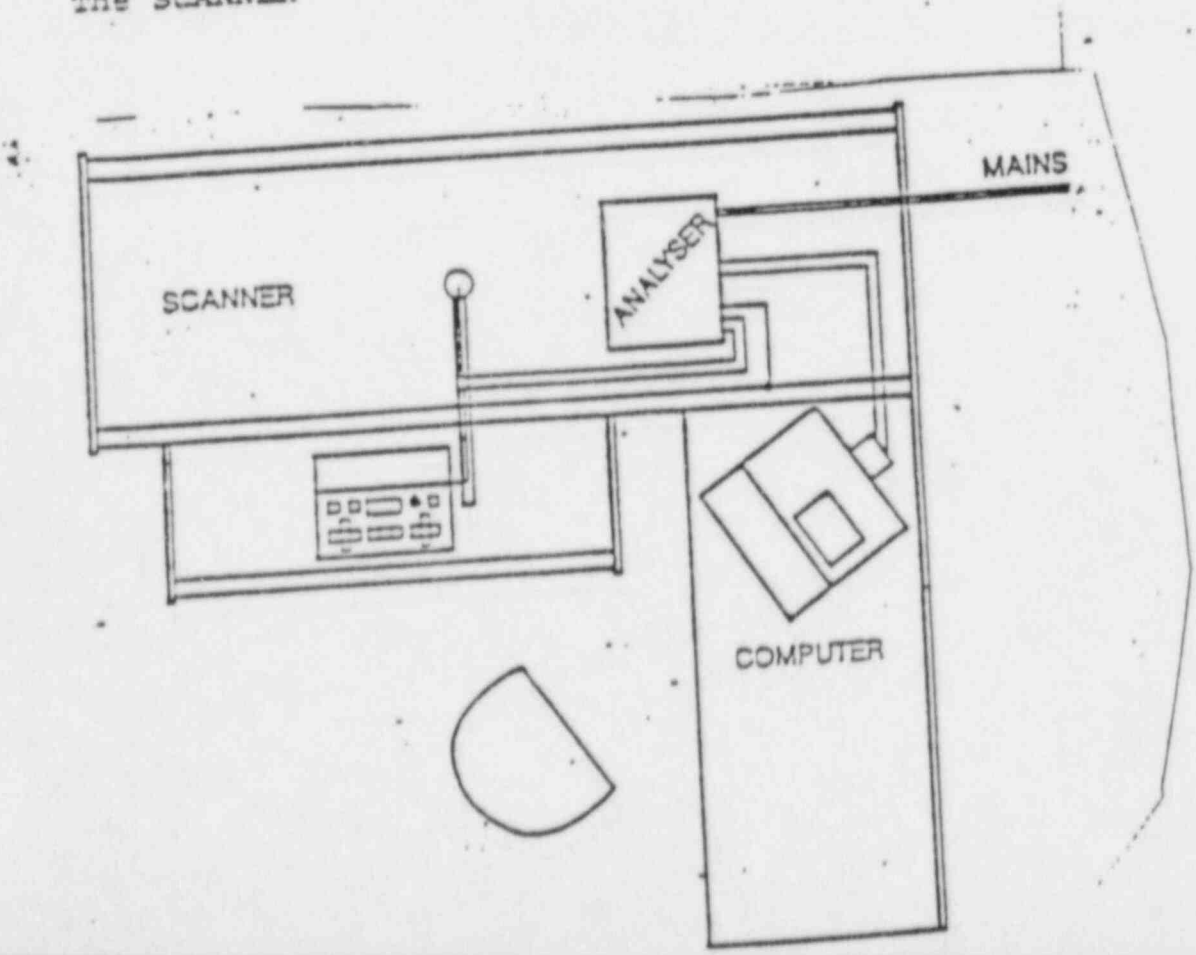

Lead
(Shutter)
Beam Path
Cross section A-A
PVC
Solenoid
-Souree
Brass
PVC
Lead



BMC-LAB 22a



The SCANNER



# QUADREX HPS Inc.

This is to certify that

Kenneth J. Scheer, M.D.

has completed

Basic Radiation Protection Training

conducted by Quadrex HPS Inc.

at Boston, Ma. on the 7th day of August 1985

Certificate No. 006

Instructor