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

Beta Osteoporosis Diagnostic Centers of
Fairfax, Virginia
8316 Arlington Boulevard
Fairfax, Virginia 22031
TELEPHONE NO.: AREA CODE (703) 698 - 8070

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

See attached

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Ernest Durst
TELEPHONE NO.: AREA CODE (301) 654 - 2250

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.)*

See attachment No. 8

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 L. Geoly, 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(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 |
|---|---|---|---|
| Iodine-125<br><br>Source Model No. AECL C-235 and C-324 and source holder Model C-236<br><br>See NRC Registration Sheet NR-482-D-102-F, August 11, 1983 | Sealed Source | 2 sources/no source to exceed 400 mCi each | Norland Bone Densitometer (Model No. N2780 with N2780 Module)<br><br>250556 |

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License Fee Information
~~on Next Page~~
Cover Letter

## 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** | |
| X | 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** | |
| | Appendix D Procedures Followed for Survey Instruments; or *(Check One)* |
| X | Equivalent Procedures Attached; and |
| | 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)* | |
| | Appendix F Procedures Followed; or |
| X | Equivalent Procedures Attached |

| | |
|---|---|
| **15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL** *(Check One)* | |
| | Appendix G Rules Followed; or |
| X | Equivalent Rules Attached |
| **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 |
| X | 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 |
| | 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 |

## 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** | **15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL** *(Check One)* |
| | Names and Specialties Attached; and | | Appendix G Rules Followed; or |
| | Duties as in Appendix B; or *(Check One)* | X | Equivalent Rules Attached |
| | Equivalent Duties Attached | **16. EMERGENCY PROCEDURES** *(Check One)* | |
| **8. TRAINING AND EXPERIENCE** | | | Appendix H Procedures Followed; or |
| X | Supplements A & B Attached for Each Individual User; and | X | Equivalent Procedures Attached |
| | Supplement A Attached for RSO. | **17. AREA SURVEY PROCEDURES** *(Check One)* | |
| **9. INSTRUMENTATION** *(Check One)* | | | Appendix I Procedures Followed; or |
| | Appendix C Form Attached; or | X | Equivalent Procedures Attached |
| X | List by Name and Model Number | **18. WASTE DISPOSAL** *(Check One)* | |
| **10. CALIBRATION OF INSTRUMENTS** | | | Appendix J Form Attached; or |
| | Appendix D Procedures Followed for Survey Instruments; or *(Check One)* | X | Equivalent Information Attached |
| X | Equivalent Procedures Attached; and | **19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS** *(Check One)* | |
| | Appendix D Procedures Followed for Dose Calibrator; or *(Check One)* | | Appendix K Procedures Followed; or |
| | Equivalent Procedures Attached | | Equivalent Procedures Attached |
| **11. FACILITIES AND EQUIPMENT** | | **20. THERAPEUTIC USE OF SEALED SOURCES** | |
| X | Description and Diagram Attached | | Detailed Information Attached; and |
| **12. PERSONNEL TRAINING PROGRAM** | | | Appendix L Procedures Followed; or *(Check One)* |
| X | Description of Training Attached | | Equivalent Procedures Attached |
| **13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL** | | **21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)** | |
| X | Detailed Information Attached | | Detailed Information Attached |
| **14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS** *(Check One)* | | **22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS** | |
| | | | Detailed Information Attached |
| | Appendix F Procedures Followed; or | **23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b** | |
| X | Equivalent Procedures Attached | | Detailed Information Attached |

## 24. PERSONNEL MONITORING DEVICES

| TYPE (Check appropriate box) | | | SUPPLIER | EXCHANGE FREQUENCY |
|---|---|---|---|---|
| a. WHOLE BODY | | FILM | | |
| | | TLD | | |
| | | OTHER (Specify) | | |
| b. FINGER | | FILM | | |
| | X | TLD | R.S. Landauer & Co., Glenwood, IL | Monthly |
| | | OTHER (Specify) | | |
| c. WRIST | | FILM | | |
| | | TLD | | |
| | | OTHER (Specify) | | |

d. OTHER (Specify)

Refer to the attached ALARA Program

## 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: 7C

(2) LICENSE FEE ENCLOSED: $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

Kenneth C. Geoly

(1) NAME *(Type or Print)*
KENNETH C. GEOLY

(2) TITLE
RADIATION SAFETY OFFICER

c. DATE
4-16-85

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.

# Certificate of Achievement

*This Certificate is presented to*

Kenneth L. Geoly, M.D.

*by* Beta Diagnostics Inc.

*for Distinguished Achievement*

Bone Densitometry Workshop

IN WITNESS WHEREOF, *we have caused this Certificate to be signed*

this 4th *day of* October *in the year* 1984

William A. Walker, Ph.D.
Signature

USNRC Lic # 37-20695-01

Walter V. Klecan MD
Signature

91810—JULIUS BLUMBERG, INC., N.Y.C. 10013

INDEX


I. Authorized User

A. Names

B. Training and Experience

1. Curriculum Vitae
2. Supplement A, DHMH-300-6C
3. Supplement A, USNRC Form 313M
4. Supplement B, USNRC Form 313M

II. Attachments

A. Facilities

B. Radiation Safety Procedures

1. Responsibilities of the RSO

2. Ordering and Receiving

3. Package Opening Procedures Report

4. Security

5. Leak Testing

6. Area Surveys

7. Personnel Monitoring

8. General Safety Rules

9. Emergency Procedures

10. Waste Management

C. Radiation Detection Instrumentation

D. Personnel Training Program

E. Administrative Procedures

F. Certification of Using Physician

AUTHORIZED USERS NORTHERN VIRGINIA

William J. Cirksena, M.D.
Michael C. Gelfand, M.D.
Alberto N. Martino, M.D.
Benjamin P. Hernandez, M.D.
Kenneth L. Geoly, M.D.

Kenneth L. Geoly, M.D. - Documentation of training and experience attached.

AUTHORIZED USERS DISTRICT OF COLUMBIA

William J. Cirksena, M.D.
Michael C. Gelfand, M.D.
Alfredo R. Zarate, M.D.
A. Kaldun Nossuli, M.D.
David B. Kessler, M.D.
Alberto N. Martino, M.D.
Benjamin P. Hernandez, M.D.

All of the above-listed physicians are currently authorized under Maryland license No. MD-31-135-01.

Please add to the list Kenneth L. Geoly, M.D., who is not authorized under Maryland license, however, is a currently licensed physician in the District of Columbia.

CURRICULUM VITAE - KENNETH L. GEOLY, M.D. F.A.C.P.

Personal

1. Date of Birth: December 2, 1943

2. Married, 1965, 3 children

3. Education:

Secondary School: Great Neck South Senior High School
Great Neck, L.I., New York 1958-1961

Undergraduate: University of Notre Dame, Bachelor of Science
(in absentia, 1965)
Notre Dame, Indiana 1961-1964

Medical School: State University of New York
Downstate Medical Center
College of Medicine
Brooklyn, New York 1964-1968

Internship: St. Vincent's Hospital and Medical Center of New York
153 West 11th Street
New York, New York Internal Medicine 1968-1969

Medical Residency: 1st year: St. Vincent's Hospital and Medical Center
153 West 11th Street
New York, New York 1969-1970

2nd year: Georgetown University Hospital
3800 Reservoir Road, N.W.
Washington, D.C. 20007 1972-1973

Fellowship: Georgetown University Hospital
3800 Reservoir Road, N.W.
Washington, D.C. 20007
Nephrology

4. Achievements: Alpha Epsilon Delta
Pre-Medical Honor Society
University of Notre Dame 1963

Diplomate of Internal Medicine June 1973

Fellowship - American College of Physicians April 1978

Diplomate of Internal Medicine - Nephrology June 1978

5. Military Experience: U.S. Army: Active Duty: Republic of Viet Nam -
March 1971-February 1972
Kimbrough Army Hospital-February 1972-September 1972

6. Hospitals:

The Fairfax Hospital - Active Status
3300 Gallows Road
Falls Church, Virginia 22042

The Arlington Hospital - Courtesy
1701 N. George Mason Drive
Arlington, Virginia 22207

Northern Virginia Doctors Hospital - Courtesy
601 S. Carlin Springs Road
Arlington, Virginia 22203

7. Positions:

Associate Medical Director - Metropolitan Washington Renal Dialysis Center of Arlington - 1978 to present

Assistant Clinical Professor in Medicine - Georgetown University Medical Center - 1976 to present

Staff Nephrologist - The Fairfax Hospital
Falls Church, Virginia -1975 to present

Medical Director - Dialysis Services
The Fairfax Hospital - 1978 to present

Member, Governors Council-Virginia Cheasapeake A.C.P.

Member, Planning Committee ESRD Network # 23 1978-1982

Member, PAB NKE National Capitol Area

Member, Network Coordinating Council ESRD Network #23 1978 to present

Member, Board of Trustees VSIM - 1983 to present

8. Certifications:

Certified, American Board of Internal Medicine - June 1973

Certified in Nephrology, American Board of Internal Medicine - June 1978

NRC FORM 313M SUPPLEMENT A (9 81) U.S. NUCLEAR REGULATORY COMMISSION

# TRAINING AND EXPERIENCE
## AUTHORIZED USER OR RADIATION SAFETY OFFICER

| 1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER | 2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE |
|---|---|
| Kenneth L. Geoly, M.D. | Virginia |

### 3. CERTIFICATION

| SPECIALTY BOARD A | CATEGORY B | MONTH AND YEAR CERTIFIED C |
|---|---|---|
| #0101-022057 | Medicine and Surgery | |

### 4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

| FIELD OF TRAINING A | LOCATION AND DATE(S) OF TRAINING B | TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours) C | TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D |
|---|---|---|---|
| a. RADIATION PHYSICS AND INSTRUMENTATION | Bone Densitometry Workshop fully meeting the duration and content for such instruction as criteria listed in USNRC Policy and Guidance Directive FC83-24; Licensing the Lixiscope and Bone Mineral Analyzer for Human Use, dated Nov. 10, 1983. | 2 hours | |
| b. RADIATION PROTECTION | | 2 hours | |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | Same as above | 1 hour | |
| d. RADIATION BIOLOGY | Same as above | 3 hours | |
| e. Principles of Photon Absortionmetry, measurements, and instrumentation | Same as above | 2 hours | 1.5 hours |

### 5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)

| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
|---|---|---|---|---|
| | | | | |

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

# TRAINING AND EXPERIENCE
## AUTHORIZED USER OR RADIATION SAFETY OFFICER

| 1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER | 2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE |
|---|---|
| Kenneth L. Geoly, M.D. | District of Columbia |

**3. CERTIFICATION**

| SPECIALTY BOARD<br>A | CATEGORY<br>B | MONTH AND YEAR CERTIFIED<br>C |
|---|---|---|
| #005852 | Medicine and Surgery | |

**4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES**

| FIELD OF TRAINING<br>A | LOCATION AND DATE(S) OF TRAINING<br>B | TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours)<br>C | TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours)<br>D |
|---|---|---|---|
| a. RADIATION PHYSICS AND INSTRUMENTATION | Bone Densitometry Workshop fully meeting the duration and content for such instruction as criteria listed in USNRC Policy and Guidance Directive FC83-24; Licensing the Lixiscope and Bone Mineral Analyzer for Human Use, dated Nov. 10, 1983. | 2 hours | |
| b. RADIATION PROTECTION | | 2 hours | |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | Same as above | 1 hour | |
| d. RADIATION BIOLOGY | Same as above | 3 hours | |
| e. Principles of Photon Absortionmetry, measurements, and instrumentation | Same as above | 2 hours | 1.5 hours |

**5. EXPERIENCE WITH RADIATION.** *(Actual use of Radioisotopes or Equivalent Experience)*

| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
|---|---|---|---|---|
| | | | | |

(9-81)

# PRECEPTOR STATEMENT

*Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.*

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Kenneth L. Geoly, M.D.

STREET ADDRESS

8316 Arlington Boulevard

| CITY | STATE | ZIP CODE |
|---|---|---|
| Fairfax, | VA | 22031 |

**KEY TO COLUMN C**

**PERSONAL PARTICIPATION SHOULD CONSIST OF:**

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.
2. Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.
3. Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

| ISOTOPE A | CONDITIONS DIAGNOSED OR TREATED B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C | COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D |
|---|---|---|---|
| I-125 | DIAGNOSIS OF THYROID FUNCTION | | Dr. Geoly participated in a two day bone densitometry workshop. During the workshop, five (5) subjects were given complete clinical bone mineral analyses under the direction of a physician, license by the State of Texas (#9-3574, 4/30/89), for the use of a bone mineral analyser. See the attached certificate of training. |
| | DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME | | |
| | LIVER FUNCTION STUDIES | | |
| | FAT ABSORPTION STUDIES | | |
| | KIDNEY FUNCTION STUDIES | | |
| | IN VITRO STUDIES | | |
| OTHER | Bone Densitometer | 5 * | |
| I-125 | DETECTION OF THROMBOSIS | | |
| I-131 | THYROID IMAGING | | |
| P-32 | EYE TUMOR LOCALIZATION | | |
| Se-75 | PANCREAS IMAGING | | |
| Yb-169 | CISTERNOGRAPHY | | |
| Xe-133 | BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES | | |
| OTHER | | | |
| Tc-99m | BRAIN IMAGING | | |
| | CARDIAC IMAGING | | |
| | THYROID IMAGING | | |
| | SALIVARY GLAND IMAGING | | |
| | BLOOD POOL IMAGING | | |
| | PLACENTA LOCALIZATION | | |
| | LIVER AND SPLEEN IMAGING | | |
| | LUNG IMAGING | | |
| | BONE IMAGING | | |
| OTHER | | | |

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS<br>*(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| P-32 (Soluble) | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | | |
| P-32 (Colloidal) | INTRACAVITARY TREATMENT | | |
| I-131 | TREATMENT OF THYROID CARCINOMA | | |
| | TREATMENT OF HYPERTHYROIDISM | | |
| Au-198 | INTRACAVITARY TREATMENT | | |
| Co-60 or Cs-137 | INTERSTITIAL TREATMENT | | |
| | INTRACAVITARY TREATMENT | | |
| I-125 or Ir-192 | INTERSTITIAL TREATMENT | | |
| Co-60 or Cs-137 | TELETHERAPY TREATMENT | | |
| Sr-90 | TREATMENT OF EYE DISEASE | | |
| | RADIOPHARMACEUTICAL PREPARATION | | |
| Mo-99/ Tc-99m | GENERATOR | | |
| Sn-113/ In-113m | GENERATOR | | |
| Tc-99m | REAGENT KITS | | |
| Other | | | |

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

6 hours - October 1984

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Gordon L. Bilbrey, M.D.

b. NAME OF INSTITUTION
Beta Diagnostics, Inc.

c. MAILING ADDRESS
7540 Louis Pasteur Drive, Suite 100

d. CITY
San Antonio, Texas 78229

5. MATERIALS LICENSE NUMBER(S)
Texas License # 9-3574

6. PRECEPTOR'S SIGNATURE
Gordon L Bilbrey MD

7. PRECEPTOR'S NAME *(Please type or print)*
Gordon L. Bilbrey, M.D.

8. DATE

NRC FORM 313M SUPPLEMENT B
9-81)



GPO 890-818

CURRICULUM VITAE

William J. Cirksena, M.D.

BIRTH: March 30, 1934 - Hastings, Nebraska

MARITAL STATUS: Married, four children

EDUCATION:

University of Nebraska, Lincoln - 1952-1953.
Hastings (Nebraska) College - 1953-1955.
B.A. Summa Cum Laude - 1956.
University of Nebraska College of Medicine, Omaha - 1955-1959.
M.D. Cum Laude - 1959.

POST-GRADUATE MEDICAL TRAINING:

Internship - General Rotating, Letterman General Hospital, San Francisco, California - 1959-1960.

Residency - Internal Medicine, Walter Reed General Hospital, Washington, D.C. - 1960-1963.

Fellowship - Renal Physiology, Laboratory Kidney and Electrolyte Metabolism, National Heart Institute, NIH, Bethesda, Maryland - 1963-1965.

STAFF APPOINTMENTS:

Research Internists, Walter Reed Army Institute of Research; 1965-1967.

Chief, Experimental Nephrology Section, Walter Reed Army Institute of Research; 1967-1969.

Chief, Department of Nephrology, Walter Reed Army Institute of Research; 1969-present.

Staff, Internal Medicine, Walter Reed General Hospital; 1965-1969.

Chief, Department of Metabolism, Walter Reed General Hospital; 1969-1972.

Consultant to the Surgeon General in Renal Diseases; 1969-present.

Clinical Associate Professor of Medicine, Georgetown University Hospital.

Co-Director, Metropolitan Washington Renal-Dialysis Center; 1972-present.

Chief, Arlington-Georgetown Dialysis Unit, Arlington Hospital; 1973-present.

PROFESSIONAL ORGANIZATIONS:

Alpha Omega Alpha, University of Nebraska - 1958

American Medical Association

American College of Physicians

American Society of Nephrology

American Federation for Clinical Research

American Physiological Society

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

# TRAINING AND EXPERIENCE
# AUTHORIZED USER OR RADIATION SAFETY OFFICER

| 1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER | 2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE |
|---|---|
| William J. Cirksena, M.D. | Virginia |

## 3. CERTIFICATION

| SPECIALTY BOARD<br>A | CATEGORY<br>B | MONTH AND YEAR CERTIFIED<br>C |
|---|---|---|
| #0101-022472 | Medicine and Surgery | |

## 4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

| FIELD OF TRAINING<br>A | LOCATION AND DATE(S) OF TRAINING<br>B | TYPE AND LENGTH OF TRAINING | |
|---|---|---|---|
| | | LECTURE/ LABORATORY COURSES (Hours)<br>C | SUPERVISED LABORATORY EXPERIENCE (Hours)<br>D |
| a. RADIATION PHYSICS AND INSTRUMENTATION | Bone Densitometry Workshop fully meeting the duration and content for such instruction as criteria listed in USNRC Policy and Guidance Directive FC83-24; Licensing the Lixiscope and Bone Mineral Analyzer for Human Use, dated Nov. 10, 1983. | 2 hours | |
| b. RADIATION PROTECTION | | 2 hours | |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | Same as above | 1 hour | |
| d. RADIATION BIOLOGY | Same as above | 3 hours | |
| e. Principles of Photon Absortionmetry, measurements, and instrumentation | Same as above | 2 hours | 1.5 hours |

## 5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
|---|---|---|---|---|
| | | | | |

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

# TRAINING AND EXPERIENCE
## AUTHORIZED USER OR RADIATION SAFETY OFFICER

| 1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER | 2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE |
|---|---|
| William J. Cirksena, M.D. | District of Columbia |

**3. CERTIFICATION**

| SPECIALTY BOARD<br>A | CATEGORY<br>B | MONTH AND YEAR CERTIFIED<br>C |
|---|---|---|
| #009468 | Medicine and Surgery | |

**4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES**

| FIELD OF TRAINING<br>A | LOCATION AND DATE(S) OF TRAINING<br>B | TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours)<br>C | TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours)<br>D |
|---|---|---|---|
| a. RADIATION PHYSICS AND INSTRUMENTATION | Bone Densitometry Workshop fully meeting the duration and content for such instruction as criteria listed in USNRC Policy and Guidance Directive FC83-24; Licensing the Lixiscope and Bone Mineral Analyzer for Human Use, dated Nov. 10, 1983. | 2 hours | |
| b. RADIATION PROTECTION | | 2 hours | |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | Same as above | 1 hour | |
| d. RADIATION BIOLOGY | Same as above | 3 hours | |
| e. Principles of Photon Absortionmetry, measurements, and instrumentation | Same as above | 2 hours | 1.5 hours |

**5. EXPERIENCE WITH RADIATION.** *(Actual use of Radioisotopes or Equivalent Experience)*

| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
|---|---|---|---|---|
| | | | | |

NRC FORM 313M SUPPLEMENT B
(9-81)

U. S. NUCLEAR REGULATORY COMMISSION

# PRECEPTOR STATEMENT

*Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.*

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

William Cirksena, M.D.

STREET ADDRESS

8A2 President Point Dr.

CITY | STATE | ZIP CODE

Annapolis, MD 21403

**KEY TO COLUMN C**

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.
2. Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.
3. Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS<br>*(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| I-125 | DIAGNOSIS OF THYROID FUNCTION | | *Dr. William Cirksena participated in a two day bone densitometry workshop. During the workshop, five (5) subjects were given complete clinical bone mineral analyses under the direction of a physician, license by the State of [illegible] # 9-3574 (4/30/89), for the use of a bone mineral analyser. See the attached certificate of training. |
| | DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME | | |
| | LIVER FUNCTION STUDIES | | |
| | FAT ABSORPTION STUDIES | | |
| | KIDNEY FUNCTION STUDIES | | |
| | IN VITRO STUDIES | | |
| OTHER | Bone Densitometer | 5 * | |
| I-125 | DETECTION OF THROMBOSIS | | |
| I-131 | THYROID IMAGING | | |
| P-32 | EYE TUMOR LOCALIZATION | | |
| Se-75 | PANCREAS IMAGING | | |
| Yb-169 | CISTERNOGRAPHY | | |
| Xe-133 | BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES | | |
| OTHER | | | |
| Tc-99m | BRAIN IMAGING | | |
| | CARDIAC IMAGING | | |
| | THYROID IMAGING | | |
| | SALIVARY GLAND IMAGING | | |
| | BLOOD POOL IMAGING | | |
| | PLACENTA LOCALIZATION | | |
| | LIVER AND SPLEEN IMAGING | | |
| | LUNG IMAGING | | |
| | BONE IMAGING | | |
| OTHER | | | |

## PRECEPTOR STATEMENT *(Continued)*

### 2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| P-32 *(Soluble)* | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | | |
| P-32 *(Colloidal)* | INTRACAVITARY TREATMENT | | |
| I-131 | TREATMENT OF THYROID CARCINOMA | | |
| | TREATMENT OF HYPERTHYROIDISM | | |
| Au-198 | INTRACAVITARY TREATMENT | | |
| Co-60 or Cs-137 | INTERSTITIAL TREATMENT | | |
| | INTRACAVITARY TREATMENT | | |
| I-125 or Ir-192 | INTERSTITIAL TREATMENT | | |
| Co-60 or Cs-137 | TELETHERAPY TREATMENT | | |
| Sr-90 | TREATMENT OF EYE DISEASE | | |
| | RADIOPHARMACEUTICAL PREPARATION | | |
| Mo-99/ Tc-99m | GENERATOR | | |
| Sn-113/ In-113m | GENERATOR | | |
| Tc-99m | REAGENT KITS | | |
| Other | | | |

### 3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

6 hours - Oct 4, 1984

### 4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Gordon Bilbrey, M.D.

b. NAME OF INSTITUTION
Beta Diagnostics, Inc.

c. MAILING ADDRESS
7540 Louis Pasteur Drive, Suite 100

d. CITY
San Antonio, Texas 78229

5. MATERIALS LICENSE NUMBER(S)
Texas License #

6. PRECEPTOR'S SIGNATURE
Gordon Bilbrey MD

7. PRECEPTOR'S NAME *(Please type or print)*
Gordon Bilbrey, M.D.

8. DATE

NRC FORM 313M SUPPLEMENT B
(9-81)

# CURRICULUM VITAE

Michael Charles Gelfand, M.D.

| | |
|---|---|
| Date of Birth: | April 21, 1942 |
| Place of Birth: | New York, New York |
| Citizenship: | United States |
| Marital Status: | Married |
| Education: | B.A., Yale University, New Haven Connecticut<br>June, 1964 |
| | M.D., State University of New York<br>Downstate Medical Center, Brooklyn, New York<br>June, 1968 |
| Employment: | Intern, Department of Medicine, Kings County<br>Hospital Center, Brooklyn, New York<br>1968-1969 |
| | Assistant Resident, Department of Medicine<br>Kings County Hospital Center, Brooklyn, New York<br>1969-1970 |
| | Staff Physician, Renal Dialysis Service<br>Walter Reed General Hospital, Walter Reed<br>Army Medical Center, Washington, DC<br>1970 - 1972 |
| | Special Fellow, Laboratory of Immunology,<br>National Institutes of Allergy and Infectious<br>Diseases, National Institutes of Health<br>Bethesda, MD<br>1972-1973 |
| | Fellow, Division of Nephrology, Department of<br>Medicine, Georgetown University Hospital, Washington, DC<br>1973-1974 |
| | Co-Director, Hemodialysis, Hemoperfusion, and<br>Transplantation Service<br>Georgetown University Hospital, Washington, DC<br>1974-Present |
| | Assistant Professor of Clinical Medicine<br>Georgetown University School of Medicine, Washington, DC<br>1975-1980 |
| | Associate Professor of Clinical Medicine<br>Georgetown University School of Medicine, Washington, DC<br>1980- |

| | |
|---|---|
| Military Service: | United States Army Medical Corps<br>1968-1970 |
| Research Interests: | Transplantation Immunology<br>Immunological Aspects of Renal Disease<br>Hemoperfusion |
| Professional Societies: | American Association of Immunologists<br>Medical Society of the District of Columbia<br>International Transplantation Society<br>American Society of Nephrology<br>American Society for Artificial Internal Organs<br>American College of Physicians<br>National Kidney Foundation |
| Licensure: | New York<br>Maryland<br>District of Columbia<br>Virginia<br>Arizona |

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

# TRAINING AND EXPERIENCE
## AUTHORIZED USER OR RADIATION SAFETY OFFICER

| 1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER | 2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE |
|---|---|
| Michael C. Gelfand, M.D. | Virginia |

**3. CERTIFICATION**

| SPECIALTY BOARD A | CATEGORY B | MONTH AND YEAR CERTIFIED C |
|---|---|---|
| #0101-025786 | Medicine and Surgery | |

**4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES**

| FIELD OF TRAINING A | LOCATION AND DATE(S) OF TRAINING B | TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours) C | TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D |
|---|---|---|---|
| a. RADIATION PHYSICS AND INSTRUMENTATION | Bone Densitometry Workshop fully meeting the duration and content for such instruction as criteria listed in USNRC Policy and Guidance Directive FC83-24; Licensing the Lixiscope and Bone Mineral Analyzer for Human Use, dated Nov. 10, 1983. | 2 hours | |
| b. RADIATION PROTECTION | | 2 hours | |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | Same as above | 1 hour | |
| d. RADIATION BIOLOGY | Same as above | 3 hours | |
| e. Principles of Photon Absortionmetry, measurements, and instrumentation | Same as above | 2 hours | 1.5 hours |

**5. EXPERIENCE WITH RADIATION.** *(Actual use of Radioisotopes or Equivalent Experience)*

| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
|---|---|---|---|---|
| | | | | |

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

# TRAINING AND EXPERIENCE
## AUTHORIZED USER OR RADIATION SAFETY OFFICER

| 1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER | 2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE |
|---|---|
| Michael C. Gelfand, M.D. | District of Columbia |

**3. CERTIFICATION**

| SPECIALTY BOARD<br>A | CATEGORY<br>B | MONTH AND YEAR CERTIFIED<br>C |
|---|---|---|
| #007972 | Medicine and Surgery | |

**4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES**

| FIELD OF TRAINING<br>A | LOCATION AND DATE(S) OF TRAINING<br>B | TYPE AND LENGTH OF TRAINING: LECTURE/LABORATORY COURSES (Hours)<br>C | TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours)<br>D |
|---|---|---|---|
| a. RADIATION PHYSICS AND INSTRUMENTATION | Bone Densitometry Workshop fully meeting the duration and content for such instruction as criteria listed in USNRC Policy and Guidance Directive FC83-24; Licensing the Lixiscope and Bone Mineral Analyzer for Human Use, dated Nov. 10, 1983. | 2 hours | |
| b. RADIATION PROTECTION | | 2 hours | |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | Same as above | 1 hour | |
| d. RADIATION BIOLOGY | Same as above | 3 hours | |
| e. Principles of Photon Absortionmetry, measurements, and instrumentation | Same as above | 2 hours | 1.5 hours |

**5. EXPERIENCE WITH RADIATION.** *(Actual use of Radioisotopes or Equivalent Experience)*

| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
|---|---|---|---|---|
| | | | | |

NRC FORM 313M SUPPLEMENT B
(9-81)

U. S. NUCLEAR REGULATORY COMMISSION

# PRECEPTOR STATEMENT

*Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.*

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Michael C. Gelfand, M.D.

STREET ADDRESS

4905 Del Ray Ave.

CITY | STATE | ZIP CODE

Bethesda MD 20814

**KEY TO COLUMN C**

**PERSONAL PARTICIPATION SHOULD CONSIST OF:**

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.
2. Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.
3. Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS<br>*(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| I-125 | DIAGNOSIS OF THYROID FUNCTION | | *Dr. Michael C. Gelfand participated in a two day bone densitometry workshop. During the workshop, five (5) subjects were given complete clinical bone mineral analyses under the direction of a physician, license by the State of Texas # 9-3574 (4/30/89), for the use of a bone mineral analyser. See the attached certificate of training. |
| | DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME | | |
| | LIVER FUNCTION STUDIES | | |
| | FAT ABSORPTION STUDIES | | |
| | KIDNEY FUNCTION STUDIES | | |
| | IN VITRO STUDIES | | |
| OTHER | Bone Densitometer | 5 * | |
| I-125 | DETECTION OF THROMBOSIS | | |
| I-131 | THYROID IMAGING | | |
| P-32 | EYE TUMOR LOCALIZATION | | |
| Se-75 | PANCREAS IMAGING | | |
| Yb-169 | CISTERNOGRAPHY | | |
| Xe-133 | BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES | | |
| OTHER | | | |
| Tc-99m | BRAIN IMAGING | | |
| | CARDIAC IMAGING | | |
| | THYROID IMAGING | | |
| | SALIVARY GLAND IMAGING | | |
| | BLOOD POOL IMAGING | | |
| | PLACENTA LOCALIZATION | | |
| | LIVER AND SPLEEN IMAGING | | |
| | LUNG IMAGING | | |
| | BONE IMAGING | | |
| OTHER | | | |

## PRECEPTOR STATEMENT *(Continued)*

### 2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| P-32 *(Soluble)* | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | | |
| P-32 *(Colloidal)* | INTRACAVITARY TREATMENT | | |
| I-131 | TREATMENT OF THYROID CARCINOMA | | |
| | TREATMENT OF HYPERTHYROIDISM | | |
| Au-198 | INTRACAVITARY TREATMENT | | |
| Co-60 or Cs-137 | INTERSTITIAL TREATMENT | | |
| | INTRACAVITARY TREATMENT | | |
| I-125 or Ir-192 | INTERSTITIAL TREATMENT | | |
| Co-60 or Cs-137 | TELETHERAPY TREATMENT | | |
| Sr-90 | TREATMENT OF EYE DISEASE | | |
| | RADIOPHARMACEUTICAL PREPARATION | | |
| Mo-99/ Tc-99m | GENERATOR | | |
| Sn-113/ In-113m | GENERATOR | | |
| -99m | REAGENT KITS | | |
| Other | | | |

### 3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

6 hours - Oct 4, 1984

### 4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Gordon Bilbrey, M.D.

b. NAME OF INSTITUTION
Beta Diagnostics, Inc.

c. MAILING ADDRESS
7540 Louis Pasteur Drive, Suite 100

d. CITY
San Antonio, Texas 78229

5. MATERIALS LICENSE NUMBER(S)
Texas License #

### 6. PRECEPTOR'S SIGNATURE

Gordon Bilbrey MD

### 7. PRECEPTOR'S NAME *(Please type or print)*

Gordon Bilbrey, M.D.

### 8. DATE

NRC FORM 313M SUPPLEMENT B
(9-81)

CURRICULUM VITAE

ALBERTO N. MARTINO, M.D.

1960: Instructor in Pharmacology, Faculty of Medicine, Buenos Aires Chairman Prof. L. Camponovo.

1960-61: Instructor in Physiology, Faculty of Odontology, Buenos Aires, Chairman Prof. A. C. Houssay.

1962: M.D. Degree, University of Buenos Aires, Argentina.

1963: Instructor in Physiology, Faculty of Medicine, Buenos Aires, Chairman Prof. Alberto C. Taquini.

1965-69: Attending Physician, Instituto Modelo de Clinica Medica, Hospital Rawson, University of Buenos Aires, Department of Nephrology.

1968-69: Nephrology consultant, Municipal Hospital of San Martin, Prov. de Buenos Aires.

1970: ECFMG Certificate.

1970-71: Rotating Internship, St. John's Hospital, Elmhurst, N.Y.

1971-73: Internal Medicine Residency, Nassau County Medical Center, East Meadow, N.Y.; Clinical Campus, State University of New York at Stony Brook.

1973-74: Clinical Fellowship in Nephrology, Nassau County Medical Center, East Meadow, N.Y.; Clinical Campus, State University of New York at Stony Brook, Director: Dr. Joseph M. Letteri, M.D.

1974-75: Clinical-Research Fellowship in Nephrology, Combined Program, Nassau County Medical Center, East Meadow, N.Y. and Brookhaven National Laboratories, Upton, N.Y.; Directors: Dr. Joseph M. Letteri, M.D and Stanton M. Cohn, Ph.D. Calcium metabolism in patients on chronic hemodialysis, uremic bone disease in the rat and response, of uremic bone rat to exogenous PTH.

1973: Licensed in New York State (FLEX).

1975: Private practive of clinical nephrology.

1977: Named chief of the Subsection of Nephrology at Providence Hospital, Washington, D.C.

1978: Associate Director of Metropolitan Washington Renal Dialysis Center.

PUBLICATIONS

1. The clinical value of $^{131}$I-Hippuran blood clearance by external counting as an index of renal plasma flow. Proc.1st Inter. Symp. Radioisotopes in the diagnosis of deases of the kidneys. Page 180, Excerpta Med. Found., Amsterdam, 1968.

2. Endogenous creatinine: correlation between its plasmatic concentration and urinary excretion with clearance as an index of renal function. Medicine (Buenos Aires), 27:159-169, 1967.

3. Simplified $^{131}$L-Hypaque clearance as index of glomerular filtration rate. Proc. 2nd Latin American Congress of Biology and Nuclear Medicine, Page 25, Mar del Plata, Argentina, 1968 (Abstr.).

4. Clinical value of $^{203}$Hg-Neohydrin renogram. Proceedings 2nd Latin American Congress of Biology and Nuclear Medicine. Page 31, Mar del Plata, Argentina, 1968 (Abstr.).

5. Three years experience with autogenous and autologous saphenous vein grafts in patients on chronic hemodialysis. Trans. American Society of Artificial Organs, 1974.

6. Loss of calcium from axial and apendicular skeleton in patients with chronic renal failure. Proc. XIth European Symposium on calcified tissues, Page 215, 1975.

7. Distribution of calcium in the rate due to chronic renal failure, Nephron, 18-124, 1977.

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY C[illegible]

# TRAINING AND EXPERIENCE
## AUTHORIZED USER OR RADIATION SAFETY OFFICER

| 1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER | 2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE |
|---|---|
| Alberto N. Martino, M.D. | Virginia |

**3. CERTIFICATION**

| SPECIALTY BOARD<br>A | CATEGORY<br>B | MONTH AND YEAR CERTIFIED<br>C |
|---|---|---|
| #0101-026482 | Medicine and Surgery | |

**4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES**

| FIELD OF TRAINING<br>A | LOCATION AND DATE(S) OF TRAINING<br>B | TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours)<br>C | TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours)<br>D |
|---|---|---|---|
| a. RADIATION PHYSICS AND INSTRUMENTATION | Bone Densitometry Workshop fully meeting the duration and content for such instruction as criteria listed in USNRC Policy and Guidance Directive FC83-24; Licensing the Lixiscope and Bone Mineral Analyzer for Human Use, dated Nov. 10, 1983. | 2 hours | |
| b. RADIATION PROTECTION | | 2 hours | |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | Same as above | 1 hour | |
| d. RADIATION BIOLOGY | Same as above | 3 hours | |
| e. Principles of Photon Absortionmetry, measurements, and instrumentation | Same as above | 2 hours | 1.5 hours |

**5. EXPERIENCE WITH RADIATION.** *(Actual use of Radioisotopes or Equivalent Experience)*

| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
|---|---|---|---|---|
| | | | | |

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

# TRAINING AND EXPERIENCE
## AUTHORIZED USER OR RADIATION SAFETY OFFICER

| 1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER | 2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE |
|---|---|
| Alberto N. Martino, M.D. | District of Columbia |

**3. CERTIFICATION**

| SPECIALTY BOARD (A) | CATEGORY (B) | MONTH AND YEAR CERTIFIED (C) |
|---|---|---|
| #008437 | Medicine and Surgery | |

**4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES**

| FIELD OF TRAINING (A) | LOCATION AND DATE(S) OF TRAINING (B) | TYPE AND LENGTH OF TRAINING: LECTURE/LABORATORY COURSES (Hours) (C) | TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) (D) |
|---|---|---|---|
| a. RADIATION PHYSICS AND INSTRUMENTATION | Bone Densitometry Workshop fully meeting the duration and content for such instruction as criteria listed in USNRC Policy and Guidance Directive FC83-24; Licensing the Lixiscope and Bone Mineral Analyzer for Human Use, dated Nov. 10, 1983. | 2 hours | |
| b. RADIATION PROTECTION | | 2 hours | |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | Same as above | 1 hour | |
| d. RADIATION BIOLOGY | Same as above | 3 hours | |
| e. Principles of Photon Absortionmetry, measurements, and instrumentation | Same as above | 2 hours | 1.5 hours |

**5. EXPERIENCE WITH RADIATION.** *(Actual use of Radioisotopes or Equivalent Experience)*

| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
|---|---|---|---|---|
| | | | | |

NRC FORM 313M SUPPLEMENT B
(9-81)

U. S. NUCLEAR REGULATORY COMMISSION

# PRECEPTOR STATEMENT

*Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.*

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Alberto Martino, M.D.

STREET ADDRESS

9401 Mt. Vernon Circle

CITY | STATE | ZIP CODE

Alexandria VA 22309

**KEY TO COLUMN C**

**PERSONAL PARTICIPATION SHOULD CONSIST OF:**

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS<br>*(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| I-125 | DIAGNOSIS OF THYROID FUNCTION | | *Dr. Alberto Martino participated in a two day bone densitometry workshop. During the workshop, five (5) subjects were given complete clinical bone mineral analyses under the direction of a physician, license by the State of T... # 9-3574 (4/30/89), for the use of a bone mineral analyser. See the attached certificate of training. |
| | DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME | | |
| | LIVER FUNCTION STUDIES | | |
| | FAT ABSORPTION STUDIES | | |
| | KIDNEY FUNCTION STUDIES | | |
| | IN VITRO STUDIES | | |
| OTHER | Bone Densitometer | 5 * | |
| I-125 | DETECTION OF THROMBOSIS | | |
| I-131 | THYROID IMAGING | | |
| P-32 | EYE TUMOR LOCALIZATION | | |
| Se-75 | PANCREAS IMAGING | | |
| Yb-169 | CISTERNOGRAPHY | | |
| Xe-133 | BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES | | |
| OTHER | | | |
| Tc-99m | BRAIN IMAGING | | |
| | CARDIAC IMAGING | | |
| | THYROID IMAGING | | |
| | SALIVARY GLAND IMAGING | | |
| | BLOOD POOL IMAGING | | |
| | PLACENTA LOCALIZATION | | |
| | LIVER AND SPLEEN IMAGING | | |
| | LUNG IMAGING | | |
| | BONE IMAGING | | |
| OTHER | | | |

## PRECEPTOR STATEMENT *(Continued)*

### 2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| P-32 *(Soluble)* | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | | |
| P-32 *(Colloidal)* | INTRACAVITARY TREATMENT | | |
| I-131 | TREATMENT OF THYROID CARCINOMA | | |
| | TREATMENT OF HYPERTHYROIDISM | | |
| Au-198 | INTRACAVITARY TREATMENT | | |
| Co-60 or Cs-137 | INTERSTITIAL TREATMENT | | |
| | INTRACAVITARY TREATMENT | | |
| I-125 or Ir-192 | INTERSTITIAL TREATMENT | | |
| Co-60 or Cs-137 | TELETHERAPY TREATMENT | | |
| Sr-90 | TREATMENT OF EYE DISEASE | | |
| | RADIOPHARMACEUTICAL PREPARATION | | |
| Mo-99/ Tc-99m | GENERATOR | | |
| Sn-113/ In-113m | GENERATOR | | |
| c-99m | REAGENT KITS | | |
| Other | | | |

### 3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

6 hours - Oct. 4, 1984

### 4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Gordon Bilbrey, M.D.

b. NAME OF INSTITUTION
Beta Diagnostics, Inc.

c. MAILING ADDRESS
7540 Louis Pasteur Drive, Suite 100

d. CITY
San Antonio, Texas 78229

5. MATERIALS LICENSE NUMBER(S)
Texas License #

6. PRECEPTOR'S SIGNATURE
Gordon Bilbrey MD

7. PRECEPTOR'S NAME *(Please type or print)*
Gordon Bilbrey, M.D.

8. DATE

NRC FORM 313M SUPPLEMENT B
(9-81)

# CURRICULUM VITAE

Name: Benjamin Pacheco Hernandez

Date of Birth: August 2, 1946

Place of Birth : Philippines

Civil Status: Married

Children: 2

Education:

June 1962 - April 1966 - University of Santo Tomas
Manila, Philippines
Bachelor of Science
Major in Psychology
Cum Laude

June 1966 - April 1971 - University of Santo Tomas
Manila, Philippines
Doctor of Medicine
Cum Laude

May 1970 - April 1971 - Rotating Internship
USAF Hospital Clark, Philippine
(as part of 5 year curriculum)

April 1971 - June 1971- Apprenticeship with physician father while preparing for the Medical Boards

June 1971 - Passed the Philippine Board of Medicine and Surgery

Training:

July 1971 - June 1972 - Medical Residency
USAF Hospital Clark, Philippine

July 1972 - June 1973 - Medical Residency
Makati Medical Center
Makati, Philippines

July 1973 - June 1974 - Medical Internship
Englewood Hospital
Englewood, New Jersey

July 1974 - June 1976 - Medical Residency
Englewood Hospital
Englewood, New Jersey

July 1976 - June 1978 - Nephrology Fellowship
North Shore University Hospit
Cornell University Affiliate
Manhasset, New York

Practice: July 1978 to present - associated with Metropolitan
Washington Renal Dialysis Centers

Privileges : Washington Hospital Center
Providence Hospital
Capitol Hill Hospital

Licensee:

| | |
|---|---|
| Virginia | - February 1976 |
| Maryland | - January 1979 |
| Washington, D.C. | - November1978 |
| Florida | - October 1978 (inactive) |

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

# TRAINING AND EXPERIENCE
## AUTHORIZED USER OR RADIATION SAFETY OFFICER

| 1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER | 2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE |
|---|---|
| Benjamin P. Hernandez, M.D. | Virginia |

**3. CERTIFICATION**

| SPECIALTY BOARD<br>A | CATEGORY<br>B | MONTH AND YEAR CERTIFIED<br>C |
|---|---|---|
| #0101-026725 | Medicine and Surgery | |

**4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES**

| FIELD OF TRAINING<br>A | LOCATION AND DATE(S) OF TRAINING<br>B | TYPE AND LENGTH OF TRAINING | |
|---|---|---|---|
| | | LECTURE/ LABORATORY COURSES (Hours)<br>C | SUPERVISED LABORATORY EXPERIENCE (Hours)<br>D |
| a. RADIATION PHYSICS AND INSTRUMENTATION | Bone Densitometry Workshop fully meeting the duration and content for such instruction as criteria listed in USNRC Policy and Guidance Directive FC83-24; Licensing the Lixiscope and Bone Mineral Analyzer for Human Use, dated Nov. 10, 1983. | 2 hours | |
| b. RADIATION PROTECTION | | 2 hours | |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | Same as above | 1 hour | |
| d. RADIATION BIOLOGY | Same as above | 3 hours | |
| e. Principles of Photon Absortionmetry, measurements, and instrumentation | Same as above | 2 hours | 1.5 hours |

**5. EXPERIENCE WITH RADIATION.** *(Actual use of Radioisotopes or Equivalent Experience)*

| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
|---|---|---|---|---|
| | | | | |

NRC FORM 313M SUPPLEMENT A (9-81) U.S. NUCLEAR REGULATORY COMMISSION

# TRAINING AND EXPERIENCE
## AUTHORIZED USER OR RADIATION SAFETY OFFICER

| 1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER | 2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE |
|---|---|
| Benjamin P. Hernandez, M.D. | District of Columbia |

### 3. CERTIFICATION

| SPECIALTY BOARD A | CATEGORY B | MONTH AND YEAR CERTIFIED C |
|---|---|---|
| #011311 | Medicine and Surgery | |

### 4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

| FIELD OF TRAINING A | LOCATION AND DATE(S) OF TRAINING B | TYPE AND LENGTH OF TRAINING: LECTURE/LABORATORY COURSES (Hours) C | TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D |
|---|---|---|---|
| a. RADIATION PHYSICS AND INSTRUMENTATION | Bone Densitometry Workshop fully meeting the duration and content for such instruction as criteria listed in USNRC Policy and Guidance Directive FC83-24; Licensing the Lixiscope and Bone Mineral Analyzer for Human Use, dated Nov. 10, 1983. | 2 hours | |
| b. RADIATION PROTECTION | | 2 hours | |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | Same as above | 1 hour | |
| d. RADIATION BIOLOGY | Same as above | 3 hours | |
| e. Principles of Photon Absortionmetry, measurements, and instrumentation | Same as above | 2 hours | 1.5 hours |

### 5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
|---|---|---|---|---|
| | | | | |

NRC FORM 313M SUPPLEMENT B
(9-81)

U. S. NUCLEAR REGULATORY COMMISSION

# PRECEPTOR STATEMENT

*Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.*

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Benjamin Hernandez, M.D.

STREET ADDRESS

4905 Del Ray Ave.

| CITY | STATE | ZIP CODE |
|---|---|---|
| Bethesda | MD | 20814 |

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.
2. Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.
3. Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

| ISOTOPE (A) | CONDITIONS DIAGNOSED OR TREATED (B) | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION (C) | COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) (D) |
|---|---|---|---|
| I-125 | DIAGNOSIS OF THYROID FUNCTION | | *Dr. Benjamin Hernandez participated in a two day bone densitometry workshop. During the workshop, five (5) subjects were given complete clinical bone mineral analyses under the direction of a physician, license by the State of Texas # 9-3574 (4/30/89), for the use of a bone mineral analyser. See the attached certificate of training. |
| | DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME | | |
| | LIVER FUNCTION STUDIES | | |
| | FAT ABSORPTION STUDIES | | |
| | KIDNEY FUNCTION STUDIES | | |
| | IN VITRO STUDIES | | |
| OTHER | Bone Densitometer | 5 * | |
| I-125 | DETECTION OF THROMBOSIS | | |
| I-131 | THYROID IMAGING | | |
| P-32 | EYE TUMOR LOCALIZATION | | |
| Se-75 | PANCREAS IMAGING | | |
| Yb-169 | CISTERNOGRAPHY | | |
| Xe-133 | BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES | | |
| OTHER | | | |
| Tc-99m | BRAIN IMAGING | | |
| | CARDIAC IMAGING | | |
| | THYROID IMAGING | | |
| | SALIVARY GLAND IMAGING | | |
| | BLOOD POOL IMAGING | | |
| | PLACENTA LOCALIZATION | | |
| | LIVER AND SPLEEN IMAGING | | |
| | LUNG IMAGING | | |
| | BONE IMAGING | | |
| OTHER | | | |

## PRECEPTOR STATEMENT *(Continued)*

### 2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| P-32 *(Soluble)* | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | | |
| P-32 *(Colloidal)* | INTRACAVITARY TREATMENT | | |
| I-131 | TREATMENT OF THYROID CARCINOMA | | |
| | TREATMENT OF HYPERTHYROIDISM | | |
| Au-198 | INTRACAVITARY TREATMENT | | |
| Co-60 or Cs-137 | INTERSTITIAL TREATMENT | | |
| | INTRACAVITARY TREATMENT | | |
| I-125 or Ir-192 | INTERSTITIAL TREATMENT | | |
| Co-60 or Cs-137 | TELETHERAPY TREATMENT | | |
| Sr-90 | TREATMENT OF EYE DISEASE | | |
| | RADIOPHARMACEUTICAL PREPARATION | | |
| Mo-99/ Tc-99m | GENERATOR | | |
| Sn-113/ In-113m | GENERATOR | | |
| Tc-99m | REAGENT KITS | | |
| Other | | | |

### 3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

6 hours - Oct 4, 1984

### 4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Gordon Bilbrey, M.D.

b. NAME OF INSTITUTION
Beta Diagnostics, Inc.

c. MAILING ADDRESS
7540 Louis Pasteur Drive, Suite 100

d. CITY
San Antonio, Texas 78229

5. MATERIALS LICENSE NUMBER(S)
Texas License #

6. PRECEPTOR'S SIGNATURE
Gordon Bilbrey MD

7. PRECEPTOR'S NAME *(Please type or print)*
Gordon Bilbrey, M.D.

8. DATE

NRC FORM 313M SUPPLEMENT B
(9-81)

CURRICULUM VITAE

ALFREDO R. ZARATE, M. D.

BIRTH: December 5, 1941, Santa Fe, Argentina

EDUCATION:

1. Jobson College, Santa Fe, Argentina, 1957-1960.

2. Pre-Medical Course, University of the Litoral, 1961.

3. University of the Litoral, Medical School, Rosario. From 1962-68.

MEDICAL TRAINING:

1. Intern, Sanatorio Britanico, Rosario, Argentina, May 1968 to August 1968.

2. Medical Residency, Institute for Medical Research (Instituto de Investigaciones Medicas), University of Buenos Aires, Buenos Aires, Argentina, September 1968 to September 1969.

3. Pulmonary Laboratory and Respiratory Care Unit, Respiratory Center, University of Buenos Aires, Argentina, August 1969 to November 1969.

4. Italian Hospital, Buenos Aires, Argentina; Intensive Care Unit, from October 1969 to November 1969.

5. Physician in Charge, Intensive Care Unit, Sanatorio Britanico, Rosario, Argentina, November 1969 to June 1970.

MEDICAL TRAINING IN U.S.A.:

6. Straight Medical Internship, Roger Williams General Hospital, Brown University, Providence, Rhode Island, July 1971 to June 1972. Chief of Service, Paul Calabresi, M.D.

7. Residency in Medicine, Roger Williams General Hospital, July 1972 to June 1973. Chief of Service, Paul Calabrisi, M.D.

8. Mayo Graduate School of Medicine, Nephrology Fellowship, July 1973 to June 1974. Chairman of Department, Cameron Strong, M.D.

9. Georgetown University Hospital, Nephrology Fellowship, July 1974 to June 1975. Chief of Service, George Schreiner, M.D.

BASIC RESEARCH EXPERIENCE:

Special research project: "Effects of Concanavalin A and Antithy I.2 Serum on Immunological Abnormalities of NZB/W Mice". Dr. A. D. Steinberg Laboratory; Arthritis and Rheumatism Branch, N.I.A.M.D.; N.I.H; 1975-1976.

CLINICAL RESEARCH EXPERIENCE:

See publications.

SCHOLARSHIPS:

Clemente Alvarez Scholarship; Given by the Medical School, Rosario, Argentina for postgraduate training in Internal Medicine, 1968-1969.

EXAMINATIONS:

1. E.C.F.M.G.: September 16, 1970.
2. F.L.E.X.: (Illinois) June 1973.
3. A.B.I.M., Certified, June 1974.
4. A.B.I.M., Subspecialty Nephrology, Eligible as of June 1975.

MEDICAL LICENSES:

Maryland, Virginia, Washington, D.C.

MEMBERSHIPS, MEDICAL SOCIETIES:

1. American Society of Internal Medicine, 1974.
2. American Society of Nephrology, 1976.
3. International Society of Nephrology, 1976.
4. Mayo Alumni Association, 1975.
5. D. C. Medical Society.
6. Pan American Medical Society, Washington, D.C.

PAST PROFESSIONAL ACTIVITIES:

Consultant Nephrologist, National Institute of Health (Temporary Appointment, Contract # NIH-76-PandA-203) March-April 1976.

Attending Physician, V.A.Hospital, Washington, D.C. August 1975-August 1976.

PRESENT PROFESSIONAL ACTIVITIES:

1. Clinical Instructor, Medicine, Georgetown University School of Medicine, Washington, D.C. From January 1976 -
2. Consultant Nephrologist, Transplantation Service and Shock-Trauma Unit, Washington Hospital Center.

3. Private Practice, Limited to Nephrology.

4. Staff Nephrologist, Metropolitan Washington Renal-Dialysis Centers, Bethesda, Maryland.

HOSPITAL AFFILIATIONS:

1. Active Staff, Washington Hospital Center.

2. Active Staff, Capital Hill Hospital.

3. Courtesy Staff, Sibley Memorial Hospital.

4. Suburban Hospital, Maryland.

PUBLICATIONS:

Abstracts: * Published but not presented
** Presented at a Meeting

** Life-threatening Hyperkalemia Resulting from Geophagia", M.C.Gelfand, J.H.Knepshield, A.R.Zarate, George E. Schreiner, American Society of Nephrology, November 1974, Washington, D.C.

** "Activation of Suppressor Cell Function in New Zealand B.W.Mice by Anti-Thy I.2 Serum", L.Klassen, A.R.Zarate, A.D.Steinberg, W. Paul, M.C.Gelfand, Federation American Societies of Experimental Biology, April 1976, Anaheim, California.

**"Interaction of Suppressor T Cell Population in Prolongation of Graft Survival in S.L.E. Bearing (N.Z.B.W. Mice)". A.R.Zarate, L.Klassen, A.D.Steinberg, M.C.Gelfand, NIH Bethesda and Georgetown University, International Congress of Nephrology June 1978, Montreal.

** "Life-threatening Hypoglycemia in Propranolol Treated Dialysis Patients: Potentiation of an Underlying Defect in Glucoe Metabolism", A.R.Zarate, M.C.Gelfand, H.G.Preuss, J.H.Knepshield, G.E.Schreiner. Metropolitan Washington Renal Dialysis Centers and Georgetown University Hospital, Washington, D.C. International congress of Nutrition in Renal Disease, Bologna, Italy, June 1979.

**"Asymptomatic Pericardial Effusion-- A Possible Complication of Minoxidel Therapy in Patients with Renal Failure". M.C.Gelfand, J. Horton, M. Gottleib, J.P. Winchester, K.Lawrie, A.R.Zarate, M.Lazarus, G.E.Schreiner, Georgetown University Hospital and Peter Bent Brigham Hospital, Boston, VII International Congress of Nephrology, Montreal 1978.

**"Hyperkeratosis Penetrans (Kyerle's Disease) A Rare Dermatological Disorder in Dialysis Patients". A.R.Zarate, A.Hood, G.L.Hardegen, J.H.Knepshield, M.C.Gelfand. From the Hospital Center and Georgetown University Hospital Conference Dialysis Transplantation Forum, New Orleans, November 1978.

* "Reversal of Hepatorenal Syndrome by Peritoneo-Venous Shunt" , A.R.Zarate, L. Diamond, M.C.Gelfand, J.Lee, S.Tucker, G.E.Schreiner, ASAIO, April 1978. Chicago, Illinois

NRC FORM 313M SUPPLEMENT A (9-81) U.S. NUCLEAR REGULATORY COMMISSION

# TRAINING AND EXPERIENCE
## AUTHORIZED USER OR RADIATION SAFETY OFFICER

| 1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER | 2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE |
|---|---|
| Alfredo R. Zarate, M.D. | District of Columbia |

**3. CERTIFICATION**

| SPECIALTY BOARD (A) | CATEGORY (B) | MONTH AND YEAR CERTIFIED (C) |
|---|---|---|
| #9119 | Medicine and Surgery | |

**4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES**

| FIELD OF TRAINING (A) | LOCATION AND DATE(S) OF TRAINING (B) | TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours) (C) | TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) (D) |
|---|---|---|---|
| a. RADIATION PHYSICS AND INSTRUMENTATION | Bone Densitometry Workshop fully meeting the duration and content for such instruction as criteria listed in USNRC Policy and Guidance Directive FC83-24; Licensing the Lixiscope and Bone Mineral Analyzer for Human Use, dated Nov. 10, 1983. | 2 hours | |
| b. RADIATION PROTECTION | | 2 hours | |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | Same as above | 1 hour | |
| d. RADIATION BIOLOGY | Same as above | 3 hours | |
| e. Principles of Photon Absortionmetry, measurements, and instrumentation | Same as above | 2 hours | 1.5 hours |

**5. EXPERIENCE WITH RADIATION.** *(Actual use of Radioisotopes or Equivalent Experience)*

| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
|---|---|---|---|---|
| | | | | |

NRC FORM 313M SUPPLEMENT B
(9-81)

U. S. NUCLEAR REGULATORY COMMISSION

# PRECEPTOR STATEMENT

*Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.*

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Alfredo R. Zarate, M.D.

STREET ADDRESS

4905 Del Ray Ave.

CITY | STATE | ZIP CODE

Bethesda MD 20814

**KEY TO COLUMN C**

**PERSONAL PARTICIPATION SHOULD CONSIST OF:**

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS<br>*(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| I-125 | DIAGNOSIS OF THYROID FUNCTION | | *Dr. Alfredo R. Zarte participated in a two day bone densitometry workshop. During the workshop, five (5) subjects were given complete clinical bone mineral analyses under the direction of a physician, license by the State of T # 9-3574 (4/30/89), for the use of a bone mineral analyser. See the attached certificate of training. |
| | DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME | | |
| | LIVER FUNCTION STUDIES | | |
| | FAT ABSORPTION STUDIES | | |
| | KIDNEY FUNCTION STUDIES | | |
| | IN VITRO STUDIES | | |
| OTHER | Bone Densitometer | 5 * | |
| I-125 | DETECTION OF THROMBOSIS | | |
| I-131 | THYROID IMAGING | | |
| P-32 | EYE TUMOR LOCALIZATION | | |
| Se-75 | PANCREAS IMAGING | | |
| Yb-169 | CISTERNOGRAPHY | | |
| Xe-133 | BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES | | |
| OTHER | | | |
| Tc-99m | BRAIN IMAGING | | |
| | CARDIAC IMAGING | | |
| | THYROID IMAGING | | |
| | SALIVARY GLAND IMAGING | | |
| | BLOOD POOL IMAGING | | |
| | PLACENTA LOCALIZATION | | |
| | LIVER AND SPLEEN IMAGING | | |
| | LUNG IMAGING | | |
| | BONE IMAGING | | |
| OTHER | | | |

## PRECEPTOR STATEMENT (Continued)

### 2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS<br>(Additional information or comments may be submitted in duplicate on separate sheets.)<br>D |
|---|---|---|---|
| P-32 (Soluble) | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | | |
| P-32 (Colloidal) | INTRACAVITARY TREATMENT | | |
| I-131 | TREATMENT OF THYROID CARCINOMA | | |
| | TREATMENT OF HYPERTHYROIDISM | | |
| Au-198 | INTRACAVITARY TREATMENT | | |
| Co-60 or Cs-137 | INTERSTITIAL TREATMENT | | |
| | INTRACAVITARY TREATMENT | | |
| I-125 or Ir-192 | INTERSTITIAL TREATMENT | | |
| Co-60 or Cs-137 | TELETHERAPY TREATMENT | | |
| Sr-90 | TREATMENT OF EYE DISEASE | | |
| | RADIOPHARMACEUTICAL PREPARATION | | |
| Mo-99/ Tc-99m | GENERATOR | | |
| Sn-113/ In-113m | GENERATOR | | |
| Tc-99m | REAGENT KITS | | |
| Other | | | |

### 3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

6 hours - Oct 4, 1984

### 4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Gordon Bilbrey, M.D.

b. NAME OF INSTITUTION
Beta Diagnostics, Inc.

c. MAILING ADDRESS
7540 Louis Pasteur Drive, Suite 100

d. CITY
San Antonio, Texas 78229

5. MATERIALS LICENSE NUMBER(S)
Texas License #

6. PRECEPTOR'S SIGNATURE
Gordon Bilbrey MD

7. PRECEPTOR'S NAME (Please type or print)
Gordon Bilbrey, M.D.

8. DATE

NRC FORM 313M SUPPLEMENT B
(9-81)

# CURRICULU.. VITAE

| | | |
|---|---|---|
| Name: | A. Kaldun Nossuli | Marital Status: Married |
| Address: | 11606 Bunnell Court<br>Potomac, Maryland 20854 | Children: Two |
| Born: | June 15, 1943<br>Beirut, Lebanon | |
| Citizenship: | U.S.A | |
| 1946-1956 | Primary School: Lycée Francais in Beirut | |
| 1956-1962 | Junior & High School: Saint Joseph College<br>Antoura, Lebanon | |
| 1962 | Passed the French Baccalaureat | |

## College Education

| | |
|---|---|
| 1962-1963 | French University of Lyon Dental School |
| 1963-1970 | French University : Lyon Medical School, Beirut Branch |
| 1970 | Obtained Medical Degree |

## Internship

| | |
|---|---|
| 1969-1970 | Broussais Hospital, Paris, France<br>Nephrology Department, Professor Milliez' Service |

## U.S. Post-Degree Education

| | | |
|---|---|---|
| Internship: | July 1970-June 1971 | Straight Medical at Mount Carmel<br>Hospital, Detroit, Michigan |
| Residency: | July 1971-June 1973 | Internal Medicine Rotation<br>Henry Ford Hospital, Detroit,<br>Michigan |

## Fellowship-Nephrology

| | | |
|---|---|---|
| 1st Year | July 1973-June 1974 | Henry Ford Hospital, Detroit,<br>Michigan<br>Chief, N.W. Levin, M.D. |
| | Clinical Nephrology | Rotation through Clinical Servi<br>Hemodialysis and Transplantatio<br>Service |

CURRICULUM VITAE

| | | |
|---|---|---|
| 2nd Year | July 1974-June 1975 | Peter Bent Brigham Hospital,<br>Harvard Medical School<br>Boston, Massachusetts<br>Director, Renal Division<br>J.P. Merrill, M.D. |
| | Clinical Hemodialysis and Transplantation Year | |
| 3rd Year | July 1975-June 1976 | Peter Bent Brigham Hospital<br>Harvard Medical School<br>Boston, Massachusetts |
| | Clinical Nephrology and Research Year | |

Licensure F.L.E.X. June 1973 (Federation of Licensing)

License: Michigan #33079 - MD #23091

Massachusetts #37365

Virginia #29684

Certification American Board of Internal Medicine 1976
American Board of Nephrology 1978

Nomination:
-Fellow in Medicine, Harvard Medical School 1974-1975, 1975-1976
-Assistant Professor in Medicine, Uniformed Services University of the Health Sciences. 1978-1981
-Clinical Assistant Professor, Georgetown University- 1978-1980

Professional Society

Member:
American Society of Internal Medicine (ASIM)
Massachusetts Medical Society
American Society of Nephrology
Harvard Alumni Association
International Society of Nephrology

Professional Life

| | |
|---|---|
| July 1976-June 1977 | Director of Medical Education, Youville Hospital, Cambridge, Massachusetts |
| June 1977-June 1978 | Medical Director, Cape Cod Artificial Kidney Center, Yarmount, Massachusetts |
| July 1978-Dec. 1980 | Assistant Chief, Nephrology Service Walter Reed Army Medical Center, Wash. D. |
| January 1981 - Present | Private Practice, 11500 Old Georgetown Rd Rockville, Maryland 20852 (301) 984-0065 |

CURRICUL' 1 VITAE

Hospital Privileges

Frederick Memorial Hospital, Fre rick, Maryland

Holy Cross Hospital, Silver Spring, Maryland

Montgomery General Hospital, Olney, Maryland

Shady Grove Adventist Hospital, Gaitherburg, Maryland

Sibley Memorial Hospital, Washington, D.C.

Suburban Hospital, Bethesda, Maryland

Washington Adventist Hospital, Takoma Park, Maryland

Presentation

1) Paper entitled, "Lactate Level in Clinical Practice", in co-authorship with F. Whitehouse, F.A.C.P. and D. Basinski, Ph.D., etabolism Division, Henry Ford Hospital at the Regional Meeting of the American College of Physicians in Gaylord, Michigan, September 1972.

2) Septicemia in Chronic Renal Failure, K. Nsouli, M. Lazarus, M. Gottlieb, M. Schocair, S. Shoenbaum, E. Lowrie, and J. Merril at the American Society of Nephrology, November 1977.

Publication Sepsis in Hemodialysis Patients. Archives of Internal Medicine, VOL 139, November 1979, p 1255-1258.

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

# TRAINING AND EXPERIENCE
## AUTHORIZED USER OR RADIATION SAFETY OFFICER

| 1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER | 2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE |
|---|---|
| A. Kaldun Nossuli, M.D. | District of Columbia |

### 3. CERTIFICATION

| SPECIALTY BOARD<br>A | CATEGORY<br>B | MONTH AND YEAR CERTIFIED<br>C |
|---|---|---|
| #011697 | Medicine and Surgery | |

### 4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

| FIELD OF TRAINING<br>A | LOCATION AND DATE(S) OF TRAINING<br>B | TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours)<br>C | TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours)<br>D |
|---|---|---|---|
| a. RADIATION PHYSICS AND INSTRUMENTATION | Bone Densitometry Workshop fully meeting the duration and content for such instruction as criteria listed in USNRC Policy and Guidance Directive FC83-24; Licensing the Lixiscope and Bone Mineral Analyzer for Human Use, dated Nov. 10, 1983. | 2 hours | |
| b. RADIATION PROTECTION | | 2 hours | |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | Same as above | 1 hour | |
| d. RADIATION BIOLOGY | Same as above | 3 hours | |
| e. Principles of Photon Absortionmetry, measurements, and instrumentation | Same as above | 2 hours | 1.5 hours |

### 5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
|---|---|---|---|---|
| | | | | |

NRC FORM 313M SUPPLEMENT B
(9-81)

U. S. NUCLEAR REGULATORY COMMISSION

# PRECEPTOR STATEMENT

*Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.*

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

A. Kaldun Nossull, M.D.

STREET ADDRESS

11500 Old Georgetown Rd.

CITY | STATE | ZIP CODE

Rockville, MD 20852

**KEY TO COLUMN C**

**PERSONAL PARTICIPATION SHOULD CONSIST OF:**

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.
2. Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.
3. Adequate period of training to enable physician to manage individual patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS<br>*(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| I-125 | DIAGNOSIS OF THYROID FUNCTION | | *Dr. A. Kaldun Nossull participated in a two day bone densitometry workshop. During the workshop, five (5) subjects were given complete clinical bone mineral analyses under the direction of a physician, license by the State of T[illegible] # 9-3574 (4/30/89), for the use of a bone mineral analyser. See the attached certificate of training. |
| | DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME | | |
| | LIVER FUNCTION STUDIES | | |
| | FAT ABSORPTION STUDIES | | |
| | KIDNEY FUNCTION STUDIES | | |
| | IN VITRO STUDIES | | |
| OTHER | Bone Densitometer | 5 * | |
| I-125 | DETECTION OF THROMBOSIS | | |
| I-131 | THYROID IMAGING | | |
| P-32 | EYE TUMOR LOCALIZATION | | |
| Se-75 | PANCREAS IMAGING | | |
| Yb-169 | CISTERNOGRAPHY | | |
| Xe-133 | BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES | | |
| OTHER | | | |
| Tc-99m | BRAIN IMAGING | | |
| | CARDIAC IMAGING | | |
| | THYROID IMAGING | | |
| | SALIVARY GLAND IMAGING | | |
| | BLOOD POOL IMAGING | | |
| | PLACENTA LOCALIZATION | | |
| | LIVER AND SPLEEN IMAGING | | |
| | LUNG IMAGING | | |
| | BONE IMAGING | | |
| OTHER | | | |

## PRECEPTOR STATEMENT *(Continued)*

### 2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| P-32 *(Soluble)* | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | | |
| P-32 *(Colloidal)* | INTRACAVITARY TREATMENT | | |
| I-131 | TREATMENT OF THYROID CARCINOMA | | |
| | TREATMENT OF HYPERTHYROIDISM | | |
| Au-198 | INTRACAVITARY TREATMENT | | |
| Co-60 or Cs-137 | INTERSTITIAL TREATMENT | | |
| | INTRACAVITARY TREATMENT | | |
| I-125 or Ir-192 | INTERSTITIAL TREATMENT | | |
| Co-60 or Cs-137 | TELETHERAPY TREATMENT | | |
| Sr-90 | TREATMENT OF EYE DISEASE | | |
| | RADIOPHARMACEUTICAL PREPARATION | | |
| Mo-99/ Tc-99m | GENERATOR | | |
| Sn-113/ In-113m | GENERATOR | | |
| Tc-99m | REAGENT KITS | | |
| Other | | | |

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

6 hours - Oct 4, 1984

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Gordon Bilbrey, M.D.

b. NAME OF INSTITUTION
Beta Diagnostics, Inc.

c. MAILING ADDRESS
7540 Louis Pasteur Drive, Suite 100

d. CITY
San Antonio, Texas 78229

e. MATERIALS LICENSE NUMBER(S)
Texas License #

5. PRECEPTOR'S SIGNATURE
Gordon Bilbrey MD

7. PRECEPTOR'S NAME *(Please type or print)*
Gordon Bilbrey, M.D.

8. DATE

NRC FORM 313M SUPPLEMENT B
(9-81)



GPO 821-818

# CURRICULUM VITAE

Name: David Bryn Kessler, M.D.
10620 Georgia Avenue,
Silver Spring, Md. 20902

Date of Birth: July 8, 1935
New York, New York

Marital Status: Married to Nancy N. Matthews
One daughter, Sarah Anne, born April 9, 1969

Education:

College: Bowdoin College, Magna Cum Laude, A.B. 1957; Phi Beta Kappa, 1956

Medical School: New York University School of Medicine, M.D., 1962

Internship: Bellevue Hospital, New York
Medicine-III Division (Professor Lewis Thomas), 1963

Residency: Walter Reed General Hospital, Washington, D.C.
Internal Medicine, 1965-67

Fellowships:

1. The Rockefeller Institute, New York; National Institutes of Health Predoctoral Fellowship, Guest Investigator (Maclyn McCarty, M.D. and Richard M. Krause, M.D.) 1960-62

2. Walter Reed Army Institute of Research, Div. of Medicine, Washington, D.C., Nephrology, 1967-68

Research:

1. The Rockefeller Institute, New York; National Institutes of Health Predoctoral Fellowship, Guest Investigator (Maclyn McCarty, M.D. and Richard M. Krause, M.D.) 1960-62

2. Armed Forces Institute of Pathology, Washington, D.C., Visitor, Department of Immunobiology, 1968-69

3. Walter Reed Army Institute of Research, Medical Investigator, 1970-71

Staff Positions:

1. Executive Office of the President, Office of Science and Technology, Washington, D.C., Staff, 1963-64

2. Walter Reed General Hospital; Staff, Renal Dialysis Unit, 1968

3. United States Army, Third Field Hospital, Saigon, Vietnam; Chief of Medicine and Commander, Renal Dialysis Unit, 1969-70

4. Washington Adventist Hospital; Assistant Chairman, Department of Medicine, 1979-81; Chairman, Department of Medicine, 1981-84

Curriculum Vitae (contd)

David Bryn Kessler, M.D.

| | |
|---|---|
| Teaching Positions: | 1. Holy Cross Hospital, Silver Spring, Maryland, Member, Department of Medicine, Renal Unit, 1971 - present |
| Military Service: | 1. United States Army, 1963 - 71<br>Resigned Lt. Colonel, Honorable Discharge, July 31, 1971 |
| | 2. Captain, United States Navy Reserves, 1976 - present |
| Current Positions: | 1. Private Practice, Internal Medicine and Nephrology, Silver Spring, Maryland, 1971 - present |
| | 2. U.S. Department of State, Washington, D.C.<br>Part-time Consultant, 1971 - present |
| | 3. Captain, United States Navy Reserves, 1976 - present |
| Board Certification: | Diplomate, American Board of Internal Medicine, 1970 |
| Societies: | American College of Physicians<br>American Society of Nephrology<br>International Society of Nephrology<br>Washington Philosophical Society |
| Related Professional Activities: | Aviation Medical Examiner, FAA<br>Commercial Pilot, Instrument Rated |

Curriculum Vitae (contd)

David Bryn Kessler, M.D.

Publications:

Synthesis of Ribonucleoside-5'-polyphosphates. Kessler, D., Moss, B. and Chambers, R.W. Biochim. Biophys. Acta, 38 (1960) 549-51

The Iodination of Tyrosine by Beef Thyroid Preparations. Klebanoff, S.J., Yip, C. and Kessler, D. Biochim. Biophys. Acta, 58 (1962) 563-74

Inactivation of Streptococcal Bacteriophage by Sulfhydryl Reagents. Kessler, D. and Krause, R.M. Proc. Soc. Exp. Biol. & Med., 114 (1963) 822-26

Bio-medical Science and Its Administration (A Study of the National Institutes of Health). Completed by the Staff of the Wooldridge Committee, Office of Science and Technology, February, 1965 (GPO-762-470)

Isolation and Characterization of E-coli Elaborated Chemotactant. Kessler, D. and Ward, P.A. (To be published)

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

# TRAINING AND EXPERIENCE
## AUTHORIZED USER OR RADIATION SAFETY OFFICER

| 1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER | 2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MED SINE |
|---|---|
| David B. Kessler, M.D. | District of Columbia |

**3. CERTIFICATION**

| SPECIALTY BOARD<br>A | CATEGORY<br>B | MONTH AND YEAR CERTIFIED<br>C |
|---|---|---|
| #5400 | Medicine and Surgery | |

**4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES**

| FIELD OF TRAINING<br>A | LOCATION AND DATE(S) OF TRAINING<br>B | TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours)<br>C | TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours)<br>D |
|---|---|---|---|
| a. RADIATION PHYSICS AND INSTRUMENTATION | Bone Densitometry Workshop fully meeting the duration and content for such instruction as criteria listed in USNRC Policy and Guidance Directive FC83-24, Licensing the Lixiscope and Bone Mineral Analyzer for Human Use, dated Nov. 10, 1983. | 2 hours | |
| b. RADIATION PROTECTION | | 2 hours | |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | Same as above | 1 hour | |
| d. RADIATION BIOLOGY | Same as above | 3 hours | |
| e. Principles of Photon Absortionmetry, measurements, and instrumentation | Same as above | 2 hours | 1.5 hours |

**5. EXPERIENCE WITH RADIATION.** *(Actual use of Radioisotopes or Equivalent Experience)*

| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
|---|---|---|---|---|
| | | | | |

NRC FORM 313M SUPPLEMENT B
(9-81)

U. S. NUCLEAR REGULATORY COMMISSION

# PRECEPTOR STATEMENT

*Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.*

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

David B. Kessler, M.D.

STREET ADDRESS

10620 Georgia Line

CITY | STATE | ZIP CODE

Silver Spring MD 20902

**KEY TO COLUMN C**

**PERSONAL PARTICIPATION SHOULD CONSIST OF:**

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.
2. Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.
3. Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS<br>*(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| I-125 | DIAGNOSIS OF THYROID FUNCTION | | *Dr. David Kessler participated in a two day bone densitometry workshop. During the workshop, five (5) subjects were given complete clinical bone mineral analyses under the direction of a physician, license by the State of Texas # 9-3574 (4/30/89), for the use of a bone mineral analyser. See the attached certificate of training. |
| | DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME | | |
| | LIVER FUNCTION STUDIES | | |
| | FAT ABSORPTION STUDIES | | |
| | KIDNEY FUNCTION STUDIES | | |
| | IN VITRO STUDIES | | |
| OTHER | Bone Densitometer | 5 * | |
| I-125 | DETECTION OF THROMBOSIS | | |
| I-131 | THYROID IMAGING | | |
| P-32 | EYE TUMOR LOCALIZATION | | |
| Se-75 | PANCREAS IMAGING | | |
| Yb-169 | CISTERNOGRAPHY | | |
| Xe-133 | BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES | | |
| OTHER | | | |
| Tc-99m | BRAIN IMAGING | | |
| | CARDIAC IMAGING | | |
| | THYROID IMAGING | | |
| | SALIVARY GLAND IMAGING | | |
| | BLOOD POOL IMAGING | | |
| | PLACENTA LOCALIZATION | | |
| | LIVER AND SPLEEN IMAGING | | |
| | LUNG IMAGING | | |
| | BONE IMAGING | | |
| OTHER | | | |

## PRECEPTOR STATEMENT *(Continued)*

### 2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| P-32 *(Soluble)* | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | | |
| P-32 *(Colloidal)* | INTRACAVITARY TREATMENT | | |
| I-131 | TREATMENT OF THYROID CARCINOMA | | |
| | TREATMENT OF HYPERTHYROIDISM | | |
| Au-198 | INTRACAVITARY TREATMENT | | |
| Co-60 or Cs-137 | INTERSTITIAL TREATMENT | | |
| | INTRACAVITARY TREATMENT | | |
| I-125 or Ir-192 | INTERSTITIAL TREATMENT | | |
| Co-60 or Cs-137 | TELETHERAPY TREATMENT | | |
| Sr-90 | TREATMENT OF EYE DISEASE | | |
| | RADIOPHARMACEUTICAL PREPARATION | | |
| Mo-99/ Tc-99m | GENERATOR | | |
| Sn-113/ In-113m | GENERATOR | | |
| e-99m | REAGENT KITS | | |
| Other | | | |

### 3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

6 hours - Oct 4, 1984

### 4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Gordon Bilbrey, M.D.

b. NAME OF INSTITUTION
Beta Diagnostics, Inc.

c. MAILING ADDRESS
7540 Louis Pasteur Drive, Suite 100

d. CITY
San Antonio, Texas 78229

e. MATERIALS LICENSE NUMBER(S)
Texas License #

### 5. PRECEPTOR'S SIGNATURE

Gordon Bilbrey MD

### 7. PRECEPTOR'S NAME *(Please type or print)*

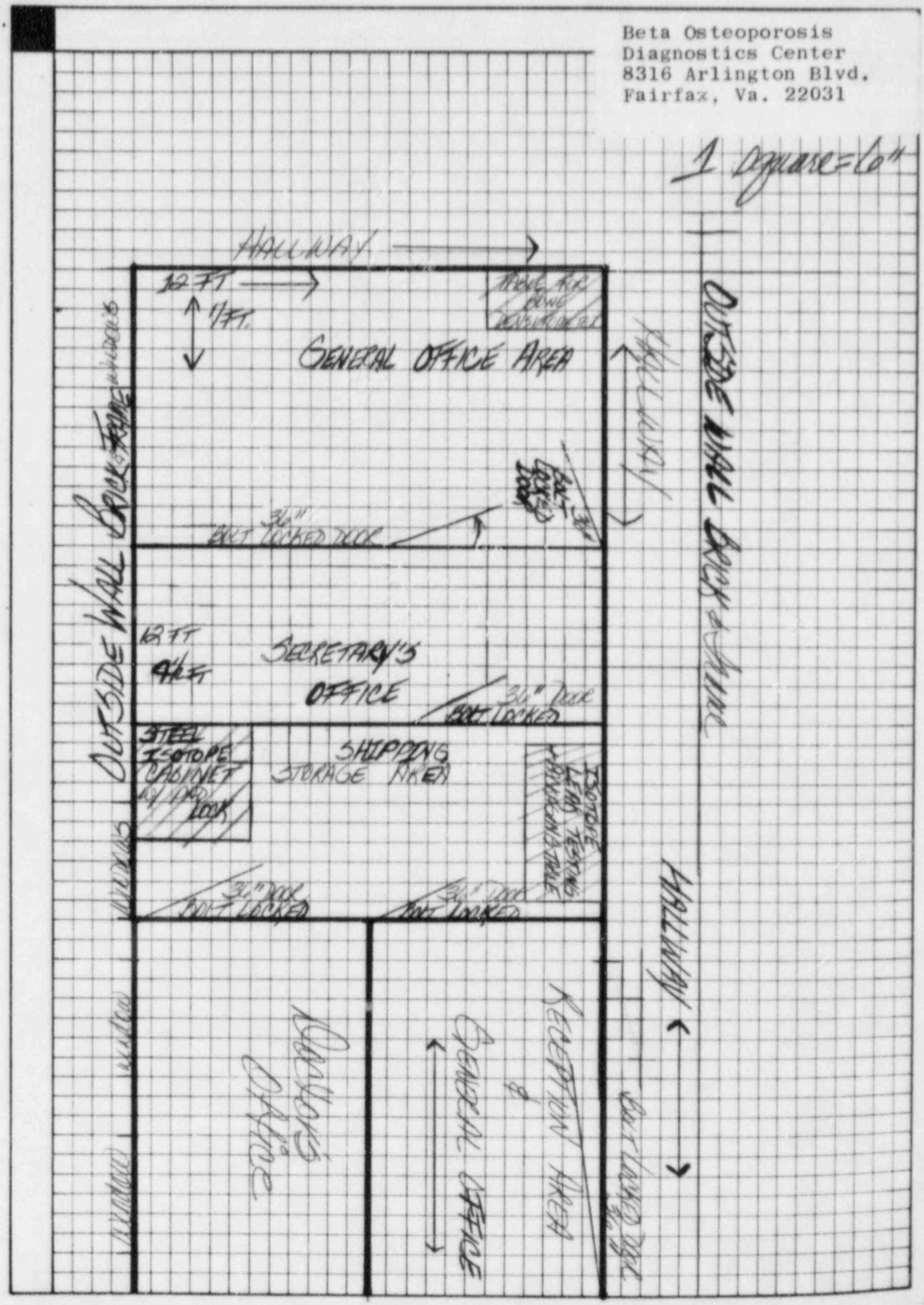
Gordon Bilbrey, M.D.

### 8. DATE

NRC FORM 313M SUPPLEMENT B
(9-81)

GPO 699-815

Beta Osteoporosis
Diagnostics Center
8316 Arlington Blvd.
Fairfax, Va. 22031



## OTHER LOCATIONS OF USE

Biomedical Applications of Capital Hill
900 M Street, S.E.
Washington, D.C. 20003

Biomedical Applications of Columbia Heights
106 Irving Street, N.E.
Washington, D.C. 20001

Biomedical Applications of Dupont Circle
11 Dupont Circle
Washington, D.C. 20007

Biomedical Applications of Greater Southeast Washington
1350 Southern Avenue S.E.
Washington, D.C. 20032

Biomedical Applications of Northeast Washington
1302 Rhode Island Avenue N.E.
Washington, D.C. 20018

Biomedical Applications of Anacostia
3829 Minnesota Avenue N.E.
Washington, D.C. 20019

Biomedical Applications of Takoma Park
235 Carroll Avenue
Washington, D.C. 20012

Biomedical Applications of Northern Virginia
1701 North George Mason Drive
Arlington, Virginia 22205

Northern Virginia Dialysis Center
5249 Duke Street
Alexandria, Virginia 22304

NOTE: At other temporary sites where the scanner will be under the direct supervision of the licensed physicians. The scanner will not remain at the temporary site unattended or overnight.

Biomedical Applications
of
Capital Hill
900 M St. S.E.
Washington, D.C. 20003

1 square = 6"

OUTSIDE WALLS BRICK & FRAME

WINDOW

GENERAL OFFICES

FIRE EXTINGUISHER

STEEL ISOTOPE CABINET W/ PAD LOCK

7 Ft

10 Ft.

GENERAL OFFICES

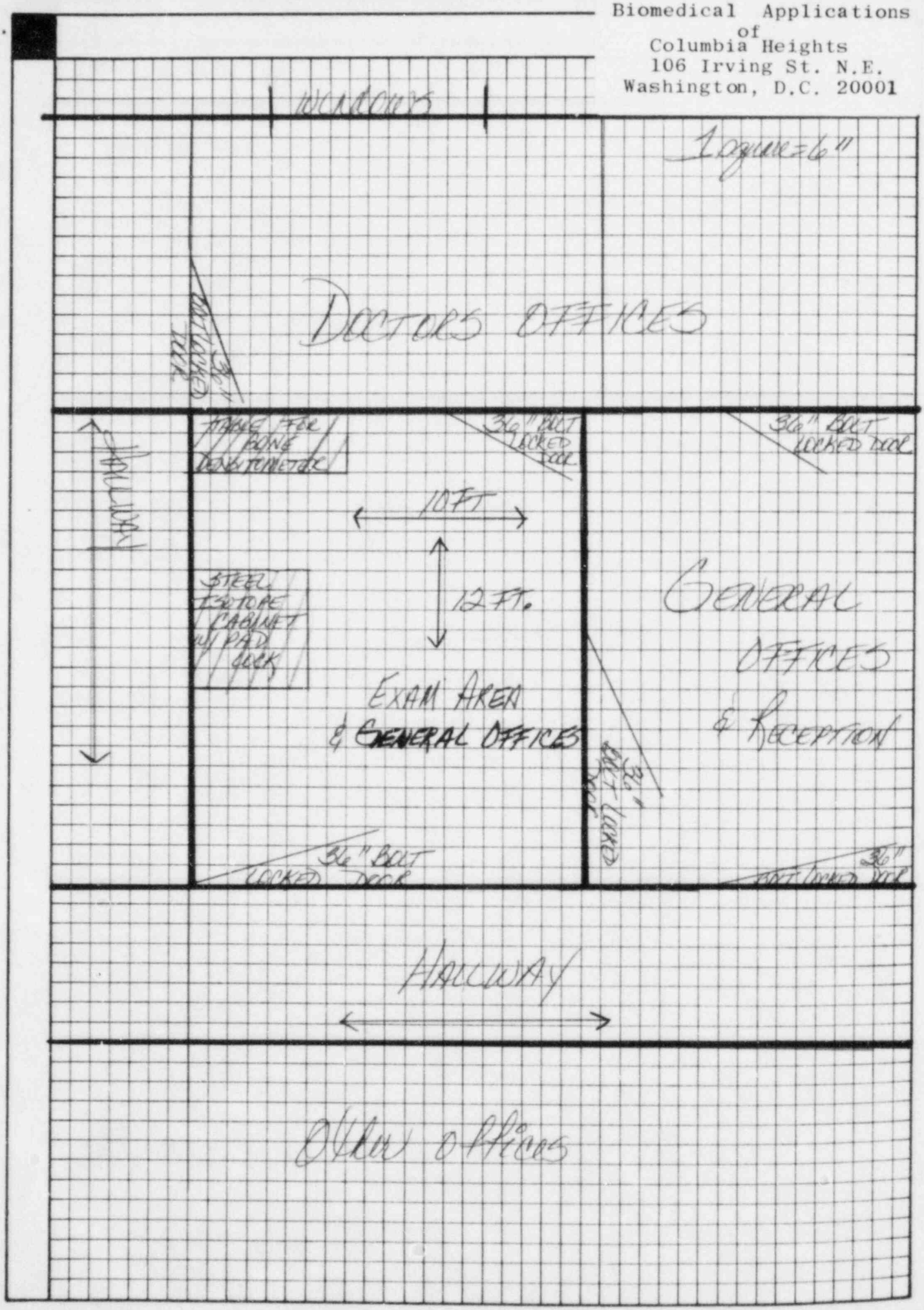
36" BOLT LOCKED DOOR

36" BOLT LOCKED DOOR

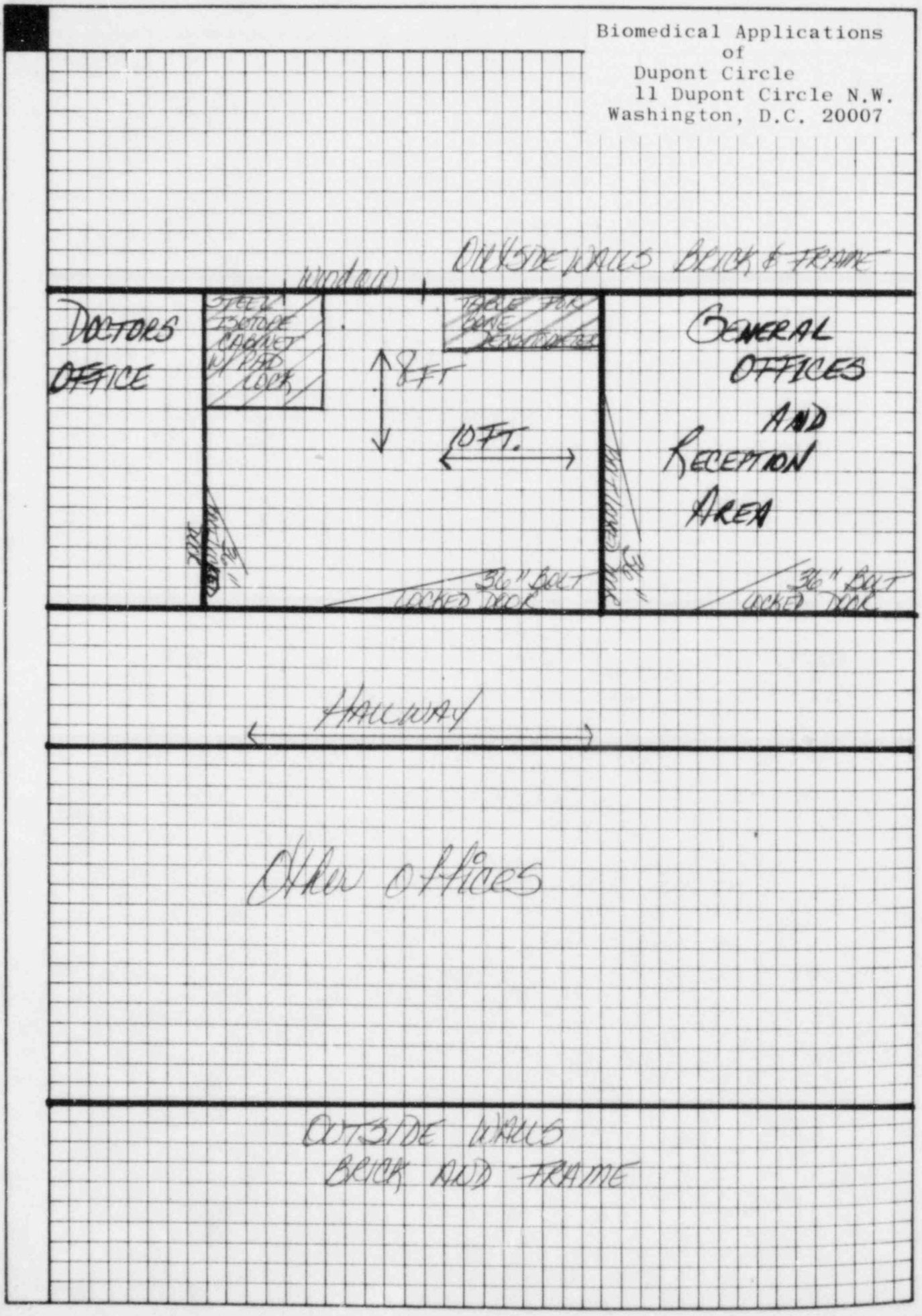
HALL WAY

GENERAL OFFICES

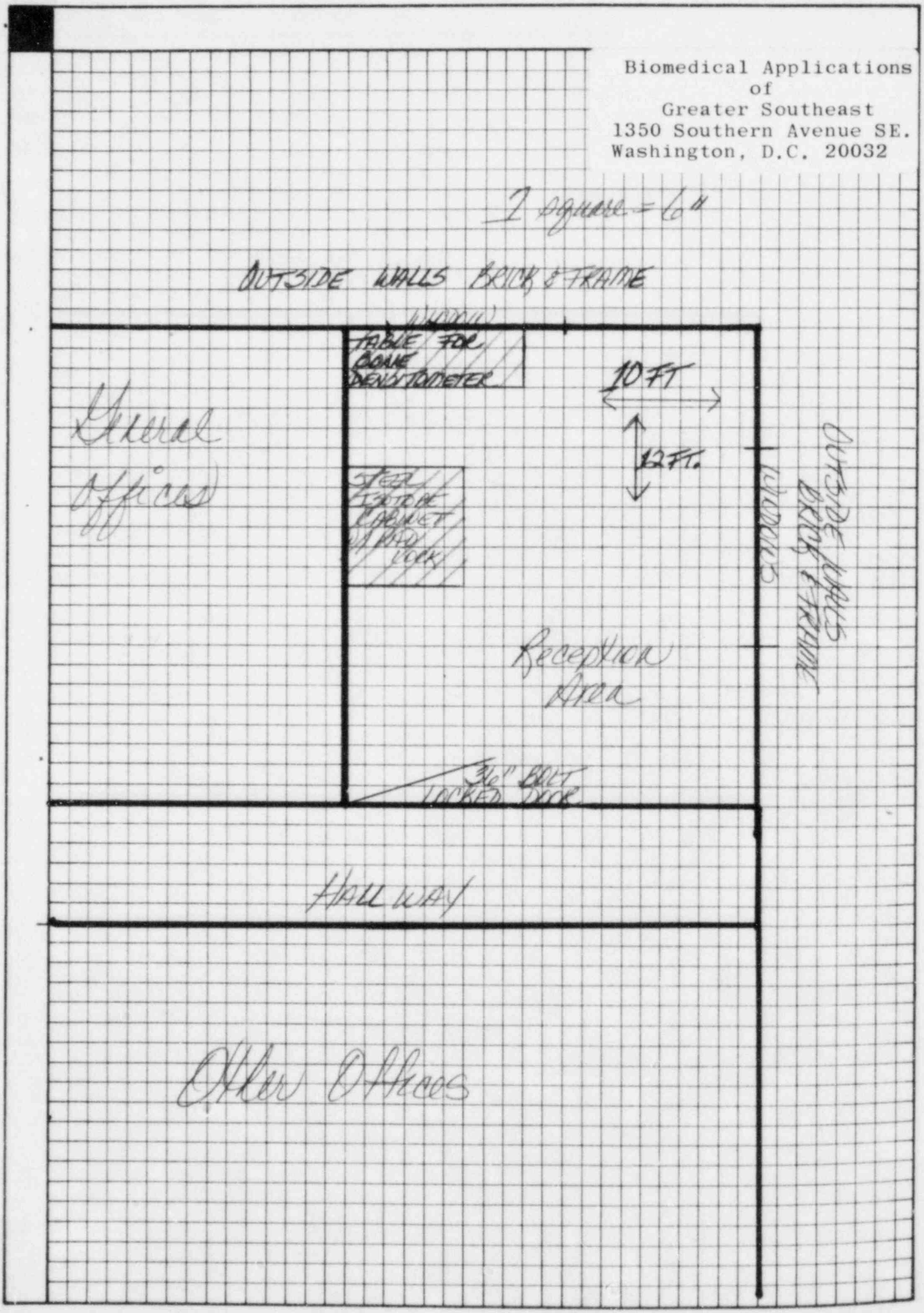
Biomedical Applications
of
Columbia Heights
106 Irving St. N.E.
Washington, D.C. 20001



Biomedical Applications
of
Dupont Circle
11 Dupont Circle N.W.
Washington, D.C. 20007



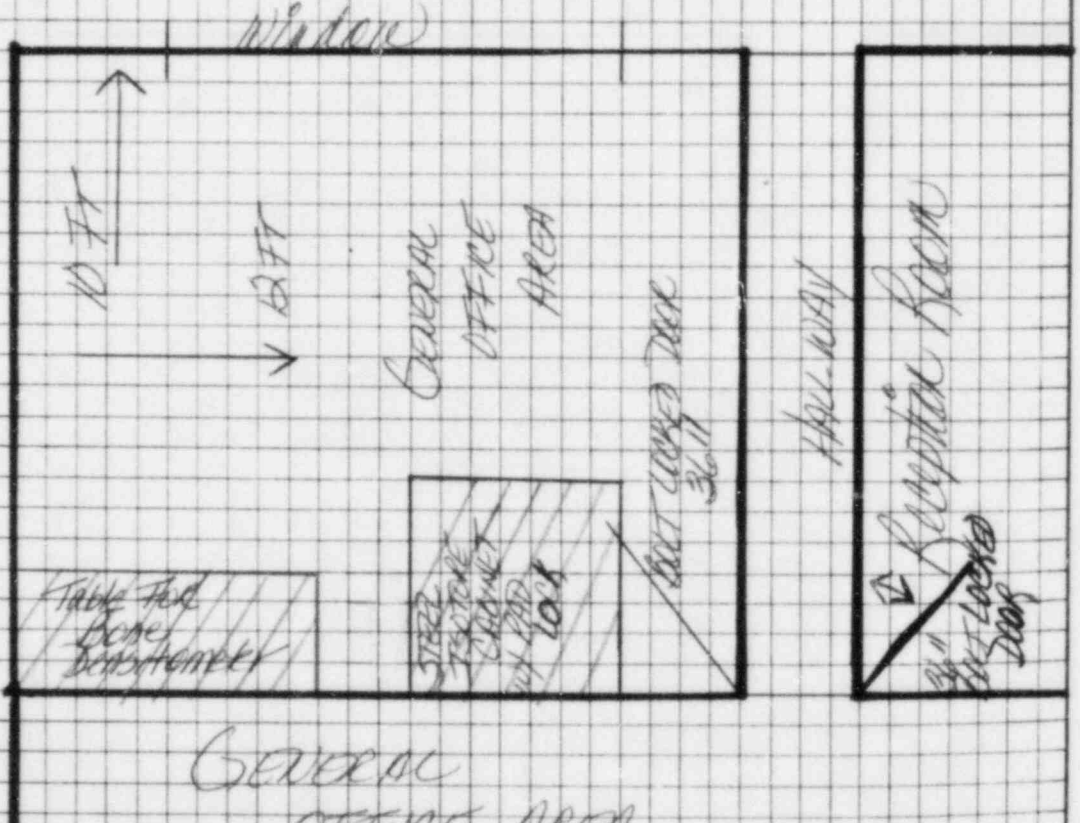
Biomedical Applications
of
Greater Southeast
1350 Southern Avenue SE.
Washington, D.C. 20032



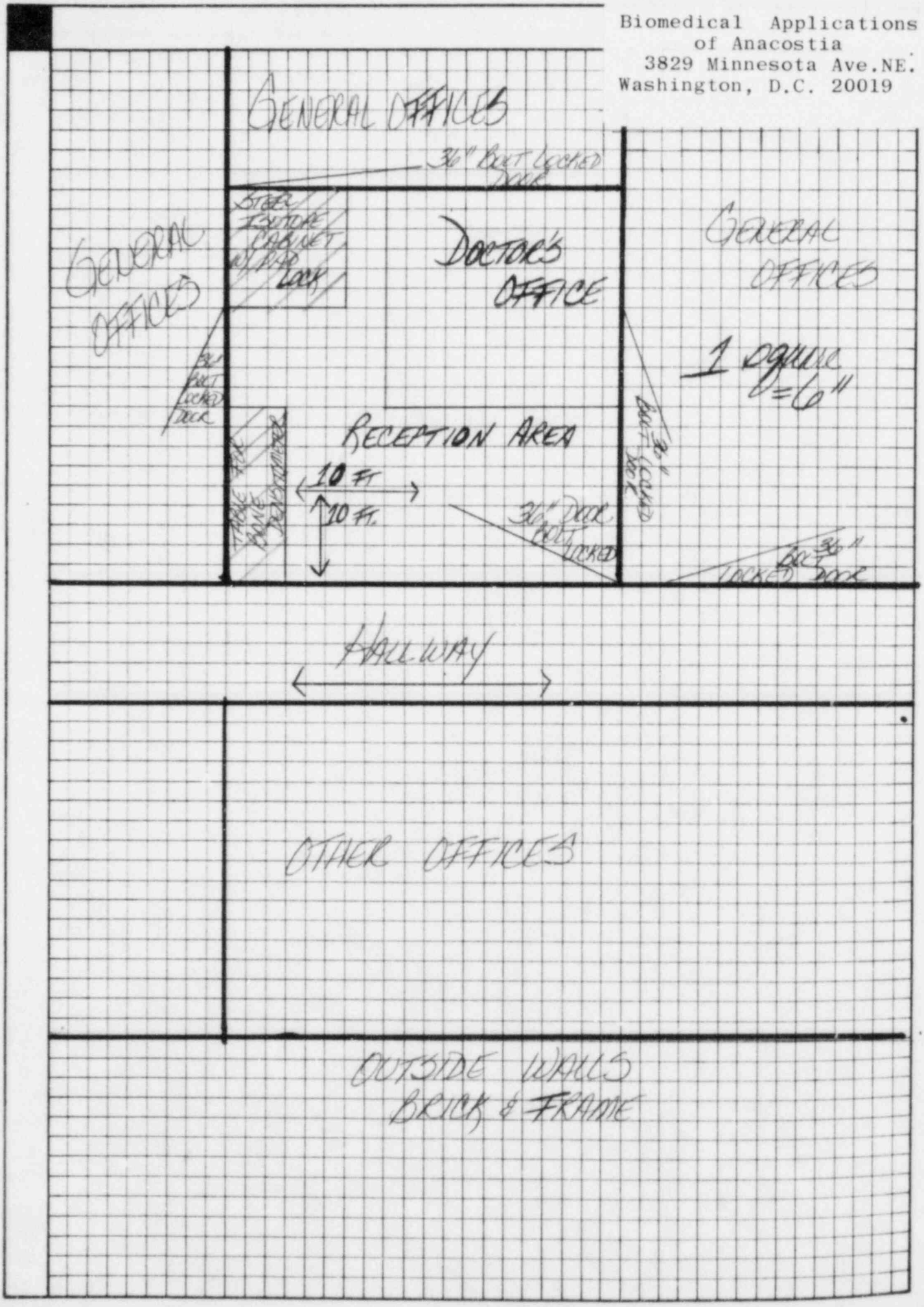
Biomedical Applications
of Northeast
1302 Rhode Island Ave.
Washington, D.C. 20018

1 square = 6"

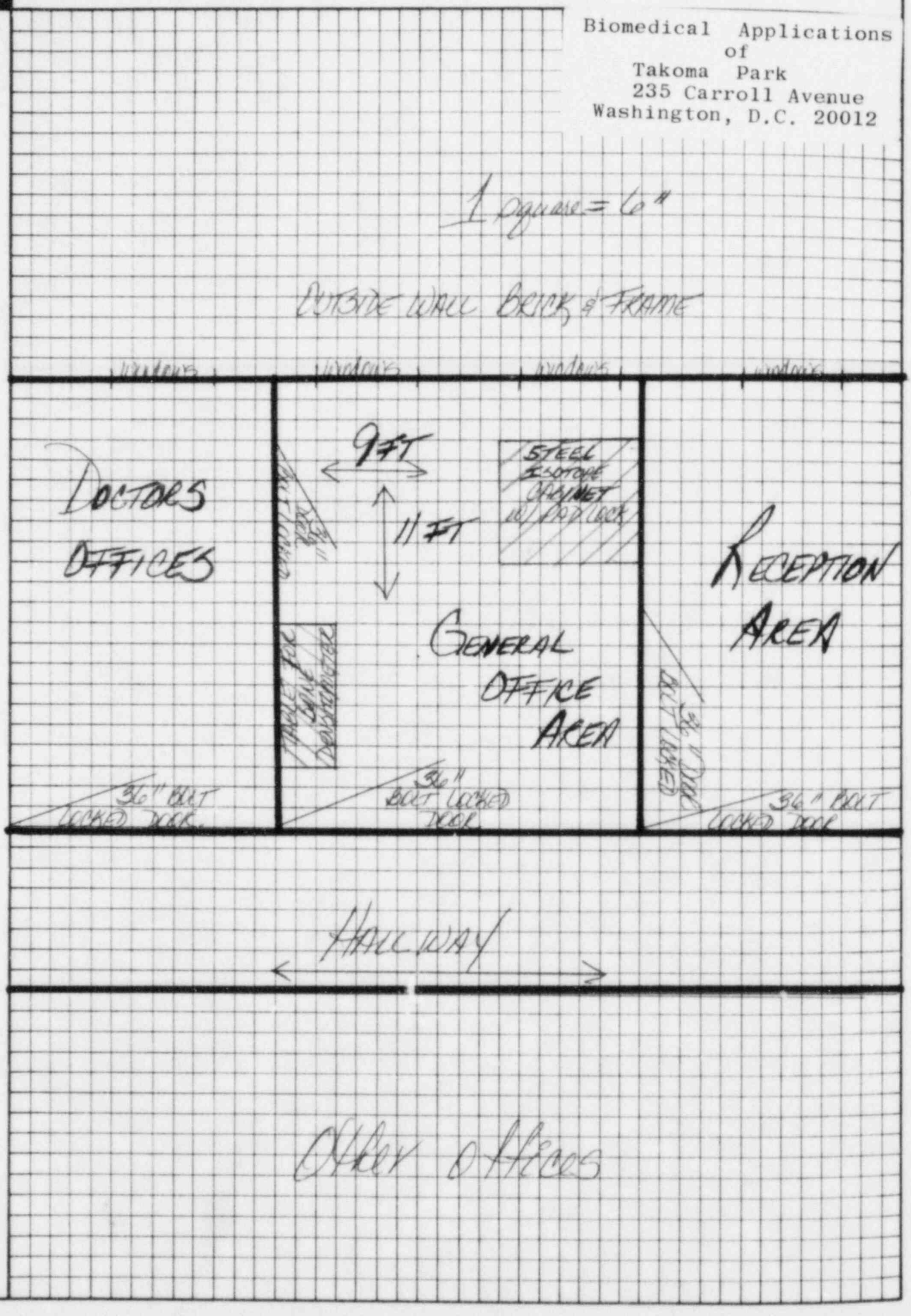
OUTSIDE WALLS - BRICK & FRAME



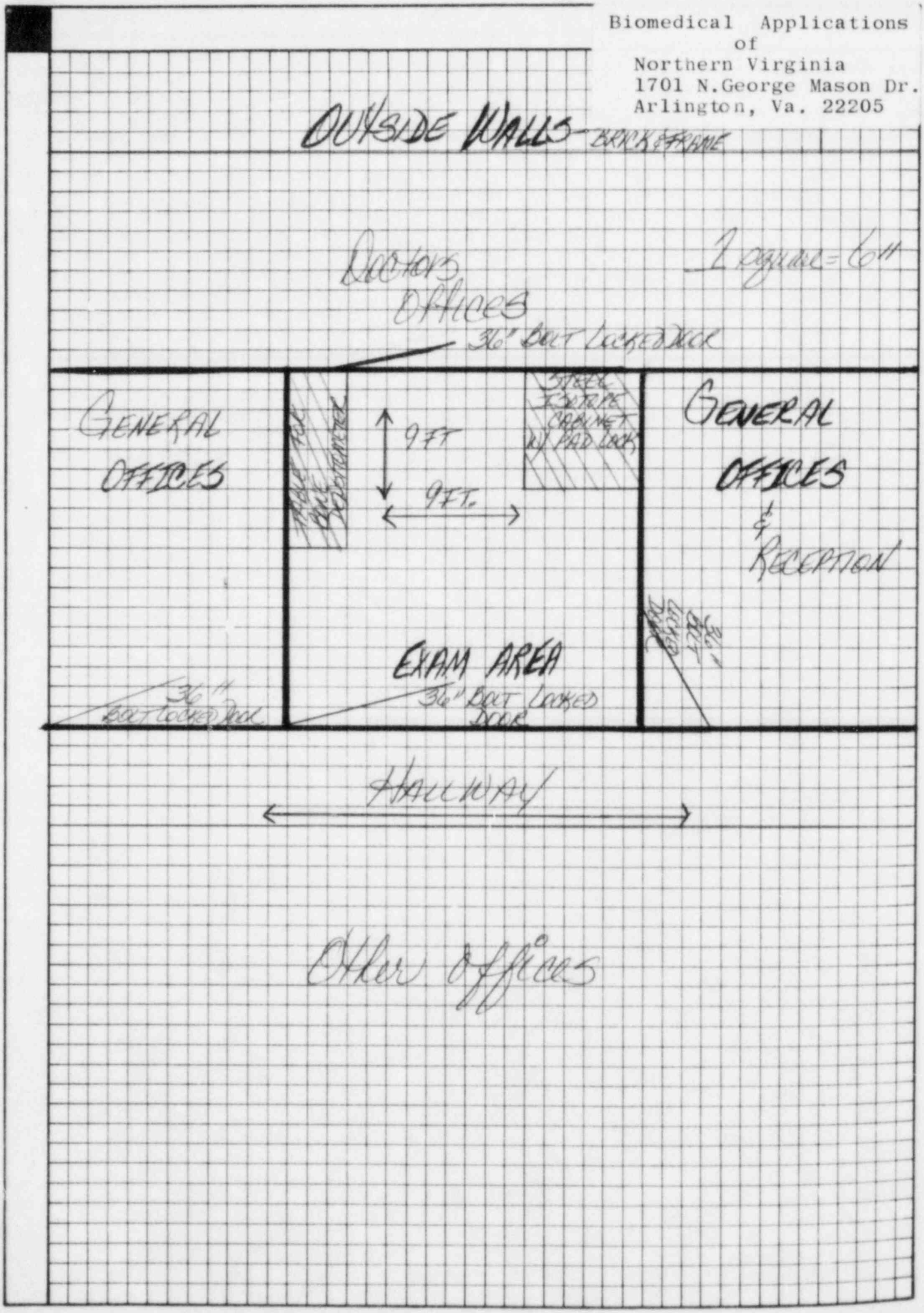
Biomedical Applications
of Anacostia
3829 Minnesota Ave.NE.
Washington, D.C. 20019



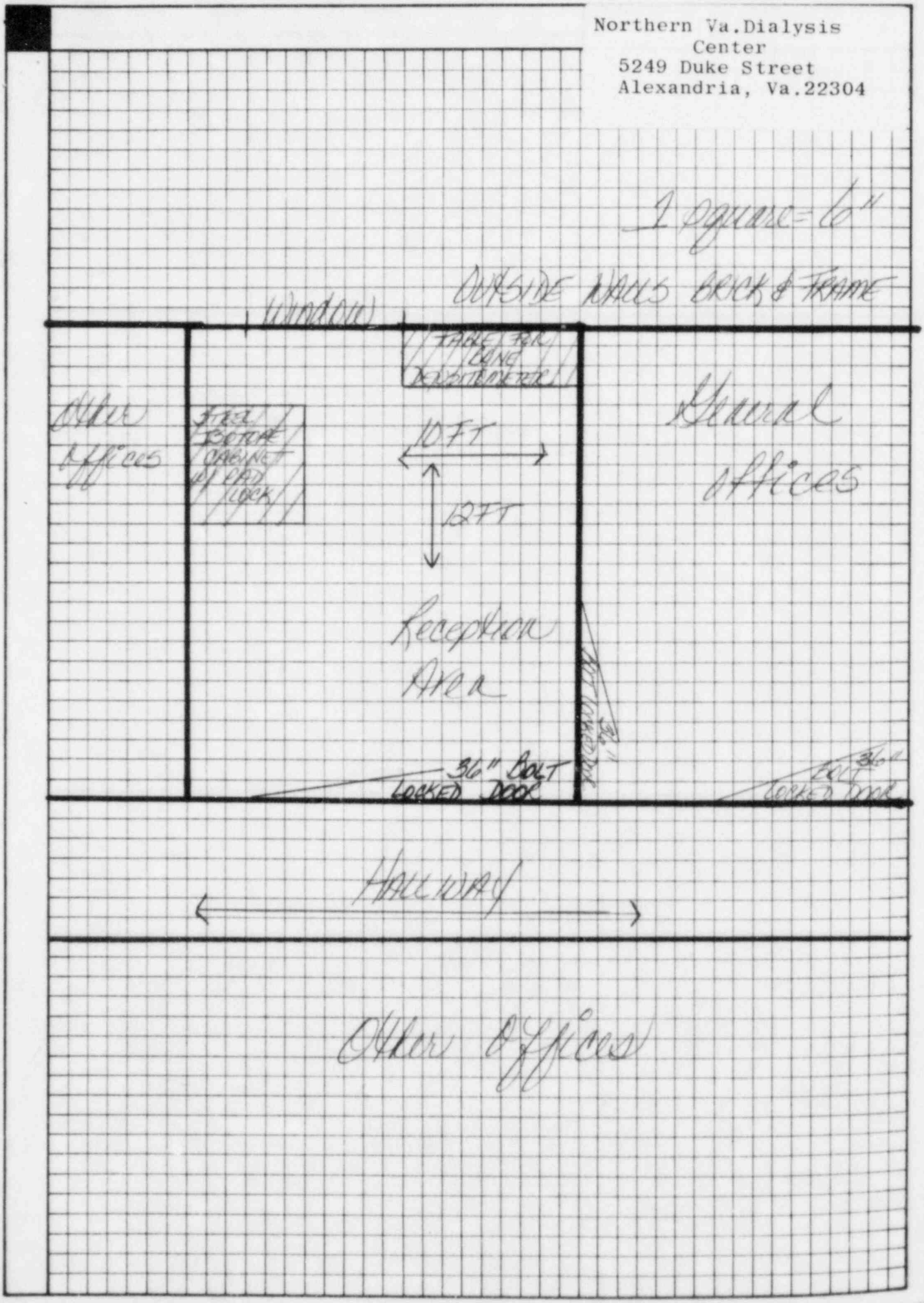
Biomedical Applications
of
Takoma Park
235 Carroll Avenue
Washington, D.C. 20012



Biomedical Applications
of
Northern Virginia
1701 N.George Mason Dr.
Arlington, Va. 22205



Northern Va. Dialysis
Center
5249 Duke Street
Alexandria, Va. 22304



RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER:

The Radiation Safety Officer is responsible for assuring continued compliance with regulations and license conditions on a day to day basis. The responsibilities of the RSO include the following:

a. Thorough familiarity with the radiation protection regulations and license conditions pertinant to the licensed facility.

b. Initial and periodic (at least annual) documented reviews of radiation safety instructions, including regulations and license conditions, to all radiation workers at the facility. This includes security or housekeeping if they have keys to the radiaiton storage area.

c. Routine review of any radiation exposure records, such as radiation survey results of incoming sources, or personnel dosimetry reports (if required), and maintain records.

d. Routine review of safe handling procedures for radioactive materials and shipments, as well as security procedures to prevent any unauthorized use, loss or theft.

e. Maintain accountability records of all incoming or outgoing radioactive material shipments or tranfers.

f. Assure proper completion and records of Department of Transportation (DOT) shipping papers and labeling of outgoing shipments or transfers.

g. Prepare amendment applications for any changes in the licensed operations. Such as changes in:

   (1) Facility address or storage room

   (2) RSO or users

   (3) Maximum possession limit

   (4) Radioactive isotopes

   (5) Handling, operating procedures or records

h. Schedule and maintain any license/regulatory requirements such as, the scheduling and maintenance of required records.

i. Maintain all records required by regulations or license conditions for inspection.

j. Be available during regulatory agency inspections.

k. Review and maintain copies of regulatory agency correspondence and notices.

l. Report any loss or theft of radioactive materials to the licensing/regulatory agency. Obtain consultation if there is doubt on whether or not a specific incident is reportable.

m. Assure proper posting of required "Notice to Employee" signs; "Instructions to Workers" notices; Caution - Radioactive Material" labels where appropriate.

n. To remove radiation labels on any empty containers that are to be discarded.

INSTRUMENTATION:

Radiation Survey Meter:

Radiation Victoreen Model 493, Beta/Gamma, X-ray GM Survey Meter or equal. End-window 1.4 mg/cm-sq, 0 to 50 mR/hr.

Bone Densitometer:

Norland Digital Bone Densitometer model 278A (N2740 and N2780), product information attached.

Item 9
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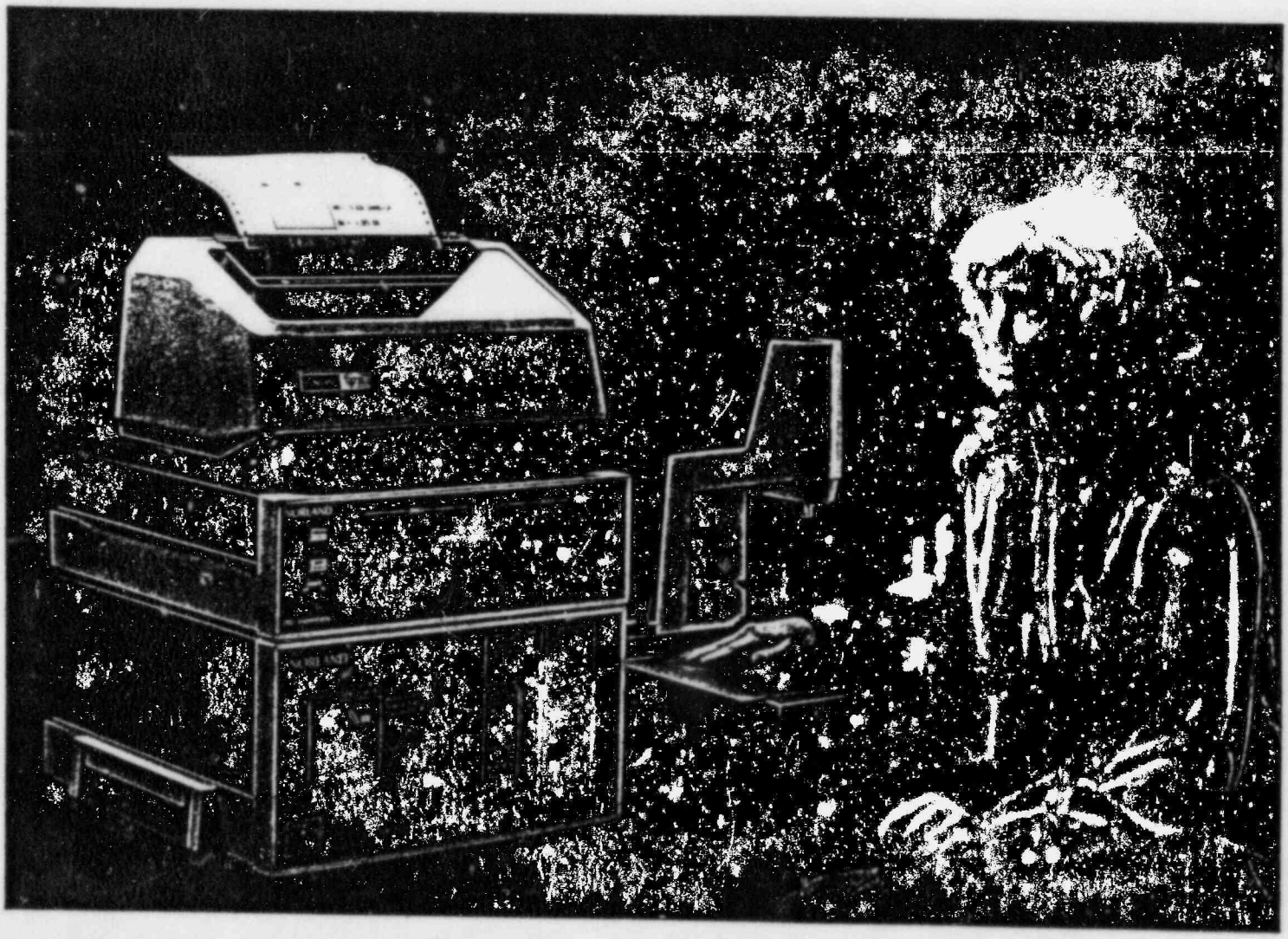
# THE NORLAND DIGITAL BONE DENSITOMETER

## MODEL 278A . . . A CRITICAL ADVANCE IN BONE QUANTIFICATION



# A CRITICAL ADVANCE IN BONE QUANTIFICATION

## A NEED — A SOLUTION

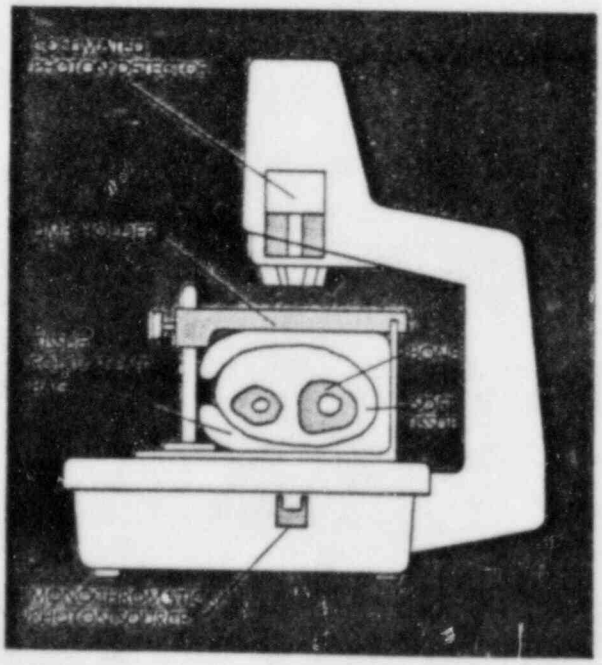
Physicians and clinicians have long recognized the shortcomings of biopsy or radiograph methods for the early detection of bone disease. In 1963, necessity once again gave birth to invention. Cameron and Sorenson reported a new in vivo, non-intrusive technique for quantifying bone mineral content—the photon absorption technique.[1] Since then, the technique has grown in sophistication and gained widespread clinical approval.[2,3]

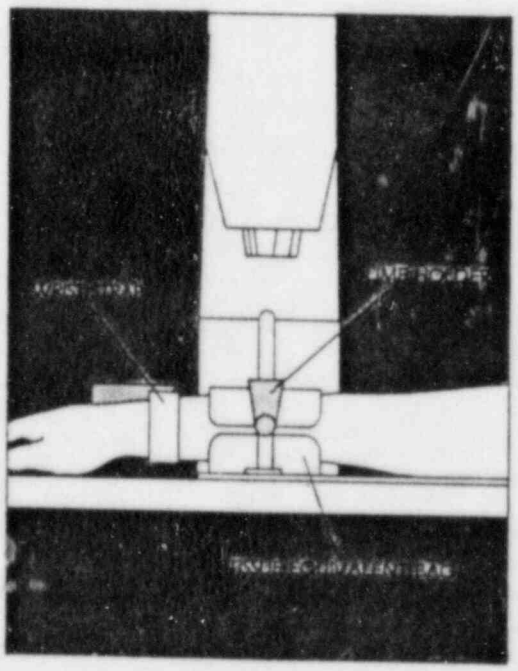
## THE PHOTON ABSORPTION TECHNIQUE

This technique replaces the broad energy spectrum of the x-ray beam with a beam of monoenergetic photons. This beam passes through the soft tissue and bone of a limb, and the resulting attenuation is monitored with a photon detector. The mass of bone mineral present may be derived from the number of photons absorbed by the bone. Using a highly collimated beam from a monochromatic photon source, this measurement technique offers great advances in sensitivity, safety, accuracy, precision, and practical usefulness.

## THE 278A DIGITAL BONE DENSITOMETER

This proven instrument makes the advantages of the photon absorption technique available to you in a simple 5 minute procedure. Without causing patient discomfort, the densitometer measures bone mineral content as a linear density in grams per centimeter and bone width in centimeters. When measuring an adult radius, you can expect precision of ± 0.006 g/cm—and even better for smaller bones.[4] Compare this sensitivity to that of the radiograph, which is unable to detect anything prior to a 30-40% change in bone mass.[2]. In addition, the expanded capacity of the 278A Densitometer allows it to detect bone mineral content as low as 0.05 g/cm.





# THE 278A BONE DENSITOMETER–APPLICATIONS

**CLINICAL INVESTIGATORS CALLED THE MODEL 278 DENSITOMETER "A PROMISING TOOL." NOW THE MODEL 278A CAN MEASURE A PENCIL-LEAD SIZED BONE WITH AS LITTLE AS 0.05 g/cm BONE MINERAL CONTENT. IT'S MORE PROMISING THAN EVER—AND MORE USEFUL:**

- to any medical specialty concerned with bone disease or disorder . . . for diagnosis of skeletal demineralization as in advanced osteoporosis . . . and for data on response to therapy.[14,15]

- to pediatricians and neonatalogists for use in small infants . . . to measure delayed bone mineralization . . . and to investigate therapeutic measures that might correct osteopenia of prematurity.[9] (Figure 1)

- to nephrologists for the monitoring of renal osteodystrophy . . . calcification after transplant . . . and the adjustment of dialysis treatment.[8]

- to researchers for rapid and accurate, in vivo, non-intrusive determinations measuring bone mineral in the laboratory rat, dog or rabbit.[10,11] (Figure 2)

- to race horse owners, trainers and veterinarians for assistance in determining when a horse is mature enough to start running.[12,13]

- and . . . to aid clinical investigators in population surveys[16], for the study of inheritance patterns[17], nutritional research[18], exercise programs[19], and pharmaceutical testing programs.[20]

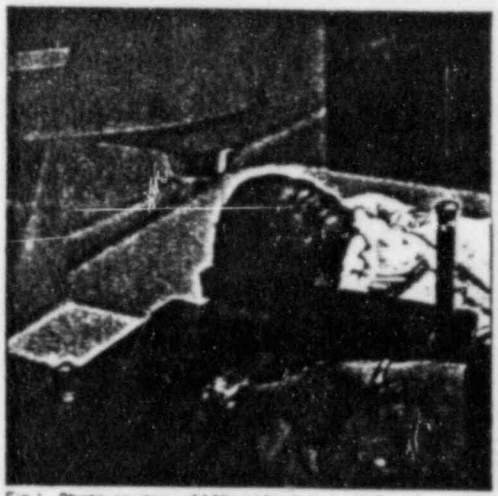


Fig. 1 Photo courtesy of Milton Werthman, M.D., of Washington Hospital Center of Washington, D.C.

Fig. 2 Photo courtesy of Brian J. Awbrey, M.D., of University of North Carolina at Chapel Hill, Chapel Hill, North Carolina

# AN ELEGANT SYSTEM— SCANNER AND COMPUTER MODULE

### HOW THE SYSTEM WORKS

The 278A provides step by step instructions for easy and effective operation. Once the patient is positioned, the scanner module transports a collimated photon beam from a radioactive source (Iodine-125) across the chosen scan site. A search scan locates the bone of interest within the limb. Then a measurement scan collects more accurate photon absorption data. The results are computed and displayed digitally on the CRT screen.

### SCAN SITE SELECTION

The densitometer primarily measures the bones of the forearm,[5] but can be adapted to measure a variety of other scan sites. Norland has recommended the forearm as the primary site because bone mineral content of the mid-distal radius has been shown to reflect with reasonable accuracy the mineralization of the entire axial skeleton.[6] The radius is also an easy bone to measure. The scanner's positioning system holds the forearm firmly but comfortably and minimizes repositioning errors.

With an accessory positioning system the densitometer can measure fingerbones,[7,8] a site often monitored in renal osteodystrophy. It can measure the ulna, tibia, fibula, and the humerus in newborn infants.[9] It can also be adapted for use with animals, ranging from the femur of the laboratory rat[10] to the tibia of the beagle[11] to the metacarpal of the horse.[12,13]

# SYSTEM CAPABILITIES AND OPTIONAL COMPONENTS

### THE 278A DENSITOMETER WASTES NO TIME—FOR PATIENT OR OPERATOR

- After power turn-on, the computer performs a rapid and extensive self-check; any malfunctions are indicated on the screen.
- Calibration is a simple five minute procedure which need be done only once every two weeks.
- Multiple scans are now possible with the 278A, and are performed without stopping for operator key press.

### COMPLETE CRT DISPLAY

All information about a scan is presented on a large, bright CRT display:

- numeric results: BMC (bone mineral content), BW (bone width), and BMC/BW
- graphic results: bone profile showing selected baseline and bone edges
- scan number: 9-digit patient I.D., date, sequence number, and disk file number
- scan parameters: which bone, edge threshold, collimator, etc.

### OPTIONAL COMPONENTS

Compact High Resolution Printer/Plotter

Provides four different modes of printed record ranging in complexity from:

Printing out the scan number with BMC, BW, and BMC/BW in about three seconds to printing all information shown on the CRT screen, including a plot of the bone profile, in about one minute.

All printouts done at a press of a button. Connects to the computer module with a single cable.

Flexible Disks, Permanent Storage Memory

Single or dual drive units with five diskettes included. Bone measurement information is written on a diskette for permanent storage. Data may be retrieved and displayed on the CRT for examination and/or computation. Connects to the computer module with a single cable. A valuable aid in serial patient measurement.

Scanning Positioning System

Adapts the scanner for measuring the arm bones, finger bones, infant subjects, and animals. Specific positioning systems allow accurate repositioning of the scan site.

For more information contact 1-800-558-0158

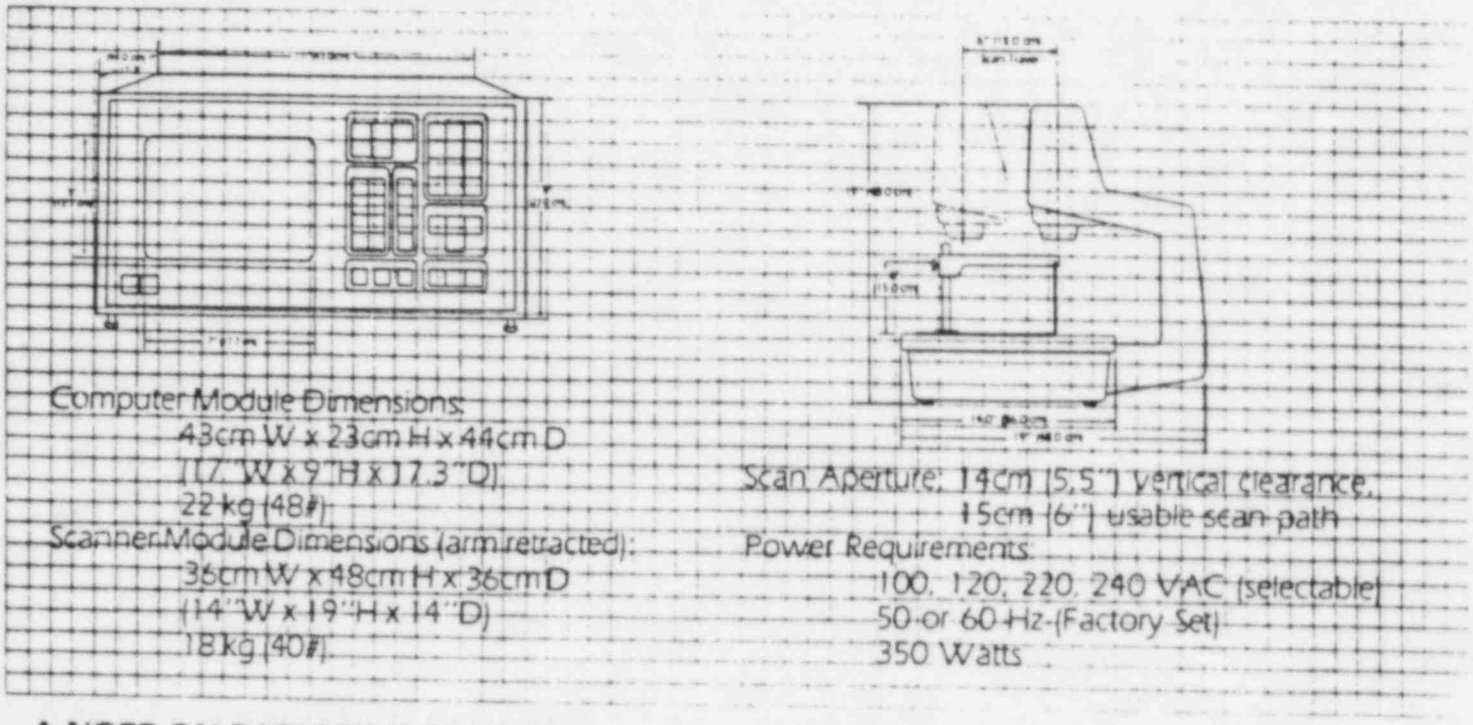
NORLAND CORPORATION

Industrial, Scientific and Medical Instrumentation
Route 4, Norland Drive
Fort Atkinson, WI 53538

1-414-563-8456 TLX 26-5448
1-800-558-0158 (Toll-Free)
Affiliate of Cordis Corp.

# THE NORLAND BONE DENSITOMETER, MODEL 278A

## PHYSICAL SPECIFICATIONS



Computer Module Dimensions:
43cm W x 23cm H x 44cm D
(17" W x 9" H x 17.3" D)
22 kg (48#)

Scanner Module Dimensions (arm retracted):
36cm W x 48cm H x 36cm D
(14" W x 19" H x 14" D)
18 kg (40#)

Scan Aperture: 14cm (5.5") vertical clearance;
15cm (6") usable scan path

Power Requirements:
100, 120, 220, 240 VAC (selectable)
50 or 60 Hz (Factory Set)
350 Watts

## A NOTE ON RADIATION DOSAGE

Comparing the densitometer with radiography for radiation dosage is conceptually difficult. A radiograph exposes a large portion of the body, while the densitometer exposes a section of tissue measuring approximately five mm wide and three cm long. A rough comparison can be made by considering the total intra-tissue ionization based on relative radiation fields, exposure times, and areas exposed. The results show the total ionization produced within a patient during a set of four densitometer scans is about 1/100 of that delivered by a radiograph of the forearm.

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NORLAND CORPORATION

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278A/10-82

CALIBRATION OF INSTRUMENTS

Calibration of Survey Instruments:

A. Survey instruments will be calibrated at least annually and following repair.

B. Procedures and sources have been approved by the State of Maryland, License MD-31-035-01 and U.S.NRC Regulatory Guide 10.8.

C. Survey instruments will be calibrated by a consultant or outside firm.

Name: Health Physics Services, Inc.

Location: 7825 Tuckerman Ln, Potomac, MD 20854-3295

SURVEY INSTRUMENT CALIBRATION PROCEDURES

Source

Sealed Cesium-137 source of approximately 500 mCi, authorized under Maryland License No. MD-31-035-01, for calibration purposes. The exposure date at discrete distances has been determined with NBS traceable ion chambers by a certified radiological physicist. These measurements are re-certified annually.

Procedures

1. Turn on instrument to be calibrated and check batteries, etc. Replace as necessary.

2. Prepare calibration certificate in duplicate.

3. Unlock calibrator and remove source plug.

4. Compare instrument at two points on each scale (approximately 30% and 70% of scale), to known exposure level. If deviation from true exposure exceeds ±10%, make appropriate adjustments in accordance with the instrument manual.

5. After appropriate adjustments, repeat Item 4 above. If deviations still exceed ±10%, forward for appropriate maintenance with customer's consent.

6. Complete calibration certificate and insure that true exposure and meter response is listed for two or more points on each scale.

7. Replace plug, lock calibrator, and sign certificate.

8. Insure that certificate accompanies instrument when returned to customer.

9. Affix calibration sticker, with date of calibration, on side of meter and pack for shipping.

NOTE: Instruments used to measure low energy range isotopes, e.g., I-125, Tc-99m, Xe-133 shall also be calibrated with a Co-57 source of approximately 10 mCi (ICN Model 77321 or equivalent) for relative response comparison.

FACILITIES AND EQUIPMENT

A. A diagram of the facility where the Bone Densitometer will be used is attached.

B. Security

1. Storage:

All sources, when not secured in the scanner, will be stored in a locked steel storage cabinet. The source in use is locked in the scanner. Keys will be controlled by the Radiation Safety officer.

2. Handling Area:

The door to the where sources are stored and used is secured and area locked when not occupied by or under the direct observation of the RSO or an individual designated by the RSO as responsible for source security. These same individuals will have possession of the keys to this area.

3. Building:

The building has an operational security system for non-working hours.

4. Remote Handling:

All sources will be received and shipped in shielded brass capsules (AECL Model C-236 source holders) to and from the supplier so no remote handling equipment will be required. However, a pair of long handled tongs will be available for emergency operations involving surface contamination of the brass capsule.

The manfacturers instructions will be followed when replacing sources.

PERSONNEL TRAINING PROGRAM:

All personnel whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) will be informed about radiation hazards and appropriate precautions.

Personnel will be properly instructed:

A. Before assuming duties with, or in the vicinity of, radioactive materials.

B. During annual refresher training.

C. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction will include:

A. All terms of the license pertinent to radiation safety.

B. Areas where radioactive material is used or stored.

C. Potential hazards associated with radioactive material.

D. Radiologial safety procedures appropriate to their respective duties.

E. Pertinent NRC regulations.

F. Rules and regulations of the license.

G. Obligation to report unsafe conditions to the radiation safety officer.

H. Apropriate response to emergencies or unsafe conditions.

I. Right to be informed of their radiation exposure and bioassay results.

J. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence).

ORDERING AND RECEIVING RADIOACTIVE MATERIALS:

A. Sources will be ordered only at the direction of the Radiation Safety Officer.

B. Sources will only be received during normal working hours and only by the Radiation Safety Officer or individuals specifically designated by the Radiation Safety Officer.

C. Packages containing sources will be received and opened in accordance with the following procedures (item 14) and proper records maintained.

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

A. Packages will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 18 hours if received after working hours. The appropriate regulatory office will be notified, in accordance with applicable regulations, if removeable contamination exceeds 0.01 uCi/100 cm sq or if external radiation levels exceed 200 mR/hr at the package surface of 10 mR/hr at 3 feet (or 1 m).

B. The following additional procedures for opening packages will be carried out:

1. Put on gloves to prevent hand contamination.

2. Visually inspect package for any signs of damage (e.g. wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.

3. Measure exposure rate at 3 feet (or 1 m) from package surface and record. If > 10mR/hr, stop procedure and notify Radiation Safety Officer.

4. Measure surface exposure rate and record. If >200mR/hr, stop procedure and notify Radiation Safety Officer.

5. Open the package with the following precautionary steps:

   a. Open the outer package (following manufacturer's directions, if supplied) and remove packing slip.

   b. Open inner package and verify that contents agree with those on packing slip. Compare requisition, packing slip, and label on source holder.

   c. Check integrity of final source container.

   d. Check also that shipment does not exceed possession limits.

6. Wipe external surface of final source container and remove wipe to low background area. Check wipes with a thin-end window G-M survey meter, and take precautions against the spread of contamination as necessary.

7. Monitor the packing material and packages for contamination before discarding.

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a. If contaminated, treat as radioactive waste.

b. If not contaminated, obliterate radiation labels before discarding in regular trash.

c. Maintain records of the results of checking each package, using "Radioactive Shipment Receipt Record". (attached)

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GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

A. Wear disposable gloves at all times while handling radioactive materials.

B. Monitor hands and clothing for contamination after each procedure when sources are handled out of the Bone Densitometer.

C. Wear personnel monitoring devices (films badge or TLD) at all times while in areas where radioactive materials are used or stored. Film badges if worn, should be worn at chest or waist level and TLD ring badge on dominant hand. Personnel monitoring devices should be stored in the designated low background a ea when not in use.

D. TLD finger badges will be worn during all source handling procedures.

E. Never remove sources from brass shielding capsules.

F. All radioisotopes will be stored in a locked steel cabinet designated specifically for that purpose. Keys will be controlled by the Radiation Safety Officer.

G. Appropriate records of serial numbers, dates, leak tests, and shipments of sources will be kept as required in the regulations.

H. Disposal of old sources will be accomplished only by shipping the sources to the supplier, who has agreed to dispose of such sources.

I. Sources not leak tested for six months, will be tested. (See attached)

J. Extremities of no one, except the patient, shall be placed in the primary beam.

K. Sources will only be exchanged by the Radiation Safety Officer or other persons designated by the Radiation Safety Officer who have had specific training by Norland/Beta Diagnostics personnel to safely exchange sources.

L. During source exchange, the open port of the source should always be directed away from other persons or occupied areas. In exchange, the port should be directed toward the windows in the scanning room.

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EMERGENCY PROCEDURES

A. In the event of a radiation incident involving the rupture of an I-125 source container, the Radiation Safety Officer or persons under his/her supervision will isolate the source by removing all persons in the immediate area and cover the source with radiation absorbing material. Removal and disposal will be coordinated by Beta Diagnostics, Inc. assisted as necessary by a qualified expert in the field of health physics (Health Physics Services, Inc.)

B. In the event of a radiation incident involving non-closure of a scanner shutter assembly, the Radiation Safety Officer or persons under his/her supervision will isolate the source by removing all persons in the immediate area and place over the scan path a radiation absorbing material. Appropriate action will be taken after careful consideration.

C. All incidents will be reported immediately to the RSO.

Radiation Safety Officer: Kenneth C. Glazy, MD

Office Phone: 703-698-8070

Home Phone: 703-620-3285

Alternate(s)

Name: William J. Cirincione, MD

Office Phone: 301-261-1053

Home Phone: 301-261-1932

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AREA SURVEY PROCEDURES

A. All source usage and storage areas will be surveyed monthly with an appropriate low-range survey meter. The surveys will consist of a measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.

B. A permanent record will be kept of all survey results, including negative results. The record will include:

1. Location, date, and identification of equipment used, including the serial number and pertinent counting efficiencies.

2. Name of person conducting survey.

3. Drawing of area surveyed, identifing relevant features such as active storage areas, etc.

4. Measured exposure rates, if any above background, keyed to location on the drawing (point out rates that require corrective action).

5. Corrective action taken in the case of excessive exposure rates, exposure rates after corrective action and any appropriate comments.

WASTE MANAGEMENT

Clinics will return used sources in their brass shields, packaged in accordance with DOT and NRC regulations, to Beta Diagnostics, Inc., Fort Atkinson, WI for disposal. The Sources will be held until a sufficient quantity has accumulated for shipment back to the ma ufacturer. This will be done in accordance with all State, NRC, and DOT regulations.

BETA DIAGNOSTICS, INCORPORATED

**BETA DIAGNOSTICS, INC.**
**I-125 RADIOISOTOPE**
**RETURN POLICY**

**DEC. 1, 1984**

Due to the ever increasing costs of materials and new safety standards we request that you return your old I-125 radioactive source as soon as you have received your new source.

Your new source is priced with the assumption that your old source will be returned to Beta Diagnostics within 30 days of the date your new source is shipped to you. This allows one week for shipping in each direction plus two weeks for you to change the source.

To simplify the return of your old source we have included all of the hazardous materials labels required by the U.S. Dept. of Transportation and United Parcel Service. Please follow the instructions enclosed with your new source. If you have any problems with local UPS pick-up call Jody Schemm of Beta Diagnostics at 414/563-9341 for assistance.

Should your old I-125 source not be retruned within the 30 day period you will be receiving an extra invoice for $50.00 to cover the value of the brass shielding and shipping capsule which we have not been able to recycle.

Please recall that if you maintain any one source in your possession for more than six months you must conduct a leak test and have data on record to prove the results were negative. To eliminate the need for your leak testing and to provide the maximum safe guards please return your source promptly and leave the leak testing to Beta Diagnostics. The recycled source capsule will also keep your costs down. If you follow our recommended five month new source cycle time you will be able to avoid all need for any leak tests except in the event of any accidental damage to the source or shipping container.

Thank you for your I-125 source order. Please call us if you have any questions or problems with your I-125 source.

Jody L. Schemm
Isotope Distribution Mgr.

210 Madison Avenue, Fort Atkinson, WI 53538 (414) 563-9341
7540 Louis Pasteur Drive, Suite 100, San Antonio, TX 78229 (512) 690-1548

PROCEDURES FOR CHANGING THE I-125 RADIOACTIVE SOURCE
IN YOUR NORLAND BONE DENSITOMETER.

The radiation source is contained in a source holder which absorbs almost all of the emitted radiation when the cover is in place. Use caution when removing the source holder cover. When the cover is removed (by unscrewing), the radiation beam emerges from the small hole with a total angular spread of approximately 30 degrees (Figure 1).

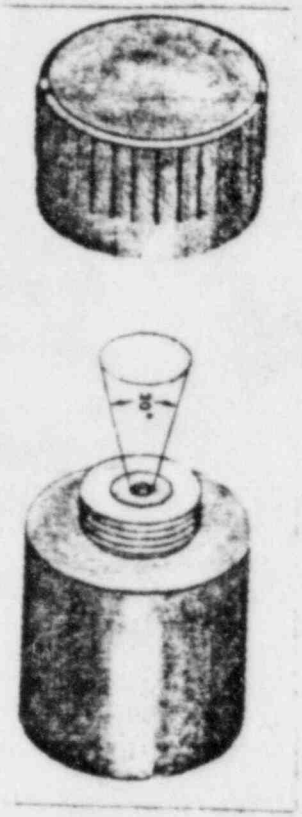


**FIG. 1**

**"Source Assembly AECL C-236 or 178A591A with shipping cap removed 30 degree radiation field illustrated."**

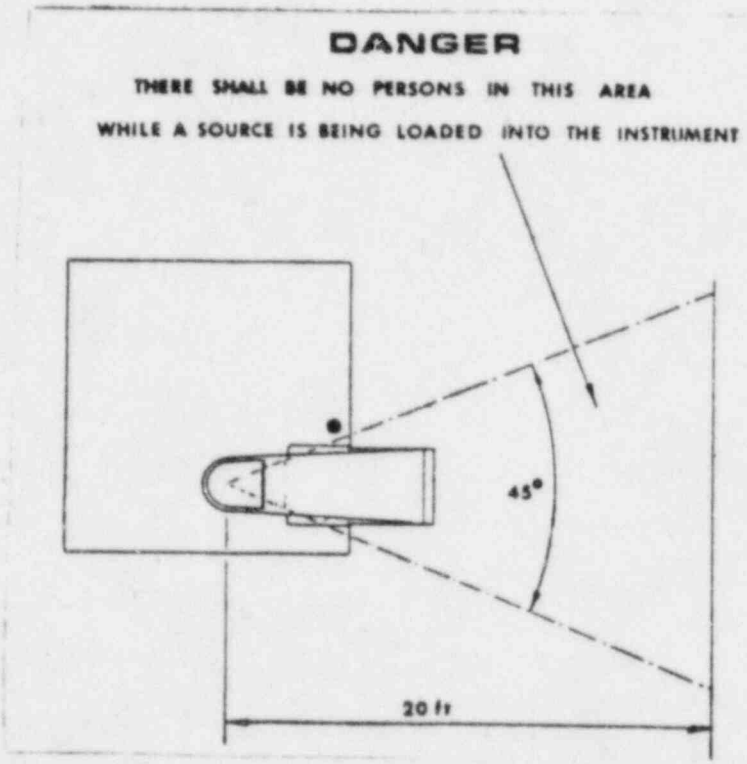



**FIG. 2**

**"Radiation Hazard area during source loading and unloading."**

A 200 mCi source delivers a maximum dose rate of approximately 200 mr/min at a distance of 2.5 cm. The protective cover should not be removed until the source is actually installed in the scanner. When installing the source, be sure that there are no persons in the scanner area indicated by Figure 2.

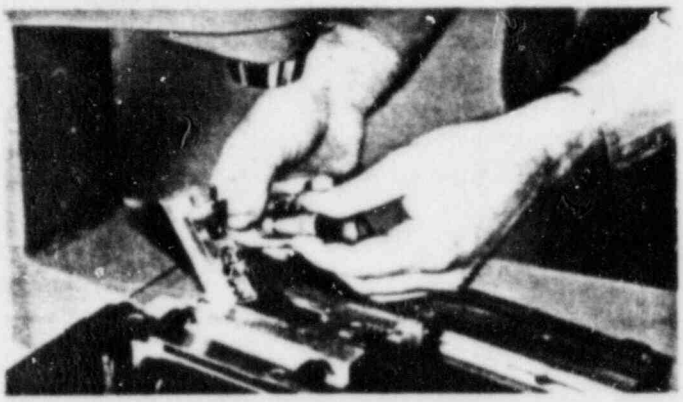
Turn off the Densitometer before starting the source installation. Remove the thumb screws holding the deck to the scanner base (two in front and one in back). Disconnect the cable from the back of the scanner. Unlock the deck from the base by turning the deck key counter-clockwise several turns until the desk is free.

While loading or unloading the source, keep fingers away from the exposed end of the source holder at all times. Do not point the exposed source toward anyone. When removing the source from the scanner, reverse the loading procedure. Be sure to replace the cap on the source holder before tranporting the source.

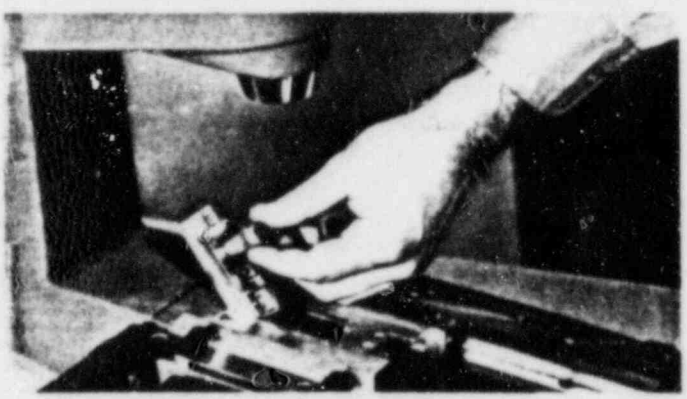
# PROCEDURE FOR LOADING SOURCE

A. Lift source/shutter door.

B. Remove source cap. Hold source in position shown.



C. Screw source into source/shutter door, then close door.



D. Store cap for later use on clip in scanner.

BETA DIAGNOSTICS, INC., 210 Madison Avenue, Fort Atkinson, WI 53538, (414)563-9341

BONE DENSITOMETER CLINIC

RADIATION SAFETY PROGRAM (ALARA)

I. MANAGEMENT COMMITMENT

A. The management of this facility is committed to the program described herein for keeping radiation exposures to as low as reasonably achievable.

B. We will perform a formal annual review of the radiation safety program including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

C. Modification to procedures will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

II. RADIATION SAFETY OFFICER IS RESPONSIBLE FOR THE FOLLOWING:

A. Annual and Quarterly Review

1. Annual review of the Radiation Safety Program. The RSO will perform an annual review of the Radiation Safety Program for adherence to ALARA concepts.

2. Quarterly review of Occupational Exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of paragraph III of this program.

B. Education Responsibilities for an ALARA Program

The RSO will assure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in ALARA philosophy and informed that management, is committed to implementing the ALARA concept.

C. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in the formulation of the procedures that they will be required to follow.

D. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

III. ESTABLISHMENT OF INVESTIGATIONAL LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION EXPOSURES

This facility hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Officer or his consultant. The Investigational Levels that we have adopted are listed in Table 1 below. These levels apply to the exposure of individual workers.

TABLE 1

| | Investigational Levels - (mrems per calendar quarter) | |
|---|---|---|
| | LEVEL I | LEVEL II |
| 1. Whole body | 125 | 375 |
| 2. Hands | 1875 | 5625 |

The Radiation Safety Officer will review the results of personnel monitoring, film badge report, not less than once in any calendar quarter, as is required by 10 CFR 20, 20.401. The following actions will be taken at the Investigational Levels as stated in Table 1:

A. Quarterly exposure of individuals to less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table 1 values for the Investigational Level I.

B. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required.

C. Exposure equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, take action. The investigation will be documented and made available to NRC inspectors for review at the time of the next inspection.

IV. SIGNATURE OF CERTIFYING OFFICIAL

I hereby certify that this institution has implemented the ALARA Program set forth above.

Signature of Radiation Safety Officer

KENNETH L. GEOLY, MD
Name (type or print)

RADIATION SAFETY OFFICER
Title