

APPLICATION FOR MATERIALS LICENSE - MEDICAL

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

David Levy, M.D.
475 N. Franklin Turnpike
Ramsey, N.J. 07446

TELEPHONE NO.: AREA CODE (201) 934-0043

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

Same

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Same as above

TELEPHONE NO.: AREA CODE ()

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.)

David Levy, M.D.

5. RADIATION SAFETY OFFICER (RSO) (Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)

David Levy, M.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES			IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED	PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED	PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP III			GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED	XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		
10 CFR 35.100, SCHEDULE A, GROUP VI					

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 (Source Model No. AECL C-235 and C-324 and source holder model C-236) See NRC registration sheet	Sealed Source NR-482-D-102-F, August 1983	2 sources/no source to exceed 400 mCi	Norland Bone Densitometer (Model N2740 with N2780 module) "OFFICIAL RECORD COPY"

FORMATION 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)	
<input type="checkbox"/>	Names and Specialties Attached; and	<input type="checkbox"/>	Appendix G Rules Followed; or
<input type="checkbox"/>	Duties as in Appendix B; or	<input checked="" type="checkbox"/>	Equivalent Rules Attached
<input type="checkbox"/>	Equivalent Duties Attached (Check One)		
8. TRAINING AND EXPERIENCE		16. EMERGENCY PROCEDURES (Check One)	
<input checked="" type="checkbox"/>	Supplements A & B Attached for Each Individual User; and	<input type="checkbox"/>	Appendix H Procedures Followed; or
<input type="checkbox"/>	Supplement A Attached for RSO.	<input checked="" type="checkbox"/>	Equivalent Procedures Attached
9. INSTRUMENTATION (Check One)		17. AREA SURVEY PROCEDURES (Check One)	
<input type="checkbox"/>	Appendix C Form Attached; or	<input type="checkbox"/>	Appendix I Procedures Followed; or
<input checked="" type="checkbox"/>	List by Name and Model Number	<input checked="" type="checkbox"/>	Equivalent Procedures Attached
10. CALIBRATION OF INSTRUMENTS		18. WASTE DISPOSAL (Check One)	
<input type="checkbox"/>	Appendix D Procedures Followed for Survey Instruments; or	<input type="checkbox"/>	Appendix J Form Attached; or
<input checked="" type="checkbox"/>	Equivalent Procedures Attached; and (Check One)	<input checked="" type="checkbox"/>	Equivalent Information Attached
<input type="checkbox"/>	Appendix D Procedures Followed for Dose Calibrator; or	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One)	
<input type="checkbox"/>	Equivalent Procedures Attached (Check One)	<input type="checkbox"/>	Appendix K Procedures Followed; or
11. FACILITIES AND EQUIPMENT		<input type="checkbox"/>	Equivalent Procedures Attached
<input checked="" type="checkbox"/>	Description and Diagram Attached	20. THERAPEUTIC USE OF SEALED SOURCES	
12. PERSONNEL TRAINING PROGRAM		<input type="checkbox"/>	Detailed Information Attached; and
<input checked="" type="checkbox"/>	Description of Training Attached	<input type="checkbox"/>	Appendix L Procedures Followed; or (Check One)
<input checked="" type="checkbox"/>	Detailed Information Attached	<input type="checkbox"/>	Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon - 133)	
<input checked="" type="checkbox"/>	Detailed Information Attached	<input type="checkbox"/>	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	
<input type="checkbox"/>	Appendix F Procedures Followed; or	<input type="checkbox"/>	Detailed Information Attached
<input checked="" type="checkbox"/>	Equivalent Procedures Attached	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
<input checked="" type="checkbox"/>	Equivalent Procedures Attached	<input type="checkbox"/>	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

Aug - 8 - 1

Applicant...	<i>1224</i>
Check No...	<i>1580-7C</i>
Amount, Fee Category	<i>APP.</i>
Type of Fee	<i>8/5/85</i>
Date Check Rec'd	<i>Jacques</i>
Received By	

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL		b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.
NAME OF HOSPITAL <i>N/A</i>		
MAILING ADDRESS		c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.
CITY	STATE ZIP CODE	

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)	b. APPLICANT OR CERTIFYING OFFICIAL (Signature)
	(1) NAME (Type or Print) <i>DAVID LEVY</i>
(1) LICENSE FEE CATEGORY:	(2) TITLE <i>MD</i>
(2) LICENSE FEE ENCLOSED: \$ <i>580.00</i>	c. DATE <i>July 2, 1985</i>

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.

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 pertinent 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 radiation 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 transfers.
- 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.

TRAINING AND EXPERIENCE

ITEM NO. 8

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER David Levy, M.D.		2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE N.J., N.Y., MASS.		
3. CERTIFICATION				
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C		
	Preventative Medicine	1984		
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	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:	2 hours		
b. RADIATION PROTECTION	Licensing the Lixiscope and Bone Mineral Analyzer for Human Use, dated March 8, 1985.	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. RADIOPHARMACEUTICAL CHEMISTRY	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

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		KEY TO COLUMN C
FULL NAME David Levy		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.
STREET ADDRESS 475 N. Franklin Turnpike		
CITY Ramsey	STATE N.J. ZIP CODE 07446	

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-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER			
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 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
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		
	TELETHERAPY 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 I-125	Bone densitometry using photon absorptiometry	Five	

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

8 hours including didactic training on The Norland 2780/2740 densitometer, on June 7, 1985. plus Radiation Physics and Radiation Biology.

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

7922 Ewing Halsell Rd.

d. CITY

San Antonio, Texas 78229

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE

Gordon L. Bilbrey

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

Gordon L. Bilbrey, M.D.

8. DATE

June 7, 1985

INSTRUMENTATION:

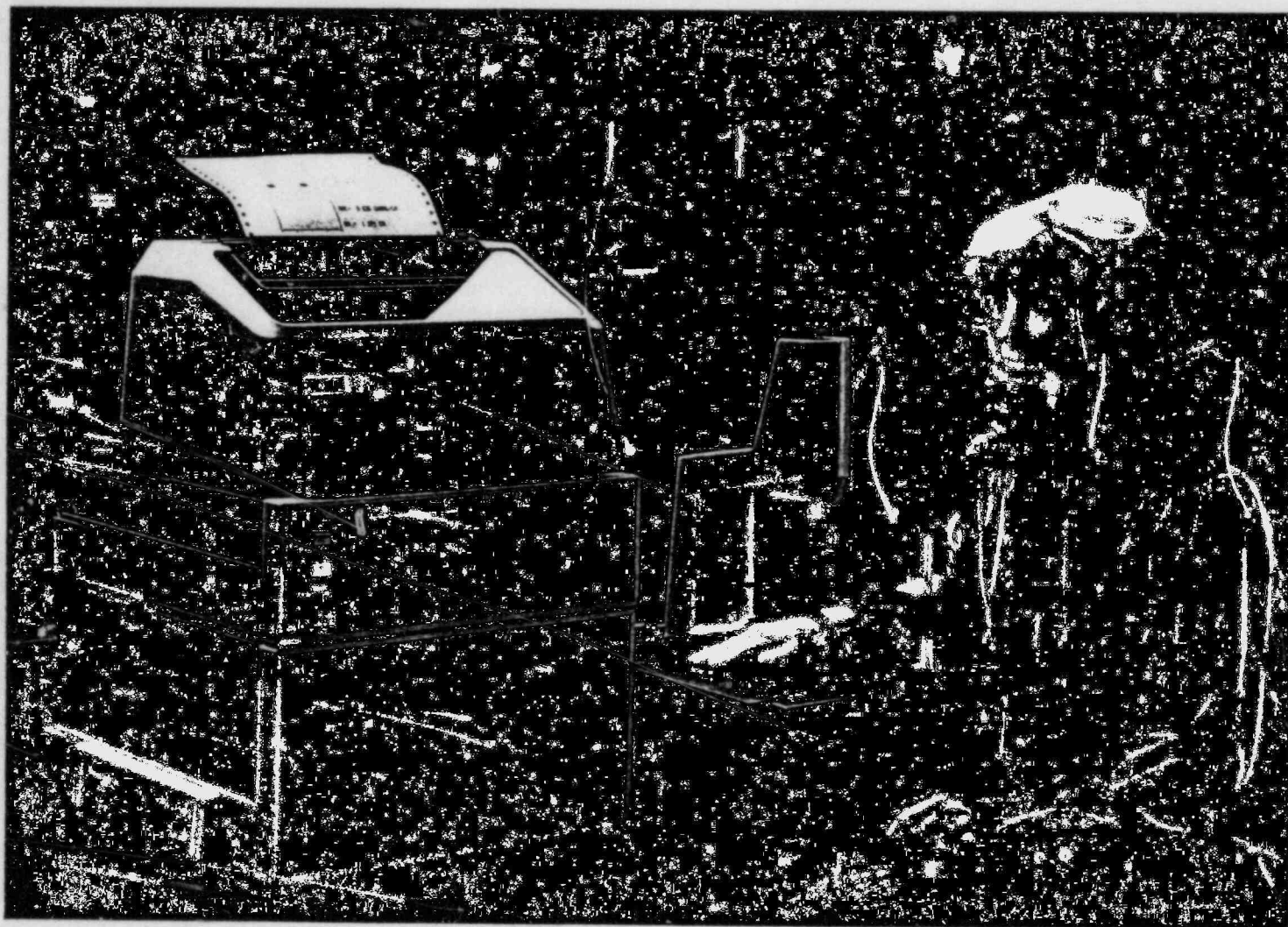
Radiation Survey Meter:

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.

**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

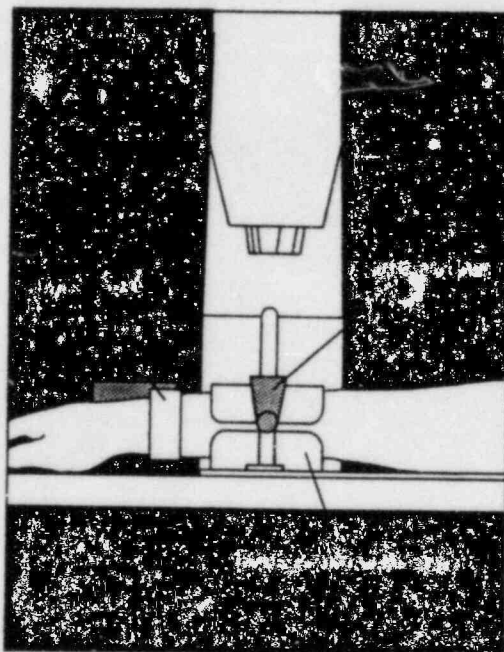
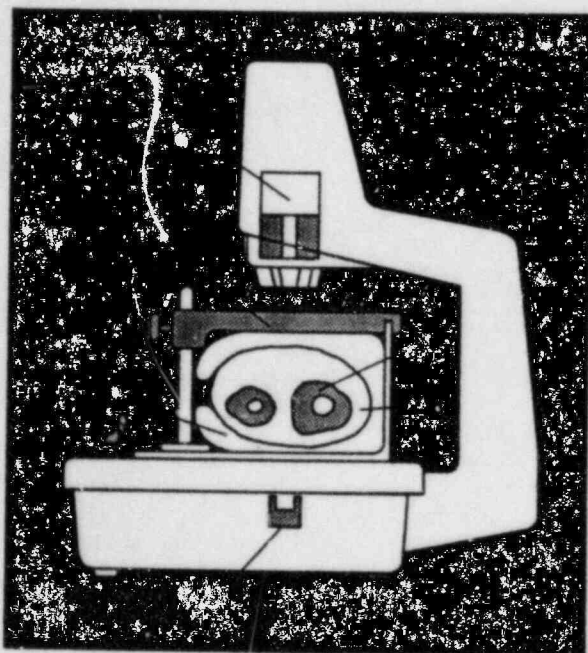
This technique replaces the broad energy spectrum of the x-ray beam with a beam of monoenergetic photons. This beam passes through the soft tissue and bone of a limb, and the resulting attenuation is monitored with a photon detector. The mass of bone mineral

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 neonatologists 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 surveys¹⁶, for the study of inheritance patterns¹⁷, nutritional research¹⁸, exercise programs¹⁹, and pharmaceutical testing programs.²⁰

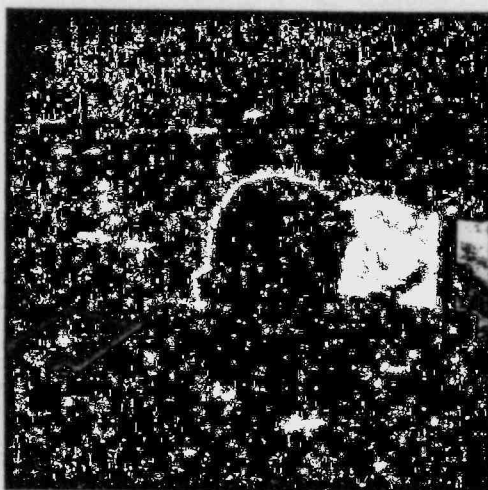
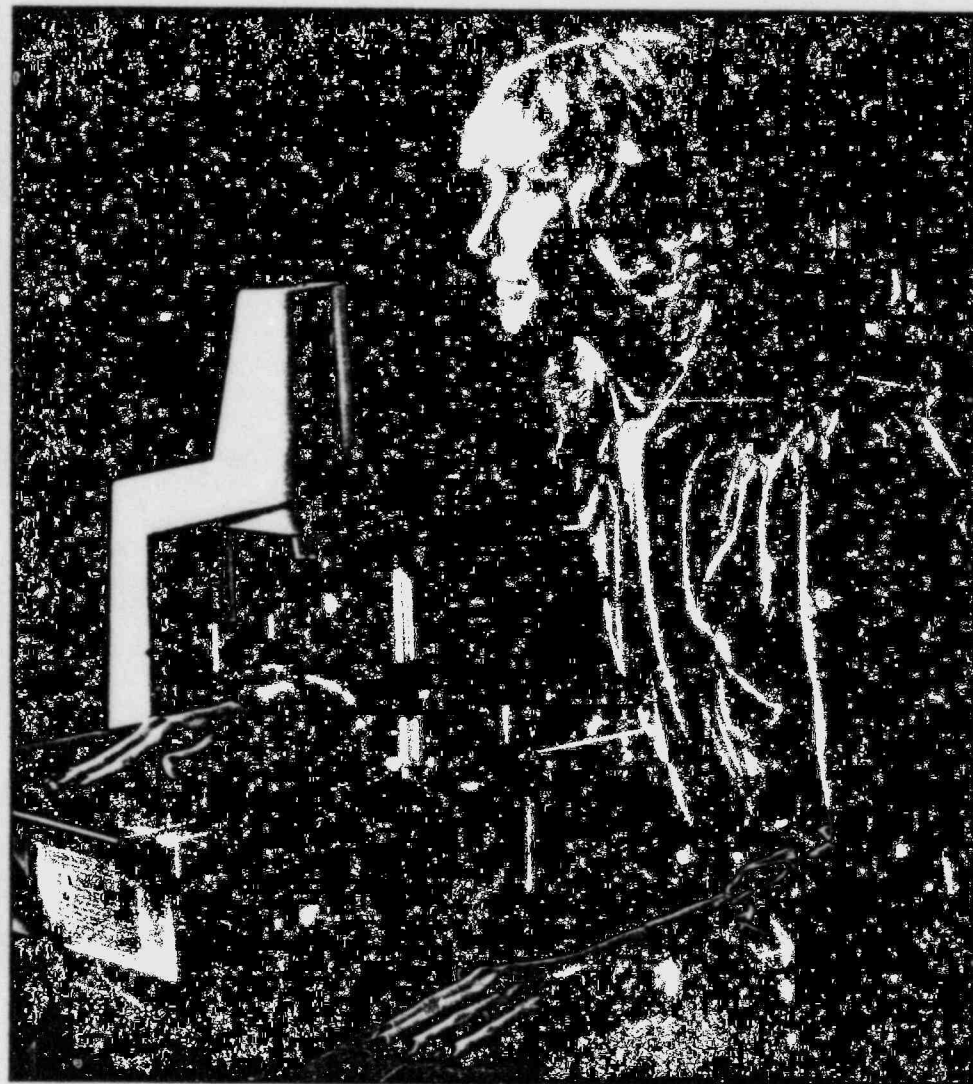
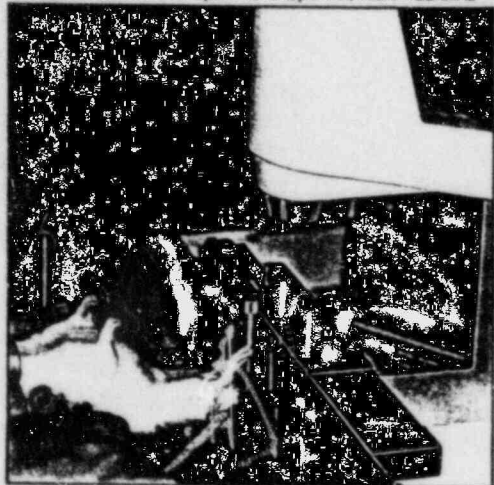


Fig. 1 Photo courtesy of Milton Werthman, M.D., of Washington Hospital Center of Washington, D.C.

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 rat¹⁰ to the tibia of the beagle¹¹ 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

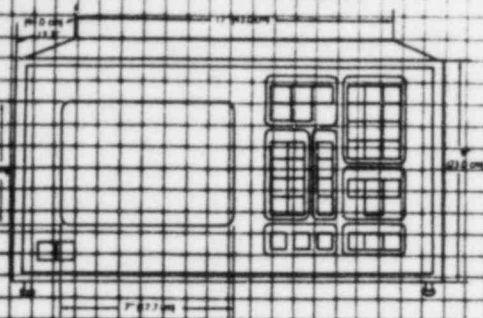
NORLAND
CORPORATION

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

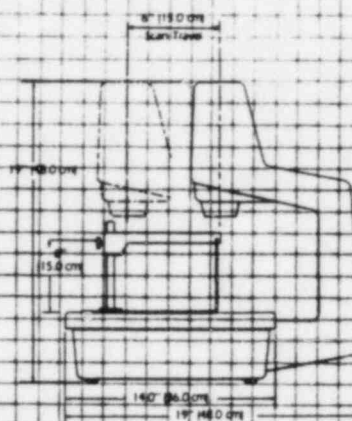


Computer Module Dimensions:

43cm W x 23cm H x 44cm D
(17\"/>

Scanner Module Dimensions (arm retracted):

36cm W x 48cm H x 36cm D
(14\"/>



Scan Aperture: 14cm (5.5\"/>

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

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.

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 rate 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 $\pm 10\%$, make appropriate adjustments in accordance with the instrument manual.
5. After appropriate adjustments, repeat Item 4 above. If deviations still exceed $\pm 10\%$, 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.

Item 10
11/12/84

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.

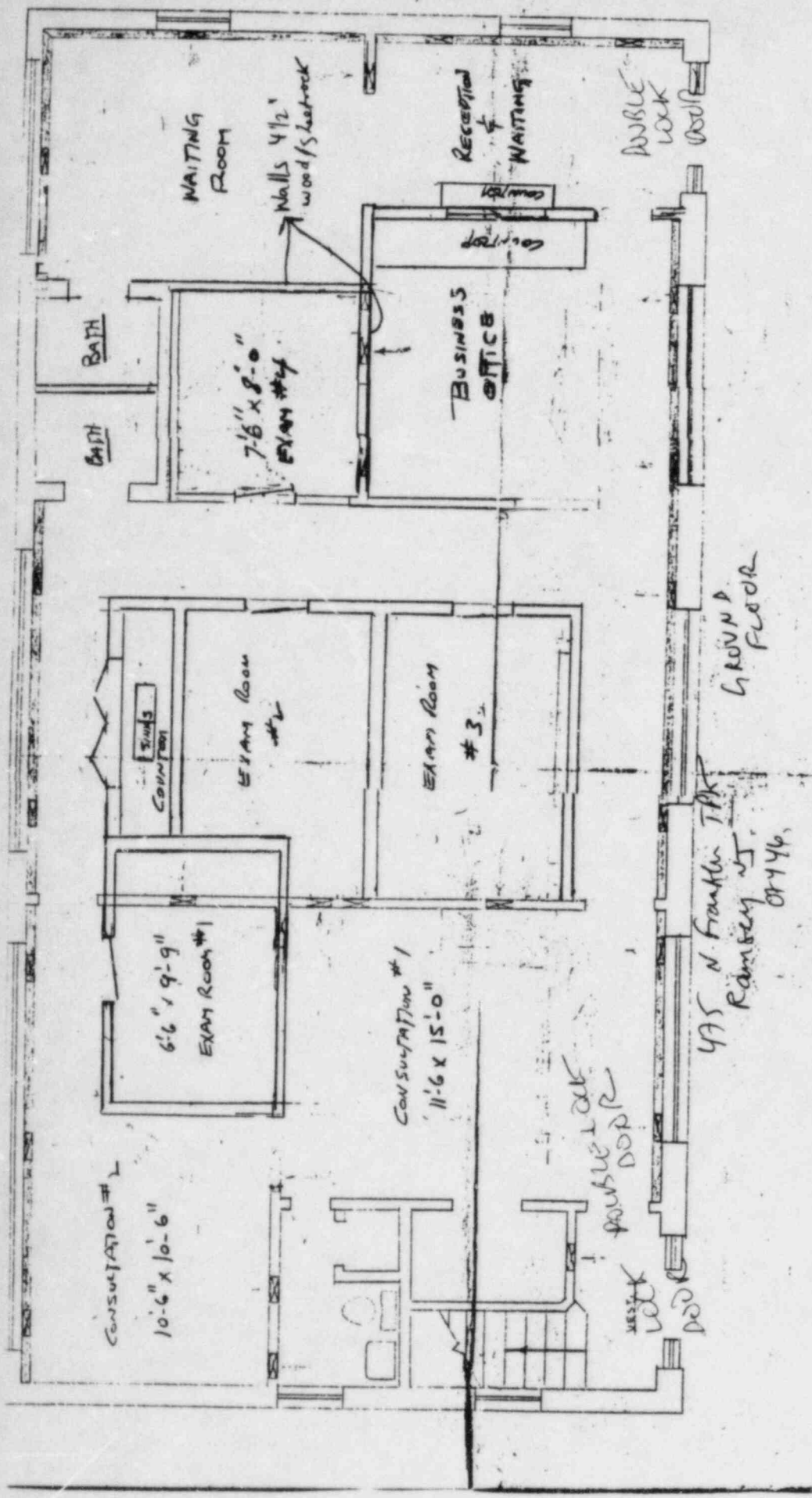
3. Building:

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 manufacturers 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. Radiological 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. Appropriate 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 removable contamination exceeds $0.01 \text{ uCi}/100 \text{ cm}^2$ 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 $> 10 \text{ mR/hr}$, stop procedure and notify Radiation Safety Officer.
 4. Measure surface exposure rate and record. If $> 200 \text{ mR/hr}$, 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.

- 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)

Item 14
11/12/84

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 area 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.

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: David Levy, M.D.

Office Phone: 201-934-0043

Home Phone: 201-934-7333

Alternate(s)

Name: Machine Secured and not in use

Office Phone: when David Levy MD not available.

Home Phone: _____

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, identifying 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 manufacturer. 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 returned 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 in 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).

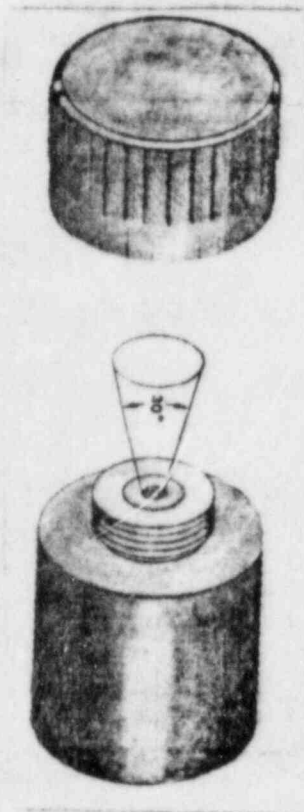


FIG. 1

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

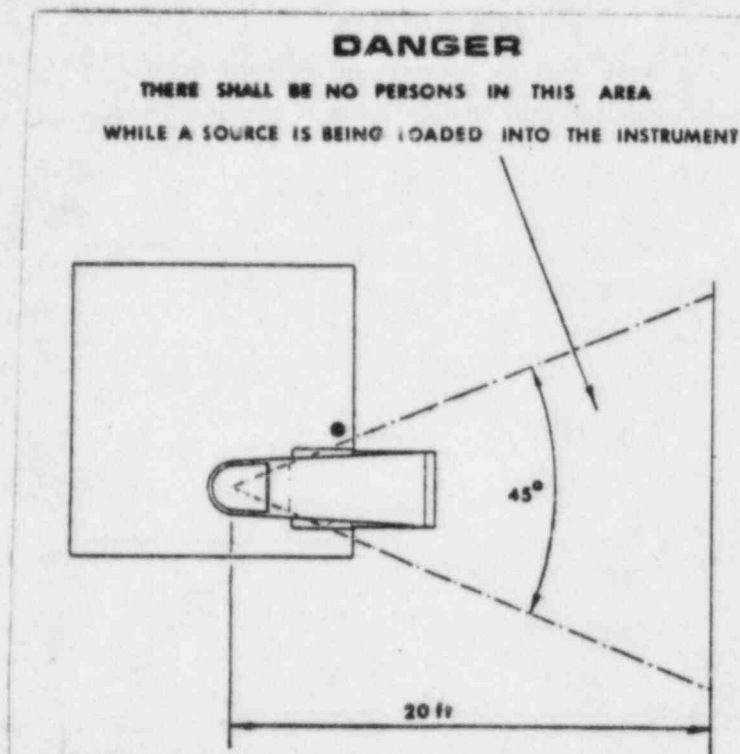


FIG. 2

"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 transporting the source.

PROCEDURE FOR LOADING SOURCE

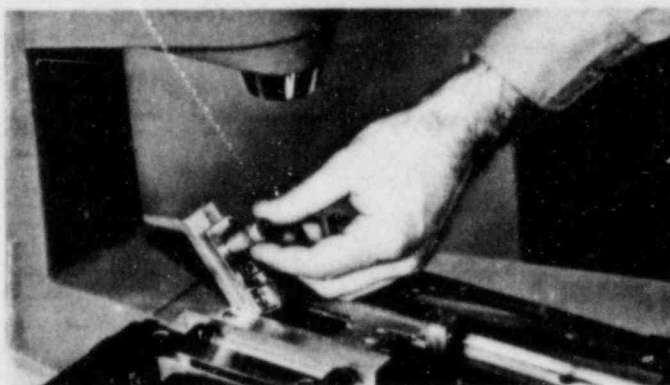
A. Lift source/shutter door.



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.



David Levy, M.D.
Family Practice and Preventive Medicine

475 N. Franklin Turnpike
Ramsey, New Jersey 07446
(201) 934-0043

Moyers Road
Tuxedo, New York 10987
(914) 351-5188

DAVID LEVY, M.D., M.Sc., A.A.F.P., F.A.C.P.M.
AMERICAN ACADEMY OF FAMILY PHYSICIANS
DIPLOMATE, AMERICAN BOARD OF PREVENTIVE MEDICINE
FELLOW, AMERICAN COLLEGE OF PREVENTIVE MEDICINE

FORWORD

Ionizing radiation is among the most versatile and useful tools of modern medicine and biomedical research. Like many other instrumentalities of medicine, ionizing radiation is potentially hazardous unless used with strict adherence to safety rules and procedures. Thus, the safety rules which govern the uses of radiation are concerned with preventing genetic damage as well as with protecting the health of the exposed individual.

The rules and procedures set forth here have one single, straightforward purpose: to protect the patients, employees, and visitors from unnecessary and potentially harmful radiation.

The existing radiation safety program has many facets designed to keep the levels of exposure to personnel at a minimum. This program has three main phases:

PHASE I

Achieve the objective of maintaining radiation exposures to "As Low As Reasonably Achievable" (ALARA) to employees, visitors.

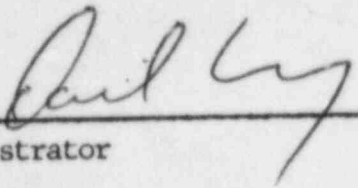
PHASE II

Control operational procedures by the user of radiation sources.

PHASE III

Evaluate the radiation safety program performed by the Radiation Safety Officer and the health physics consultant.

We, the management, are committed to the program procedures and develop new procedures as appropriate to implement the ALARA concept.



Administrator



Date

July 2, 1985

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)	
	<u>LEVEL I</u>	<u>LEVEL II</u>
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.

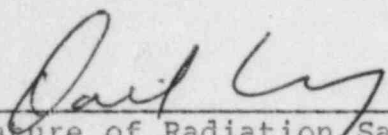
The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required.

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
~~DAVID~~ DAVID LEVY

Name (type or print)
MD

Title

BETWEEN: William O. Miller, Chief
License Fee Management Branch
Office of Administration -

John E. Glenn, Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: David Levy, M.D.

Application Dated: 7/2/85

Control No.: 04130

License No.: New

2. FEE ATTACHED

Amount: \$ 580.00

Check No.: 1224

3. COMMENTS

Signed Bronck P. Hatchek

Date 7/19/85

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: \$580 - 7 C

2. Correct Fee Paid. Application may be processed for:

Amendment

Renewal

License ✓

Signed J. Jackson

Date 8/7/85

DAVID LEVY, M.D.
475 N. FRANKLIN TURNPIKE
RAMSEY, N.J. 07446

1224


G-30 85

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David Levy

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