NRC FORM 313
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 5-31-87

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

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

- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

M. Rashid A. Khairi, M.D.
7430 North Shadeland
Indianapolis, Indiana 46250

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

Same as #2

Telephone: (317) 845-1006

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Stan Buhr or Jim Mikowski, Standard Nuclear Consultants, Westchester, IL

TELEPHONE NUMBER: (312) 344-7308

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY: 7C

AMOUNT ENCLOSED: $580.00

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE - CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
	M. Rashid A. Khairi, M.D.	Owner	5/10/85

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

- [ ] <$250K
- [ ] $250K–500K
- [ ] $500K–750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$10M

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION *(dollar and/or staff hours)* ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(NRC regulations permit it to protect confidential commercial or financial—proprietary—information furnished to the agency in confidence)*

- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
APP	May 24 III	7C		MAY 2 [illegible] REGION III

AMOUNT RECEIVED	CHECK NUMBER	DATE
$580	4839	5/19/85

RECEIVED MAY 20 1985

CONTROL NO. 78995

8507150566 850619
REG3 LIC30
13-24511-01 PDR

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 313. 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, 32, 33, 34, 35 and 40 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 (a) provided to State health departments for their information and use; and (b) provided 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 an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.

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. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.

5. **SYSTEM MANAGER(S) AND ADDRESS:** U.S. Nuclear Regulatory Commission
Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

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M. Rashid A. Khairi, M.D.
7430 North Shadeland
Indianapolis, Indiana 46250

Reference: NRC Form 313(1-84)

Item 5: RADIOACTIVE MATERIAL

a. Element and Mass #: Iodine-125
Gadolinium-153

b. Chemical and/or Physical form: I-125: sealed source, model C234 manufactured by AECL.

Gd-153: sealed source, model GD-1 manufactured by Gulf Nuclear.

c. Maximum Amount to be Possessed at any one Time:

300 mCi of I-125, each source approximately 200 mCi +/-20%.

2.0 curies of Gd-153, each source approximately 1 curie +/-20%.

A higher possession limit is being requested to provide for times when the sources are being replaced and because of the variability in source activity at time of receipt.

Item 6: PURPOSE FOR WHICH RADIOACTIVE MATERIAL WILL BE USED

I-125: The I-125 source will be used in a Lunar Radiation Corp., Model STP Forearm Scanner, (NRC device registration #SP2 NR-430-D-102-S).

Gd-153: The Gd-153 source will be used in a Lunar Radiation Corp., Model DP3 Spine/Femur Scanner, (NRC device registration #DP3 NR-430-D-101-S).

Item 7: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM/TRAINING AND EXPERIENCE

The individual responsible for the radiation safety program will be the Radiation Safety Officer, M. Rashid A. Khairi, M.D. He is licensed to practice medicine in Indiana and has received instructions as outlined in NRC Policy and Guidance Directive FC 83-24, "Licensing the Lixiscope and Bone Mineral Analyzer for Human Use." The instructions were given by Stan Buhr and Jim Mikowski of Standard Nuclear Consultants, Ltd. and followed the training course outline in that license (#12-20362-01). The 25 question test was given upon completion of the instructions and Dr. Khairi received a passing score of 96%. Documentation of the training is attached.

Radiation Safety Officer Duties and Responsibilities

The Radiation Safety Officer will be familiar with the principles of radiation protection and will have the authority to set radiation policy and to stop any use of radioactive material deemed unsafe. Typical duties of the RSO and/or his delegate include the following:

a. General surveillance over all activities involving radioactive material, including routine monitoring and special surveys of all areas in which radioactive material is stored.

b. Determining compliance with rules and regulations and license conditions.

c. Furnishing consulting services on all aspects of radiation safety to personnel at all levels of responsibility.

d. Receiving, delivering, and surveying all shipments of radioactive material arriving at the facility.

e. Distributing and processing of personnel dosimeter devices (if needed), keeping personnel exposure records (if needed), and notifying individuals of exposures approaching maximum permissable amounts and recommending appropriate remedial action.

f. Conducting training programs and otherwise instructing personnel in the proper procedures for working near the radioactive materials prior to use, at periodic intervals (refresher training), and as required by changes in procedures, equipment, regulations, etc.

g. Supervising and coordinating the radioactive waste disposal program, including keeping source transfer and disposal records.

h. Performing leak tests on sealed sources.

i. Maintaining an inventory of all radionuclides and limiting the quantity to the amounts authorized by the license.

Item 8: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Before any receipt and approximately annually thereafter, all personnel who may come in contact with or frequent areas where radioactive materials are handled or stored will receive the Attachment I minimum instructions.

Records of the dates, topics and attendance for these instructions will be maintained for NRC review.

Item 9: FACILITIES AND EQUIPMENT

Equipment: One (1) Lunar Radiation Corp. Model DP3 Spine/Femur Scanner
One (1) Lunar Radiation Corp. Model SP2 Forearm Scanner

Attached is a sketch describing the room which is planned for use of the instruments containing the radioactive materials. The entrance door will be locked whenever authorized personnel are not present. When not in use, the instruments will be locked to prevent use and access to the sources. Keys to the instruments and to the room will only be available to authorized personnel who have received the instructions defined in Item 8.

The building, Shadeland Medical Building, is owned by Dr. Khairi and there are no other tenants in the building. The building is also protected by Rex Alarm of Indianapolis. The nearest neighboring building is approximately 30 yards to the south.

Item 10: RADIATION SAFETY PROGRAM

A. General Safety Rules:

1. We confirm the radiation safety precautions of the manufacturer's operating instructions will be followed.

2. All containers of radioactive material are to be clearly marked as to the radioactive content.

3. In the event of theft or loss of radioactive materials, every attempt will be made to recover the materials as quickly as possible. A calculation will be made of the amounts of radioactive material involved and an evaluation will be made of the 10CFR20.402 reporting requirements. A report will then be filed (if needed) by the Radiation Safety Officer within the specified time limit.

B. Source Exchanges:

Manufacturer's instructions for source installation and exchange will be followed. These are contained in the device registration documents DP3 NR-430-D-101-S and SP2 NR-430-D-102-S.

Source exchanges will only be performed by individuals who have received device-specific training concerning the radiation safety precautions needed. Extremity exposures will be evaluated either by wearing an extremity badge (TLD or film) or by use of a low level survey meter. If the latter method is used, a direct mr/hr reading will be taken and the amount of time recorded for calculation of total radiation dose. These calculations will be made to ensure the levels are well below the Maximum Permissable Dose extremity limit of 18.75 Rems per calendar quarter. At no time will personnel place their hands directly in the unshielded radiation beam from the source holder. The RSO will be responsible for ensuring that all personnel exposures are kept as low as reasonably acheivable.

C. Leak Testing:

Leak tests on the I-125 sources will be performed semi-annually and on the Gd-153 sources annually according to the frequencies specified in the above device registration documents. The leak tests will be performed with the Standard Nuclear Consultants, Ltd. Leak Test Kit-1 as described in that firm's license #12-20362-01. We also request authorization to use any other leak test kit from other individuals or companies which are authorized by the NRC to perform these services.

ITEM 11: WASTE MANAGEMENT

Disposal of unused sealed sources will follow one or more of the following methods:

a. Return to supplier.

b. Transfer to an NRC licensed commercial waste disposal service.

c. Transfer to other authorized recipient.

CONTROL NO. 78995

PERSONNEL TRAINING PROGRAM

I. Individuals who work in or frequent restricted areas will be instructed in the items specified in 10 CFR 19.12 at the time of initial employment and at least annually thereafter.

This 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), as required by 10 CFR Part 19.

II. Individuals whose duties may require them to work in the vicinity of licensed material will be informed about radiaiton hazards and appropriate precautions at the time of initial employment, at least annually thereafter and as required by significant changes in procedures, equipment and/or regulations.

DP3 SPINE/FEMUR SCANNER and SP2 FOREARM SCANNER SPECIFICATIONS

Computer

NorthStar Advantage

Dimensions: 28x51x32cm (20kg)

Processor: Z80A CPU and INTEL 8035; option IBM compatible

Display: 28cm diagonal P31 Phosphor; 1920 character (24 lines x 80 characters); graphics 240x640 pixels bit-mapped; screen dump to printer

Disks: Two 5-¼" floppy diskette drives (double-sided, double density); 360K byte per diskette (10 sector); holds 25 spine or femur scans or 55 forearm scans per diskette

Nuclear Instrumentation

High voltage: Programmable 600 to 1600V

Amplifier: High-speed (0.25 microsec shaping time)

Dual-channel analyzer: Low-drift fast analyzers

Dual-scalers: 10 MHz scalers (16-bit)

Timer: Crystal-controlled programmable

Detector: Collimated NaI (Tℓ) scintillation detector with Bialkali Cathode

Motors and Control

Motors: 4-phase stepping motors

Control: Programmable controller; menu-driven step interval and speed

Scan Table (for DP3)

Dimensions: 183 x 81 x 69cm (50kg)

Materials: 2.5 x 5cm chrome plated steel legs; laminate covered wood top

Console Table (for both DP3 and SP2)

Dimensions: 152 x 76 x 69cm (30kg)

Materials: 2.5 x 5cm chrome plated steel legs; laminate covered wood top

Scanner Mechanism

DP3-Dimensions: 60 x 60 x 25cm metal enclosure below table (30kg)

SP2-Dimensions: 56 x 54 x 46cm metal enclosure

Source access: Through locked table top

Software

Operating system, graphics and BASIC are standard.
Compiled programs include: spinal scanning, femoral scanning, quality control; reanalysis of data from diskette

Warranty

Ninety day complete parts and labor coverage warranty. One-year parts warranty on Lunar Radiation components (scanner and counting electronics).

Service Contracts

Extension of the complete warranty service can be obtained under a service contract. Service contracts provide for the continued operation of your systems at a predictable cost. Benefits include one-day replacement service in case of failure and on-site service if necessary.

Radionuclide sources

153-GD (1 Ci) sources are supplied by Gulf Nuclear of Webster, Texas (713-332-3581) for approximately ~~$6700~~ $7200 and can be used for 12-18 months.

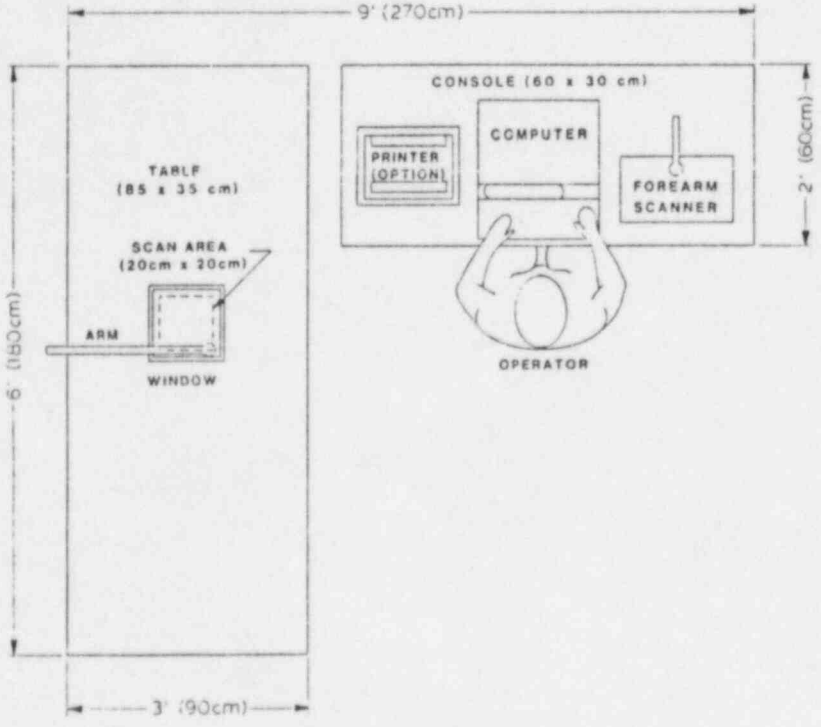
125-I sources (200mCi) are supplied by Atomic Energy of Canada, Ltd. (613-592-2790, ext. 2048) for about $600 and can be used for 6 months.

N.R.C. Device Registration: DP3 NR-430-D-101-S, SP2 NR-430-D-102-S. 8-hours training required for license.

Delivery

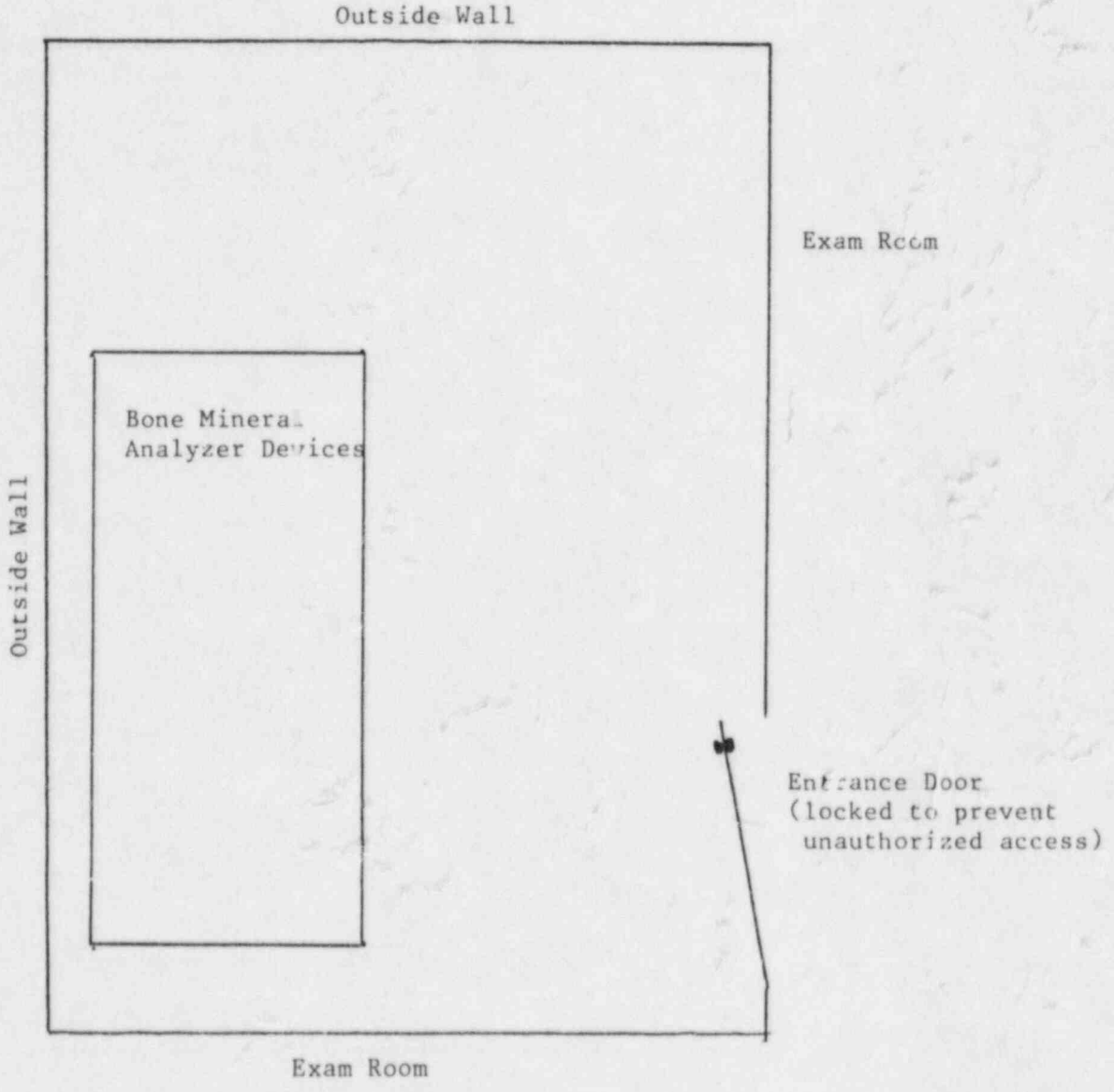
30 days ARO.

System Configuration (typical)



LUNAR RADIATION CORPORATION
916 Williamson Street—Madison, Wisconsin 53703
(608) 258-8545

M. Rashid A. Khairi, M.D.
7430 North Shadeland
Indianapolis, Indiana 46250



Standard Nuclear Consultants, Ltd.

Nuclear Medicine • Radiology • Industrial Specialists

STAN BUHR
JIM MIKOWSKI
(312) 344-7308

P.O. Box 362, Manhattan, IL 60442 □ 1340 Balmoral Avenue, Westchester, IL 60153

To Whom It May Concern:

This is to certify that Rashid ~~Kahri~~ KHAIRI, M.D. has participated in and satisfactorily completed an eight (8) hour course, "Medical Users Training for Bone Mineral Analyzer Diagnostic Devices." The content of the course followed that given in the November 10, 1983 NRC Policy and Guidance Directive FC 83-24 and as described in the Standard Nuclear Consultants, Ltd. NRC license # 12-20363-01. This training was geared toward radiation safety aspects of use and handling of I-125 and Gd-153 sources in bone mineral analyzer devices.

This training was given by Stan Buhr and Jim Mikowski of Standard Nuclear Consultants, Ltd. These individuals' credentials are on file with the NRC under license #12-20362-01. They have also received device-specific training for the Lunar SP-2 (I-125 sources) and Lunar DP-3 (Gd-153 sources) bone mineral analyzer devices, as documented in that NRC license file.

Date of training: May 4, 1985

Stan W. Buhr
Stan Buhr

James J. Mikowski
Jim Mikowski

Rashid Kahri, M.D.

CONTROL NO. 78995