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)*

Steven A. Mollov, M.D.
Women's Health Care
291 Main Street
West Newbury, MA 01985

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

291 Main Street
West Newbury, Massachusetts 01985

8603060208 860212
REG1 LIC30
20-20966-01 PDR

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION: Neil A. Gaeta, CHP — TELEPHONE NUMBER: (617) 458-7081

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: see attached

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

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE: S.A.Mollov, M.D. & Neil Gaeta

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS: see attached

9. FACILITIES AND EQUIPMENT: see attached

10. RADIATION SAFETY PROGRAM: see attached

11. WASTE MANAGEMENT: see attached

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
Steven A. Mollov M.D.	Steven. A. Mollov, M.D.	vice-president	Dec. 16 1985

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	Jan. 14	7C	"OFFICIAL RECORD COPY" 104906 ML18 JAN 14 1986	
AMOUNT RECEIVED	CHECK NUMBER			DATE
$580	004953			1/25/86

PRIVACY ACT STATEMENT ON THE REVERSE

LICENSED MATERIAL

Item 5 - Radioactive Material

Element and mass number: Gadolinium - 153 (Gd)

Chemical and/or physical form: sealed source of $Gd\hat{O}_2$ (Lundar Model GD, New England Nuclear Model NER-430, Amershau Model GDC.CY1, Gulf Nuclear Model GD-1), or any equivalent NRC registered sealed source.

Maximum amount which will be possessed: 3. sources at 1.5 Ci per source

Item 6 - Purposes For Which Licensed Material Will Be Used

Use in Model Lunar DP3 bone mineral analyzer for patient diagnostic studies performance testing and development, training, and demonstration. The Model DP#-AT bone mineral analyzer has received custom device approval from the NRC.

Items 7 and 8

TRAINING AND EXPERINECE

Name of Authorized User	Physician's License No.
Steven A. Mollov, M.D.	42450
Jeanne LaMont, M.D.	53168
Joseph M. Heyman, M.D.	35323
Gary Kraus, M.D.	30452

CERTIFICATION

Speciality Board	Category	Month & Year Certified
OB/GYN	-	November, 1980
OB/GYN	-	--
OB/GYN	-	November, 1975
OB/GYN	-	November, 1968

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUE

Neil Gaeta shall provide the required training on January 18 and 25, 1986 as per directive FC 83-24 attached. He shall also provide the training to all staff prior to assuming duties with or in the vicinity of radioactive materials (10 cFR 19.12).

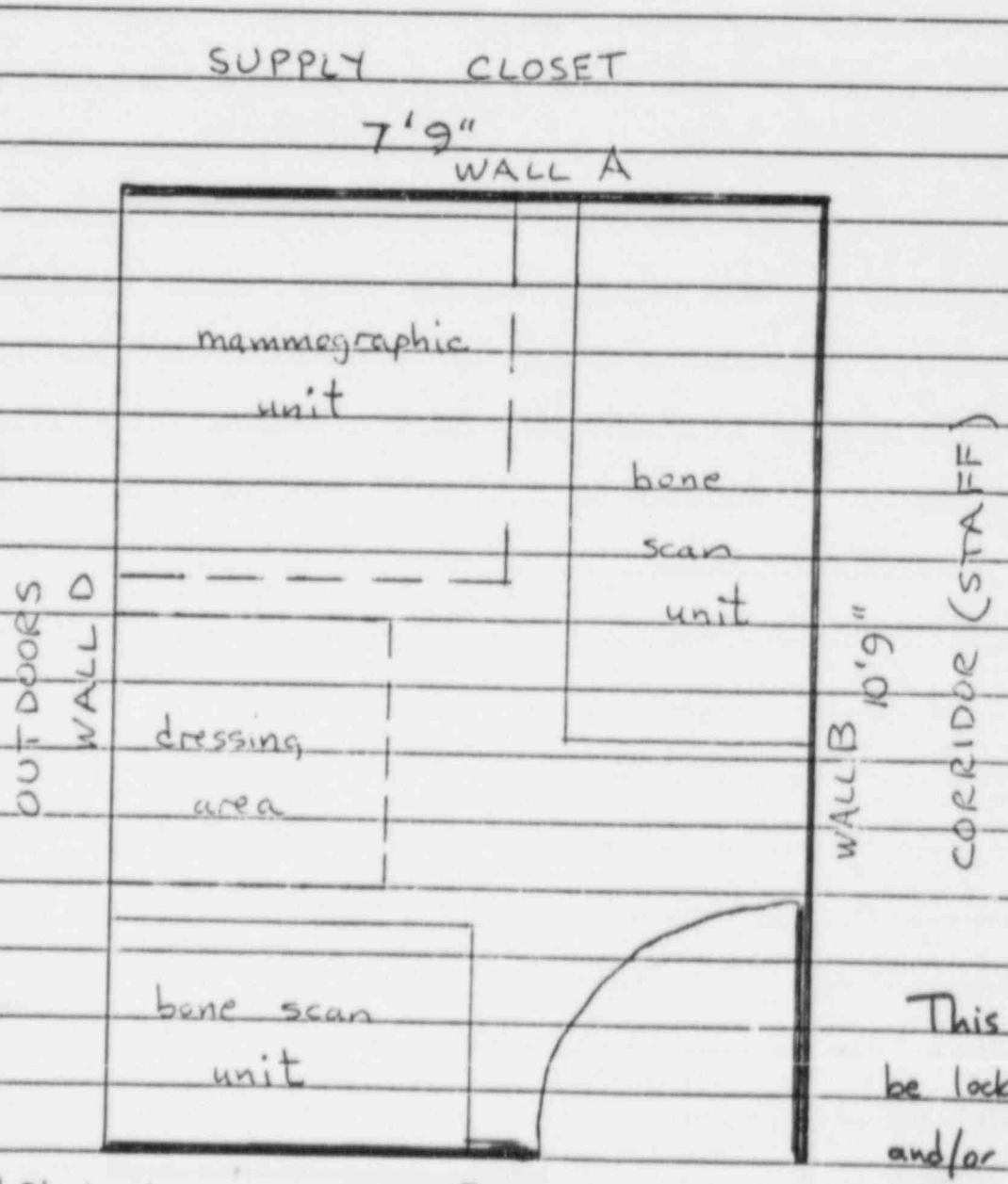
Each LUNAR bone mineral analyzer is installed by LUNAR personnel who will provide one day (6 hours minimum) of device specific training. The training includes source installation and exchanges, leak testing, scan operations, and data analysis and interpretation. The training is performed with an empty source holder. Neil Gaeta shall be present for this instruction and leak testing prior to exchanging sources. LUNAR's procedures, as part of their technical manual, will be followed for all source exchanges.

Item 9

Room Layout

(attached sheet)

ITEM 9



This room can be locked if required, and/or locked box shall be used. (LUNAR) (old/new sources)

—— 1/32" Pb lined walls

1/2" = 1 FOOT

Women's Health Care
W. Newbury, MA
N. Gaeta 12/6/85

ITEM 9

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Ludlum or equivalent

   Manufacturer's model number: Model 14C Geiger Counter with model 44-7 ~~GM probe (or Equivalent)~~

   Number of instruments available: one

   Minimum range: 0 mR/hr to 0.05 mR/hr

   Maximum range: 0 mR/hr to 2000 mR/hr

   b. Manufacturer's name: _____

   Manufacturer's model number: _____

   Number of instruments available: _____

   Minimum range: _____ mR/hr to _____ mR/hr

   Maximum range: _____ mR/hr to _____ mR/hr

2. Dose calibrator

   Manufacturer's name: _____

   Manufacturer's model number: _____

   Number of instruments available: _____

3. Instruments used for diagnostic procedures

   Dual photon Bone

Type of Instrument	Manufacturer's Name	Model No.
Dual photon Bone Mineral Analyzer (NRC Registration No. 430-D-101-S)	Lunar Radiation Corp.	DP3

4. Other (e.g., liquid scintillation counter, area monitor, velometer)

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

X 1. Survey instruments will be calibrated at least annually and following repair.

X 2. Calibration will be performed at two points on each scale used for radiation protection purposes, i.e., at least up to 1 R/hr.

The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10 percent of the calculated or known values for each point checked. Readings within ± 20 percent are considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings to within ± 10 percent. Also, when higher scales are not checked or calibrated, an appropriate precautionary note will be posted on the instrument.

3. Survey instruments will be calibrated

____ a. By the manufacturer

____ b. At the licensee's facility

(1) Calibration source

Manufacturer's name _____
Model no. _____
Activity in millicuries _____
or
Exposure rate at a specified distance _____
Accuracy _____
Traceability to primary standard _____

____ (2) The calibration procedures in Section I of Appendix D will be used

or

____ (3) The step-by-step procedures, including radiation safety procedures, are attached.

X c. By a consultant or outside firm

(1) Name Neil A. Gaeta

(2) Location 35 Grove St. Medford, MA 02155

(3) Procedures and sources

X have been approved by NRC and are on file in License No. 20-20743-01

____ have been approved by an Agreement State; a copy of the Agreement State license, the procedures, and a description of the sources are attached, and the consultant's report will contain the information on

____ the attached "Certificate of Instrument Calibration."
____ the consultant's reporting form as attached.

____ are described in the attachment, and the consultant's report will contain the information on

____ the attached "Certificate of Instrument Calibration."
____ the consultant's reporting form as attached.

Item 10

RADIATION SAFETY PROGRAM

This shall be equivalent to Appendices E, F, G, H, I, J and O or NUREG Guide 10.8. The consultant health physicist shall work with the licensee to provide these services.

1. SURVEY PROGRAM

1.1. The use of the sealed source in the bone mineral analyzer consists of placing the source in a fixed geometry position in the analyzer. Once it is in place, the shielding and beam direction cannot change unless the analyzer suffers some damage.

1.2. A detailed radiation survey will be performed with the source in a Lunar unit. The results of the survey will be normalized to a full strength 1500 mCi source. A decay curve will be provided so that the radiation levels for any source strength can be estimated.

2. RECORDS MANAGEMENT PROGRAM

2.1. Records of source receipt and transfer shall be kept for at least five years.

2.2. Records of leak tests of sealed sources shall be kept for at least five years.

2.3. Records of personnel exposure shall be kept indefinitely.

2.4. Records of source disposals shall be kept indefinitely.

2.5. Records shall be reviewed for completeness and accuracy semi-annually by the Radiation Safety Officer and the consultant health physicist.

3. LEAK TEST PROCEDURES

3.1. Leak tests shall be performed on sources in use every six months. The leak tests shall be able to detect 0.005 uCi of activity. Results of the leak tests shall be documented. Leak tests shall be performed according to the LUNAR procedures.

3.2. The consultant health physicist will provide the leak test analysis per his License No. 20-20743-01 (August '88).

4. PACKAGE RECEIVING AND OPENING PROCEDURES

4.1. The Gd-153 sources are also less than Type A quantities of radioactive material. Consequently, no radiation surveys are required on receipt of the package. When shipped from the manufacturer, the packages carry a WHITE-I radioactive label, indicating that radiation levels on the surface are less than 0.5 mR/hr.

4.2. Open the outer shipping container. Open the inner shipping container with the lead course capsule. Take and wipe the lead source capsule. The consultant H.P. will analyze the swipe to verify there is not removable contamination greater than 200 dpm/100 cm.

4.3. Verify the serial number on the source against the serial number on the shipping documents. Log the receipt of the source into the source receipt log.

4.4. Leave the source in the original shipping container until it is actually installed in the analyzer.

5. SOURCE REPLACEMENT PROCEDURES

Except during source exchanges, the Gd-153 sealed source will be in the Lanar DP3 Scanner. This Gd-153 source is contained in a lead lined source holder, Lunar Model DP3-A-SRC-0100-0. If necessary, the source will be temporarily stored in a lead container within the secure room area. The scanner is equipped with a locking device to maintain the security of the source while in the scanner.

6. SOURCE PACKAGING AND SHIPPING PROCEDURES

6.1. Place the source with the cap tightly screwed on in the foam insert from the original shipping container.

6.2. Place the foam insert in the original inner container (metal can) and tape the lid on the can with fabric-backed tape.

6.3. Place the metal can in the original outer shipping box and tape the box closed with security tape.

6.4. Remove old shipping labels, packing slips, and other old labels from the box. Make sure the words "RADIOACTIVE MATERIAL", "TAPE 'A' PACKAGE", "I.A.E.A. C.T.C-12B25", and the manufacturer's name and address are still clearly legible on the box.

6.5. Place two new RADIOACTIVE WHITE-I labels over the old ones on the box. Enter Gd-153 as the contents. Calculate and enter the activity of the source.

6.6. Place a shipping label on the box with the name and address of the facility shipped from and shipped to.

6.7. Write or stamp the words 'RADIOACTIVE MATERIAL, N.O.S." and "UN2982" on the box in letters at least 1/2" high.

6.8. Fill out the shipping papers for the shipment. The proper shipping name for the source is "Radioactive Material, N.O.S. (Gadolium-153)" and the proper classification is "Un2982".

7. INVENTORY REQUIREMENTS

7.1. An inventory of all sources in use and in storage shall be made every six months. Records of the semi-annual inventories shall be kept.

8. EMERGENCY PROCEDURES

Lunar has engineered their bone mineral analyzers to include safety precautions against accidental opening of the leaded shutter shielding the radioactive source.

The static state of the solenoid controlling the shutter is closed. A +12V dc signal must be applied to the circuit for any solenoid action, hence, disconnection of the AC power cable will de-energize the circuit and close the shutter. Disconnection of the interface cable will remove the "solenoid control" signal and de-energize the solenoid therefore closing the shutter.

The low energy gamma and x-rays emitted from the Gd-153 source are completely absorbed by the lead source holder.

9. DUTIES AND RESPONSIBILITIES

9.1. The authorized users and the consultant health physicist will be responsible for:

9.1.1 Receipt of sources received and logging in the source receipt log.

9.1.2. Storage of sources received in the radioactive materials storage area.

9.1.3. Source replacement in the Lunar Unit.

9.1.4. Packaging of sources for shipping and delivering to a carrier for shipment to the manufacturer.

9.1.5 Leak testing of sources in use over six months.

9.2. The Radiation Safety Officer and consultant health physicist will be responsible for the following:

9.2.1. Assuring that byproduct materials possessed under the license conform to the materials listed on the license.

9.2.2. Assuring that use of the device is only by individuals authorized by the license.

9.2.3. Assuring that all users wear personnel monitoring equipment when required.

9.2.4. Assuring that the sources are properly secured against unauthorized removal at all times when not in use.

9.2.5. Serving as a point of contact to give assistance in case of an emergency, and assuring that proper authorities are notified in case of an emergency.

9.2.6. Assuring that the terms and conditions of the license are met and that required records are periodically reviewed for compliance with NRC regulations and license conditions.

Item 11

WASTE MANAGEMENT

1. Sources that have decayed below an acceptable level will be removed from the bone mineral analyzer and stored in a locked storage area.

2. The storage area will be posted with a "CAUTION - RADIOACTIVE MATERIALS" sign.

3. When sources are transferred to the source manufacturer for final disposal, the disposal shall be noted on the receipt/disposal log.

4. Sources will be returned to the manufacturer in the original shipping containers. The requirements of 10 CFR 49 shall be followed with regards to packing, labelling, marking, and surveying of the package and filling out the shipping documents.

5. In the event the manufacturer is no longer in business, or for other reasons cannot accept the source, alternative waste disposal will be sought.

FROM DIRECTIVE FC 83.24

Recommended Medical Users Training for Lixiscope
and Bone Mineral Analyzer Diagnostic Devices

TRAINING BY N.GAETA ON JAN. 18 & 25, 1986

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

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

Group B - Radiation Biology (3 hours)

1. Acute and chronic exposures
2. Somatic and genetic effects
3. Basis of Maximum Permissible Dose
4. Typical Somatic effects at various dose levels
5. Genetic effects and Genetically Significant Dose
6. Factors Affecting Biological Damage (dose, dose rate, type of radiation, type of tissue, amount of tissue, biological variation and chemical modifiers)

Group C - Radiation Protection (2 hours)

1. Principles of Radiation Safety and ALARA Management Program
2. "Standards for Radiation Protection" 10 CFR Part 20 and "Instructions to Radiation Workers" 10 CFR Part 19, and Equivalent Agreement State Regulations
3. License Conditions for Radiation Safety Program
4. Radioactive Shipment Receiving, Opening, Handling, Storage and Security Procedures
5. Radiation labels and required posting and documents
6. Routine proper use, inventory and accountability procedures for sealed sources, or devices containing sealed sources
7. Leak Test of Sealed Sources and Contamination Control
8. Shipment Returns, DOT Regulations and Supplier Instructions and Forms
9. Radiation Detection Instrumentation
10. NRC Draft Regulatory Guide "Instruction Concerning Radiation Exposure" dated May 1980 and NRC Regulatory Guide 8.13 "Instructions Concerning Prenatal Radiation Exposure" dated November 1975
11. Title 10 CFR Part 35 "Medical Use of Radionuclides" and NRC Regulatory Guide 10.8 Procedures and License applications
12. Radiation Safety References, NCRP and ICRP Publications
13. Review and discussion of the sealed source "device specific" manufacturer literature and instructions

030222162

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: Women's Health Care

Application Dated: 12/17/85

Control No.: 104906

License No.: New

2. FEE ATTACHED

Amount: $580.00

Check No.: 004953

3. COMMENTS

Signed Brenda Pilatchak

Date 1/15/86

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 7C ($580)

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

Amendment _____

Renewal _____

License ✓

Signed L Jackson

Date 1/25/86

GION I FORM 213
ARCH 1983)