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Amount Fee Category 3.120
Type of Fee 1 Cam
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THE UNIVERSITY OF CHICAGO
RADIATION PROTECTION SERVICE
5841 SOUTH MARYLAND AVENUE
CHICAGO · ILLINOIS 60637
(312) 962-6299

January 22, 1986

RECEIVED
JAN 27 AM 8:03
REGION III
TECHNICAL BRANCH

Materials Licensing Section
Region III, Nuclear Regulatory Commission
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Re: License 12-509-3

Gentlemen:

We respectfully request that by-product material license 12-509-3 be amended to provide for an additional dual photon bone densitometer containing up to 1.5 curies of gadolinium-153. An increase in the possession limit from 1.5 curies to 4 curies of gadolinium-153 is requested. This level of authorization will permit short term possession of replacement sources awaiting installation and spent sources awaiting disposition.

The densitometer is manufactured by Nuclear Data, Inc. Schaumburg, Illinois, as model ND 2100 and contains a Gulf Nuclear model GD-1 source, or Amersham Corp model GDC.CY1 source, or New England Nuclear Corp models NER-430/431 gadolinium-153 source. The densitometer is designed so exposure to the source is impossible under normal conditions of use. The densitometer has been evaluated by NRC and found to be acceptable for general use. A copy of the NRC evaluation of this densitometer is enclosed. The unit will be operated in accord with all conditions specified in the NRC evaluation.

The unit will be used in a clinical service to assess bone mineral content in the spine in peri- and menopausal women to screen for Osteopenia and Osteoporosis. The unit may also be used for demonstration purposes on humans only to the extent that authorized observers may be present while routine clinical assessments are in progress; demonstrations involving exposure to humans solely for the benefit of observers will not be permitted.

a. Training.

The approved user of the device has had training covering radiation physics and instrumentation (3 hours), Radiation protection (2 hours), and radiation biology (3 hours) in accord with NRC requirements. The user will be instructed in the proper operation of the unit including a detailed description of the unit and the function of the safety devices. This training will include actions to be taken in case of possible emergencies and their responsibility to report promptly any condition that may lead to exposure to radiation or radioactivity from the source. We believe these subjects are commensurate with potential radiological health protection problems associated with the irradiator.

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b. Emergencies.

If leakage is suspected, the immediate area will be evacuated. Radiation Protection and security will be notified immediately.

In case of fire, the fire alarm will be activated and Radiation Protection will be notified immediately. If appropriate, a fire extinguisher may be used.

If tampering by unauthorized personnel is suspected, Radiation Protection, and the Security Dept will be notified immediately.

In case of an electrical power failure, the shutter that exposes the source is automatically closed by a spring.

c. Maintenance.

No maintenance will be attempted without written instructions from the manufacturer and approval of Radiation Protection. The door to the room in which the densitometer is located will be locked when unattended.

d. Survey instruments.

Calibrated survey instruments are available and can be provided by Radiation Protection Service when needed. Assistance from Radiation Protection Service is available whenever required.

e. Maintenance and interlock tests.

Maintenance will not be attempted without approval of Radiation Protection. Interlock testing and leak testing will be done by Radiation Protection according to the manufacturer's recommended procedures. Results of maintenance, interlock tests, leak tests, and unusual occurrences will be recorded in a log book.

f. Leak tests.

Radiation Protection will make the necessary leak tests initially and at six month intervals thereafter. If the manufacturer prefers to conduct the tests, such tests will be done in the presence of representatives of Radiation Protection Service.

g. Security.

The door to the densitometer room will be locked at all times when the room is unoccupied for long periods of time and when the clinic is closed. Only the approved user will have keys required to operate the unit.

h. Source exchange

The source will be exchanged by the manufacturer or the manufacturer's representative in the presence of Radiation Protection Service personnel or by Radiation Protection personnel in strict accord with the manufacturer's directions.

i. Source disposal

Decayed sources will be returned to the manufacturer or disposed as radioactive waste according to approved waste disposal procedures described in the original application for the subject license.

j. Personnel monitoring devices

Film badges will be issued monthly for the first three months of use. If the cumulative exposures are less than 25% of the radiation protection guides shown in 10CFR20.101, personnel monitoring may be discontinued since such monitoring is not required by 10CFR20.202(a)(1).

k. Location of use

The densitometer will be located in Chicago Lying-in Hospital, 5815 Maryland Avenue. This hospital is part of the University of Chicago Hospitals and Clinics.

Please note that the Committee on Radiation Hazards has approved the use with the following conditions.

1. Radiation Protection Service will be present during installation and maintenance procedures.

2. Radiation Protection will make a survey of the area in which the device is located, record the results, and post any signs required.

3. The applicant is prohibited from conducting any maintenance on the device which might expose the source.

4. Radiation Protection Service will regularly monitor the area in which the irradiator is located. We believe quarterly monitoring is adequate for this type of device.

Enclosed is a University of Chicago check #20322 for $120 to cover the license amendment fee for category 3E as specified in 10CFR170. We trust these procedures are satisfactory and will be glad to provide any further information you may need to grant our request.

Sincerely,

E. W. Mason
Director

encl

pc w/o encl: Nathan Sugarman
Dr. Frank Fitch
Walter Massey

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: NR-495-D-102-S DATE: SEP 26 1985 PAGE: 1 of 6

DEVICE TYPE: Bone Density Scanner

MODEL: ND 2100

DISTRIBUTOR:

Nuclear Data, Inc.
Instrumentation Division
Gulf and Meacham Roads
Schaumburg, IL 60196

MANUFACTURER:

Molesgaard Medical
Rungsteduej 13
Dk-2970 Horsholm
Denmark

SEALED SOURCE MODEL DESIGNATION: Gulf Nuclear Model GD-1 or Amersham Corp. Model GDC.CY1 or New England Nuclear Model NER-430 or NER-431

ISOTOPE:
Gadolinium-153

MAXIMUM ACTIVITY:
1.5 curie

LEAK TEST FREQUENCY: 6 months

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

CUSTOM DEVICE: _____YES ___X__NO

CONTROL NO. 80552

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: NR-495-D-102-S DATE: SEP 26 1985

DEVICE TYPE: Bone Density Scanner

DESCRIPTION:

The ND2100 Spine Scanner is an instrument which can perform scans of the lumbar region of the spine as well as the neck of either femur. This instrument is based on one which was developed at the University of Washington, Seattle.

The ND2100 is a complete system consisting of mechanical, electrical, computer, display, reporting and software components. Each of these components are described in the following sections.

ELECTRICAL AND MECHANICAL SYSTEM COMPONENTS SCANNER TABLE

The scanner table consists of a bed which the patient lays on in the supine position. Attached to the bed is a computer controlled scanning arm which holds the radiation detector (above the patient) and the radiation source (below the patient) as well as motors, etc., which move the arm over the scanning area. Manual controls, on the face of the scanning arm, facilitate patient (and scan arm) positioning. The table is mounted on wheels for ease of placement in the lab or clinic. The radiation source is contained in a lead-lined stainless steel holder with a fail-safe shutter mechanism plus a keyed lock to prevent unauthorized use of the instrument.

DATA ACQUISITION AND CONTROL ELECTRONICS MODULE

This module is a microprocessor-based control unit, which controls the scan, based on parameters from the main computer. It also contains all the necessary data acquisition electronics for the system.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: NR-495-D-102-S DATE: SEP 26 1985 PAGE: 3 of 6

DEVICE TYPE: Bone Density Scanner

DESCRIPTION (CONTINUED):

SOURCE, SOURCE HOLDER AND DETECTOR

The radiation source used in this system is a 1 Curie Gadolinium-153 (GD-153) source which emits gamma rays at two different energy ranges; 44 keV and 100 keV. The skin dose incurred, by the patient, during a typical scan of 20-40 minutes, is approximately 12 mRad.

The physicians or technician who will be scanning patients for 40 hours a week, 13 week a quarter, will receive an exposure of less than 40 mRem/quarter. This exposure assumes the operator will be working 100 centimeters from the Gd-153 source and will be scanning (i.e., the source will be on) constantly.

The source is placed in the source holder below the bed of the scanning table. The source holder contains a computer controlled shutter which, when open, allows the radiation to "shine" through a collimator. The shutter is disabled via a keyed lock on the system, which prevents unauthorized scanning of a patient. The shutter is held in the closed position by a spring. In the event of power failure the shutter automatically closes.

Directly opposite of the source is the detector, a common NaI(TI) crystal, attached to a photomultiplier tube.

SYSTEM COMPONENTS

A red light flashes at the control console to indicate an open shutter. Futhermore, a computer prompt tells the user when the shutter is open.

LABELING:

The device is labeled in accordance with 10 CFR 20.203. Additionally the user's manual contains a statement and drawing that outlines the possible radiation area the source holder moves through.

DIAGRAM:

See Attachments 1 and 2.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: NR-495-D-102-S DATE: SEP 26 1985 PAGE: 4 of 6

DEVICE TYPE: Bone Density Scanner

CONDITIONS OF NORMAL USE:

The ND2100 is a clinical tool for making a non-invasive in-vivo measurement of an individual's bone mineral content (BMC). It is subjected to controlled environs. It measures the BMC in the critical areas of the lumbar spine and the femur neck. Determining the BMC in these sensitive areas allows accurate diagnosis of a patient's bone loss due to aging, osteoporosis or other related bone disease. The manufacture estimates the useful life of the source to be 18 months.

PROTOTYPE TESTING:

The unit is constructed of 8 mm lead aluminum plate with a lexan table top. The approved sources are further protected by a lead-lined stainless steel source holder. The manufacturer did not perform any testing on the device but relied on the source ANSI classification which was augmented by the source holder and device frame and the unlikelihood of an accidental situation such as fire to demonstrate integrity of the device.

EXTERNAL RADIATION LEVELS:

The manufacturer reports that an operator of the device would not receive an exposure greater than .08 mRem/hr based on a 40-hour constant use work week. The manufacturer provided the following dose rates, in mRem/hr around the scanner using various angles above the table.

ANGLE (degree)	Without Phantom			With Phantom	
	5 cm	30 cm	100 cm	30 cm	100 cm
0	1.5	0.090	0.015	0.090	0.015
45	7.6	0.070	0.018	0.059	0.012
135	6.0	0.070	0.018	0.060	0.015
180	4.2	0.100	0.015	0.090	0.012

CONTROL NO. 80552

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: NR-495-D-102-S DATE: SEP 26 1985 PAGE: 5 of 6

DEVICE TYPE: Bone Density Scanner

QUALITY ASSURANCE AND CONTROL:

The manufacture states that their Quality Assurance program is designed on the military specification MIL-Q-9858A. Futhermore, the program meets FDA's 21 CFR 820 Subpart J manufacturing protective requirements. All devices are checked for removable contamination prior to shipment to the end users.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- Model ND2100 bone scanner is acceptable for licensing for distribution pursuant to Section 30.33, 10 CFR Part 30 and Section 35.13, 10 CFR Part 35 or equivalent regulations of an Agreement State.
- Reviewer Note: Nuclear Data, Inc. does not install the source into the holder or into the bone scanner. The sources are usually sent directly from the source manufacturer in the source holder to the user. The installation of the source and source holder is the responsibility of the user. Furthermore, any service done on a source holder or a device containing a source will have to be performed by persons specifically licensed by the NRC or an Agreement State. The source holder has a collimator that the user can change. The manufacturer has provided instructions to person of the task. The manufacturer estimates a dose less than 1 mRem received during this procedure.
- The source shall be leak tested at six (6) month intervals using techniques capable of detecting 0.005 microcurie of removable contamination.
- This registration sheet and the information contained within the references shall not be changed or transferred without the consent of the NRC.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: NR-495-D-102-S DATE: SEP 26 1985 PAGE: 6 of 6

DEVICE TYPE: Bone Density Scanner

SAFETY ANALYSIS SUMMARY:

The Model ND2100 is to be used by trained and specifically licensed personnel to measure the bone mineral content of the spine of patients. The manufacturer calculated a approximate patient dose of 12 millirem per scan.

The device is used in clinical diagnostic laboratories and the most probable environmental hazard the source would encounter is fire. The sources has been tested in accordance with American National S andard Institute requirements for medical use. Futhermore, the source is enclosed within a stainless steel source holder, it could be expected to maintain containment integrity for normal and accident conditions applicable to the uses specified in this certificate.

Based on our review of the information and test data contained in the references cited below. We conclude that the Model ND2100 bone density scanner is acceptable for licensing purposes.

REFERENCES:

The following supporting documents for the Nuclear Data Model ND2100 Bone Scanner are hereby incorporated by reference and are made a part of this registry document.

- Nuclear Data, Inc. letters dated May 9, 1985, June 7, 1985, and September 4, 1985 with enclosures thereto.

ISSUING AGENCY:

U. S. Nuclear Regulatory Commission

DATE: SEP 26 1985 REVIEWER: Steve Baggett

DATE: SEP 26 1985 CONCURRENCE: Stuart W Bell

CONTROL NO. 80552

V/M

NOTE TO: License Fee Management Branch, ADM

FROM: Region III

SUBJECT: VOIDED APPLICATION

Control Number 380553

Applicant Univ. of Chicago

Date Voided 2/27/86

Reason for Void Combined with Control No 380552 after review

Signature W. Adam

Attachment:
Application

OK LFMS

Jan 24 III
80553
7C
No refund after review

RECEIVED MAR 7 1986
CHECKED MAR 7 1986