WELL CARE CENTER



October 15, 1985



John Glenn, Ph.D.
Material Licensing Branch
Division of Fuel Cycle and Material Safety
US Nuclear Regulatory Commission
Region I, 631 Park Avenue
King of Prussia, PA 19406

RE: Amendment of NRC License #37-20873-01
Docket #030-21285

Dear Doctor Glenn:

I would like to amend our license to obtain and use an Osteon Analyzer for bone mineral analysis. This is to be purchased from Osteon Incorporated, P.O. Box 430, 649 California Avenue, Wahiawa, Hawaii, 96786. This equipment, Osteon Analyzer Model #SPSHA 110, is manufactured by Osteon Incorporated. It has been approved by the Nuclear Regulatory Commission for general medical use under NRC Certificate #NR-525-D-101-S.

We are requesting permission to possess the maximum of two (2) sealed sources, each having an activity equal to 800 mCi of I-125 for use with the bone densitometer described above.

Enclosed is a copy of the Custom Device Certificate supplied by Osteon Inc. Enclosed you will also find a check for $120.00 to cover the amendment fee.

If you need any further information, please do not hesitate to contact me.

Very truly yours,

William Donofrio

William Donofrio



ENCLOSURES (2)

WD/ejs



*We care about your Health*
624 Lysle Blvd., McKeesport, PA 15132
412-672-9611

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-525-D-101-S DATE: APR 04 1985 

DEVICE TYPE: Bone Mineral Analyzer (Osteo-Analyzer)

MODEL: SPSHAXXX (XXX indicates the unit has been wired for 110 V AC or 220 V AC)

MANUFACTURER/DISTRIBUTOR: Osteon, Inc.
P.O. Box 430
649 California Avenue
Wahiawa, HI 96786

SEALED SOURCE MODEL DESIGNATION: AECL Source Model Number C-235, in a Model C-236 source holder

ISOTOPE: Iodine-125

MAXIMUM ACTIVITY: 800 millicuries

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (V) General Medical Use

CUSTOM DEVICE ____ YES __X__ NO

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DEVICE TYPE: Bone Mineral Analyzer (Osteo-Analyzer)

DESCRIPTION:
The Osteo-Analyzer is a three axis scanning bone densitometer, using an AECL Mo. C-235 I-125 source in a C-236 holder. The Osteo-Analyzer is fabricated entirely of machine aluminum and stainless steel, with ball bearings and stainless steel shafts used for major bearing surfaces.

The C-236 source holder is held in the lockable source compartment of the yolk, a welded aluminum piece that maintains proper orientation with the detector during all motion. The source is screwed to position in the source compartment, then locked in place with a locking cover to present loss or unauthorized removal of the source.

The shutter blocks the exit beam during all times that scanning is not being performed. The shutter is designed to close automatically upon loss of power to the scanner.

LABELING:
The C-236 source holder manufacturer by AECL is engraved with the manufacturer, isotope, source holder model, and source serial number.

The Osteo-Analyzer will have a warning label on the outside of the case. The source compartment will be marked with the standard warning symbol and the words "Caution-Radioactive Material." The beam direction will also be shown on the yolk. (See Attachment No. 1.)

DIAGRAM:
See attachments 2,3, and 4.

CONDITIONS OF NORMAL USE:
The Osteo-Analyzer will be used by physicians or hospitals under a specific license issued by NRC or Agreement State for the device. The analyzer will be secured in the office or room used for the storage and use of the analyzer.

Under normal conditions, the user will not need to remove the cover to the analyzer, except to change sources. The sources are expected to last 60-90 days before replacement is necessary.

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DEVICE TYPE: Bone Mineral Analyzer (Osteo-Analyzer)

PROTOTYPE TESTING:
The manufacturer did not test the device, rather, they relied on data submitted on each electronic part and its use to make a determination that the device would operate under the given conditions of use. Additionally, the sources were tested by the source manufacturer to the requirements of ANSI N542 and received the classification of 77C34334. The source holder is constructed of lead-lined stainless steel. This would further protect the source during normal and accidental conditions associated with the use of the device.

EXTERNAL RADIATION LEVELS:
The time period necessary for the patient to receive a dose of 10 mR is about 3 seconds at any one location, based on the calculated dose rate to the skin of 3.8 Rem/Sec. Since the beam is tightly collimated to 3 mm and is constantly moving, only a portion of the skin is exposed at any one time.

With the 800 mCi source, the scan speed is 4 mm/Sec, resulting in an exposure period to any portion of the skin of 0.75 Sec. Such an exposure period will result in an exposure to the skin of 2.85 mRem. Ostean reports that a dose rate of .001 mR/hr is obtained on any surface of the analyzer with the shutter closed, and reported 1 mR/hr at 3 cm from the device with the shutter open.

QUALITY ASSURANCE AND CONTROL:
The following items will be tested for proper operation on every unit:

- Operation of shutter mechanism, including fail-safe provision in case of power failure.
- Fit of source holder (C-236) to source compartment and fit of locking cover over source.
- Source-on indication or computer display when the source is actually on.

The checks shall be part of a final test/QC program developed for testing the Osteo-Analyzer results on the tests shall be documented for each unit.

Checks for removable contamination will be made on each unit before shipment to the user. The check will be capable of detecting 0.005 microcurie of removable contamination.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
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NO.: NR-525-D-101-S DATE: APR 04 1985 

DEVICE TYPE: Bone Mineral Analyzer (Osteo-Analyzer)

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The Osteo-Analyzer scanning bone densitometer shall be distributed only to persons specifically licensed by the NRC or an Agreement State.
- The device shall be leak tested at six (6) month intervals using techniques capable of detecting 0.005 microcurie of removable contamination.
- The device shall be installed and initially tested for proper operation of the source exposure mechanism, safety warning mechanism, safety warning components, labels, external radiation levels (source exposed, source shielded) and leak tested by Ostean, Inc., or other persons specifically licensed by the NRC or an Agreement State.
- Reviewer Note: Ostean recommends the user remove and install the source in the source holder only. However, the user may request authorization to install the source in the source holder.
- This registration sheet and the information contained within the references shall not be changed or transferred without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:
Based on our review of the information and test data cited below, the device is equivalent to those previously deemed acceptable for licensing, we conclude that the Model SPSHAXXX Osteon bone mineral analyzer design is acceptable for licensing purposes.

Furthermore, we conclude that this device should be accepted to maintain its containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REFERENCES:
The following supporting documents for the bone mineral analyzer (Osteo-Analyzer) are hereby incorporated by reference and are made a part of this registry document:

- Osteon, Inc. letters dated on January 15, 1985, and February 20, 1985.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-525-D-101-S DATE: [illegible] PAGE 5 of 5

DEVICE TYPE: Bone Mineral Analyzer (Osteo-Analyzer)

ISSUING AGENCY:
U.S. Nuclear Regulatory Commission

DATE: APR 04 1985 REVIEWER: _____

DATE: APR 01 1985 CONCURRENCE: Joseph M. Brown Jr.

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: Well Care Center

Application Dated: 10/15/85

Control No.: 104521

License No.: 37-20873-01

2. FEE ATTACHED

Amount: $120.00

Check No.: 2401

3. COMMENTS

02201
10/90

Signed Brenda Platchek

Date 10/18/85

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 7C - $120

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

Amendment _____

Renewal _____

License _____

Signed _____

Date 11/4/85

REGION I FORM 213
(MARCH 1983)

"SECTION COPY"

WILLIAM DONOFRIO
624 LYSLE BLVD.
MC KEESPORT, PA 15132

2401

10-15-1985

8-12
430

PAY TO THE ORDER OF U.S. Nuclear Regulatory Comm. $ 120.00

One Hundred Twenty & 00/100 — DOLLARS

Union National Bank
The Union National Bank of Pittsburgh
Pittsburgh, PA

MEMO

William Donofrio

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