PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRA. .ING AND EXPERIENCE OF ABOVE NAM 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		
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			

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

6 hours - Aug. 1st and 2nd , 1985

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
David M. Player

b. NAME OF INSTITUTION
Beta Diagnostics, Inc.

c. MAILING ADDRESS
7540 Louis Pasteur Drive, Suite 100

d. CITY
San Antonio, Texas 78229

5. MATERIALS LICENSE NUMBER(S)
Texas License #

6. PRECEPTOR'S SIGNATURE
David M. Player MD

7. PRECEPTOR'S NAME *(Please type or print)*
David M. Player

8. DATE
Aygust 6, 1985

NRC FORM 313M SUPPLEMENT B
(9-81)

460954

GPO 880-818

Beta Osteoporosis Diagnostic Centers
Of America™ OKLAHOMA CITY, OKLA.

February 7, 1986

Mr. Jack Whitten
U.S. Nuclear Regulatory Commission, Region IV
611 Ryan Plaza Drive, Suite 1000
Arlington, Texas 76011

Dear Mr. Whitten:

Please accept this letter as a formal request to amend my materials license #35-23173-01 to include use and overnight storage of the bone densitometer, Norland N2740, at two temporary-use subsites. The instrument will be used and maintained as per all conditions pertaining to the license conditions and the manufacturer's recommendations. Letters from the administrators of each facility granting permission to perform bone densitometry studies, as well as diagrams of each facility and source-use areas designated, are enclosed for your review. Also included is a letter from the Medical Quality Coordinator of Beta Diagnostics, Inc. regarding the transportability of the instrument, and the specific safety procedures which will be followed during use of the instrument at the temporary-use subsites. The two subsite facilities are listed below:

1) Stillwater Medical Center
P.O. Box 2408
1323 W. 6th Street
Stillwater, Ok. 74075

2) Clinton Regional Hospital
100 N. 30th Street
Clinton, Ok. 73601

If there is anything that I may be of assistance in, or if there are any questions that I can clarify, please let me know.

Sincerely,

B.J. Matter, M.D.
Radiation Safety Officer

enclosures:
BJM:sao

Applicant Ltr. 3 IV
Check No. 136 (Beta Diagnostics (Caitlin))
Amount/Fee Category $120 (2C)
Type of Fee ANMD
Date Check Rec'd 2/27/86
Received By SH

BETA DIAGNOSTICS, INCORPORATED

October 14, 1985

Mr. Jack E. Whitten
U.S. Nuclear Regulatory Commission, Region IV
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

Dear Mr. Whitten:

The Norland 2780/2740 is a single-photon bone densitometer used to monitor early bone mineral loss by measuring appendicular bones of the forearm. There are well over 600 units in the United States and around the world, with a dependability record unmatched by any other manufacturer of similar products. These instruments are portable and have an excellent record of maintaining precision and accuracy even after thousands of miles of travel as in the case of the units used for demonstrations. Calibration is routinely performed on a weekly basis with precision and accuracy standards maintained to within 1% of know calibration values. The rugged steel frame design and the solid state electronics enable the instrument to be transported with no effect on instrument function.

If I can be of any further assistance to you, please contact me at (512-690-1548).

Sincerely,

Jeff Weix
Medical Quality Coordinator

~~8607290379~~

2pp.

7922 Ewing Halsell, Suite 100, San Antonio, TX 78229 • (512) 690-1548

BETA DIAGNOSTICS, INCORPORATED

SPECIFIC SAFETY PROCEDURES FOR ISOTOPE TRANSPORT

THE SPECIFIC SAFETY PROCEDURES ARE AS FOLLOWS:

1) Upon transport of the source and the bone densitometer, the I-125 source capsule will be removed from the scanner unit and secured within an approved D.O.T. shipping container and carton. Proper hazardous materials labels will be applied, and a GM survey meter will accompany the source for minitoring purposes. The source will be monitored before and after each transport for radiation levels.

2) The source will be secured in an automobile, and will be transported directly to the temporary-use subsite facility.

3) Strict documentation as to the source, date of last leak test, model and serial number, as well as source activity are maintained in our facility files for reference when needed. All source receipt and return verifications are documented and completed as per established procedures of Beta Diagnostics, Inc., and per the manufacturer's recommended guidelines.

4) Scanner operation after each transport is evaluated per established quality assurance procedures of the manufacturer as well as those procedures established by Beta Diagnocstics, Inc. After transport of the bone densitometer, the instrument is programmed for a series of scans on a calibration phantom with calibrated known values. Precision and accuracy standards are calculated and are to be within 1% of the known values. If fluctuation in the values occurs, the instrument is recalibrated to adjust the precision and accuracy.

5) No I-125 source will be held or utilized for a period of 6 months. Isotopes in our facility are rotated on a 5 month basis with the spent source being returned to the distributor per D.O.T. standards. In the event that a source is held for a period of 6 months, a leak test will be performed utilizing a certified leak test kit provided by Health Physics, Inc. of Potomac MD., and will be returned for documented evaluation of radiation levels.

6) The bone densitometer will be operated by a trained absorptiometrist under the direct supervision of the Radiation Safety Officer. Any scan to be performed in a subsite location will occur only after a physician has granted approval for the scans to be performed. The absorptiometrist performing the scans has attended a formal training session in San Antonio, TX provided by Beta Diagnostics, Inc., as well as continued training in the facility by a certified installation and training specialist of Norland Corporation, Ft. Atkinson, Wisc.

460954

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