BETA
DIAGNOSTICS,
INCORPORATED

September 30, 1985

Evelyn R. Matson
U.S. Nuclear Regulatory Commission Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Ms. Matson:

This letter is in response to the NRC's request for additional information regarding transport of the bone densitometer. The purpose of transporting the instrument to the two locations is to provide bone densitometry services on-site for those patients on chronic hemodialysis and related therapies. As requested in your letter of September 3, 1985, I will address each question separately.

1) Upon transport of the bone densitometer, the I-125 source will be removed from the scanner unit and secured within an approved DOT shipping container and carton. A GM survey meter will accompany the isotope and will be used to monitor radiation levels before and after transport.

2) The isotope and bone densitometer will be secured in the rear of the automobile (trunk area) with the key being maintained by the absorptiometrist under my direct supervision to prevent any unauthorized removal during transport. The isotope will be transported directly to each subsite location without delay. In the event of an unforseen accident, the survey meter will be utilized to monitor for any possible radiation emission. The DOT shipping container as well as the shielded brass source capsule are well documented to withstand even adverse handling during transport. As the source capsule is well cushioned within the DOT container, any impact would be of an indirect nature to the capsule itself.

We maintain strict and consise records of all isotopes used in the bone densitometer for patient scanning. In the event of the loss of the licensed material, the NRC Region III as well as Beta Diagnostics, Inc. would be notified. Beta Diagnostics, Inc. provides the I-125 source through AECL and also receives the spent sources for shipment back to AECL. All documentation as to the isotope, date of last leak test, model and serial number, as well as source activity are maintained in the event of loss of the licensed material.

3) Scanner operation after each transport is evaluated on a routine basis as per established quality assurance guidelines of the manufacturer as well as those procedures established by Beta Diagnostics, Inc. After transport of the instrument a series of scans is performed on a calibration phantom to monitor precision and accuracy of the instrument. Improper function of the device would result in erroneous

License Fee Information
on Next Page

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

values and therefore would not be used on a patient until the correct calibration standards had been satisfied. Precision and accuracy standards are maintained within 1% for patient scanning.

Please also find enclosed a letter from Mr. Jeff Weix of Beta Diagnostics, Inc. as to the transportability of the instrument, and its reliable function after years of tested operation and transport.

4) No I-125 source will be used in our facility for a six-month period. All isotopes are rotated on a five-month basis through Beta Diagnostics, Inc. in Ft. Atkinson, Wisconsin. In the event that a source is held for a period of six months, a leak test consisting of wet and dry samples will be obtained using an approved leak test kit provided by Health Services, Inc., of Potomac Maryland. All samples will be monitored for radiation levels and then sent to Health Services, Inc. for documented evaluation.

If there are any further questions or clarifications needed, please let me know.

Sincerely,

Joan C. Stryker, M.D.

Joan C. Stryker, M.D.
Professor
Department of Obstetrics
and Gynecology
Wayne State University
School of Medicine

enclosures

JCS/jw

addl info

FEE EXEMPT
Ta CN 9118

RECEIVED BY LFMB
Date 10/15/85
Log Oct 17th
By
Orig. To R/W
Action Compl. CJ

CONTROL NO. 79913