FEB 20 1987

Miami Valley Hospital
Department of Nuclear Medicine
ATTN: Dr. Ruegsegger
1 Wyoming Street
Dayton, OH 45409

Dear Dr. Ruegsegger:

We have reviewed your letters dated May 6, 1986 and July 28, 1986 requesting an amendment to License Number 34-00341-06 and find that we will need additional information as follows:

1. Please provide a model number for the gamma ray computed tomography scanner to uniquely identify the device. This is necessary for automated tracking and retrieval purposes.

2. Provide a diagram and description of the entire device. Include the following:

   a. Dimensions.

   b. Construction material.

   c. Shutter operation.

   d. On-off indicators.

   e. Interlocks or guards.

   f. Any computer controlled safety related operations (shutter status displayed on terminal screen, etc.)

   g. Location and construction material of labels. Confirm that the label will contain the radioactive material trefoil symbol.

3. Your letter dated July 28, 1986 states on Page 2 that the sealed source activity is two curies per source. However, on Page 3 you describe the label which states the maximum activity is one curie. Please state clearly the maximum activity of iodine-125 that will be placed in the device and confirm this information will be on the device label.

4. The radiation profile that was submitted for a similar device is acceptable, however, you must demonstrate that the geometry between the devices is the same.

5. Describe the dose rate from the source holder, the length of time for patient scans and any other parameters affecting patient dose.

6. Describe the radiation fields and the amount of time involved when an individual performs a source exchange.

7. Describe the dose rate around a completed device and submit calculations showing the expected dose to the device operator.

8. Please specify the tests that will be performed on the finished custom device to verify that the device meets specifications furnished to the NRC. As a minimum, the tests should include those listed below. Specify the name(s), training and experience of the person(s) who will perform the test; and a description of the procedures and equipment to be used for performing the tests. Please confirm that copies of the test results on the custom device shall be maintained for inspection by the Commission.

   a. Radiation profiles (isodose curves, for example, dose rates at 5 cm, 30 cm, and 100 cm.) of the custom device with shutter(s) and/or beam control mechanism(s) in both the (1) open ("on") and (2) closed ("off") positions. Radiation levels should be measured using the maximum activity of each kind of radioactive material to be used in the device.

   b. Visual or other quality control inspections to determine if cracks, voids, or other manufacturing defects exist.

   c. Shutter or other "ON"-"OFF" beam control operations.

   d. Leak tests for radiation leakage or contamination prior to use.

   e. Other Tests: Specify any additional tests to be done on the finished custom device to verify that the device can be operated safely with minimum radiation hazard.

9. Provide the procedures and/or instructions given to operators on how to operate the device and perform a leak test.

10. Describe how you will ensure that the set screw which appears to hold the source in place is not over tightened. For example, the set screw may have a teflon tip and/or may be secured at a given torque specification.

11. Recent experience involving this sealed source design has raised concern about moisture coming into contact with the source causing a galvanic reaction that corrodes the source capsule leading to leakage of iodine-125. Please describe what precautions you will take to prevent this from occurring. This may include something in the nature of the device's design and/or written procedural instructions to users.

12. If two or more of these devices are to be built, submit evidence that you have notified the Food and Drug Administration and obtained any necessary approvals for using a custom made device for the treatment of humans. FDA requires premarketing approvals, i.e., 510K or equivalent. If only your device is to be built, please so state. FDA approval is not required for one device.

13. Clearly state which institution (and which NRC license) will be responsible for performing device installation, relocation, repair, maintenance, source exchange, etc.

14. Describe the procedures and safety precautions that will be followed when handling the sealed source during servicing operations. Procedures should include steps to be taken to reduce personnel exposure, steps to ensure the device specifications are not changed and that the device shutter mechanism operates properly following servicing.

15. Describe the training and experience that Dr. Hangartner has with similar devices and with sealed sources containing radioactive material. Include the approximate number of hours of training he has received in the following topics and where the training was obtained:

    a. Principles and practices of radiation protection.

    b. Radioactivity measurements, and monitoring techniques.

    c. Mathematics and calculations basic to radioactivity.

    d. Biological effects of radiation.

    Describe the radionuclides with which he has experience, the maximum quantities, duration of experience and type of use.

16. Confirm that the device will be used only on patients for which there is a medical need to evaluate bone density.

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16. Confirm that the device will be used only on patients for which there is a medical need to evaluate bone density.

17. Provide the names of the physicians who will use or supervise the use of the device. If a physician is not currently authorized for one or more of Groups I though VI, submit a description of their training and experience with radioactive materials.

If you have any questions or require clarification on any of the information stated above, you may contact us at (312) 790-5625.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 81304.

Sincerely,

Bruce L. Mallett for

Evelyn R. Matson
Materials Licensing Section

BG for

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

FACSIMILE SERVICE REQUEST

DATE 2/3/87

"PLEASE USE DARK PEN WHEN FILLING OUT & REMOVE ALL STAPLES

MESSAGE TO: Dixie Mattson

CITY & STATE Rg III

TELECOPY NUMBER _____

VERIFICATION NUMBER _____

NO. OF PAGES 4 EXCLUDING COVER SHEET RETURN COPIES YES ( ) NO ( )

MESSAGE FROM: Steven Baggett

TELECOPY NUMBER _____ RAPIFAX AUTOMATIC

301-427-4403 3M VRC AUTOMATIC

VERIFICATION NUMBER 301-427-4072

___ BUILDING WILLSTE OFFICE PHONE _____ MAIL STOP _____

CLASS OF SERVICE _____ OVER NIGHT ____ 4 HOUR ____

_____ 1 HOUR ____ IMMEDIATE

3 FEB 87 9:30