MVH Miami Valley Hospital One Wyoming Street 513/223-6192
Dayton, Ohio 45409-2793

March 26, 1987

Evelyn R. Matson, Ph.D.
Materials Licensing Section
Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellen, IL 60137

Dear Dr. Matson:

Enclosed is our reponse (in duplicate) to your letter of February 20, 1987 requesting more information for our current amendment request to our License No. 34-00341-06, Control No. 81304. The enclosed information is numbered according to the questions of the February 20, 1987 letter.

I want to thank you and Dr. Mallett for your quick review of our amendment once it came back from Washington. This device appears to have great clinical promise, and we are anxious not to hold up Dr. Hangartner any longer than necesary with the further development of his unit. I certainly hope that it does not take the NRC staff in Washington another four months to respond to this information as it did to the first amendment request.

Thank you again for your help. Please let me know if any further information is required.

Sincerely,

Donald R. Ruegsegger, Jr.

Donald R. Ruegsegger, Jr., Ph.D.
Chief, Medical Physics Section
Radiation Safety Officer

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ADDITIONAL INFORMATION TO THE

APPLICATION FOR CUSTOM MADE DEVICE, REQUESTED 20 FEBRUARY 1987

1. Model number of scanner: CT6

2. a. Drawing #1.

   b. *Construction Material*: Aluminum alloy for most of the machined parts, steel for gliding and rotational gear system, fiberglass for cover.

   c. *Shutter Placement on Source Holder*: Drawing #2.

   Shutter Operation: The shutter is opened by applying power to the rotary solenoid. If power is lost, the solenoid closes by spring action. The electronic system that actuates the shutter works in the following way:

   Immediately before a scan with data collection is initiated, the software issues a command to open the shutter. This command produces a 0.5 s pulse on a monoflop. If the stepping motors are started through further computer commands, the shutter is kept open for another 0.5 s for each stepping-motor pulse issued. When the scan is finished, or for some reason the communication between scanner and computer is interrupted, the shutter will be closed within 0.5 s automatically. For service operation, the shutter can be opened manually.

   d. *On-Off Indicators*: A warning light is placed on the scanner cover indicating, when on, that the shutter is open.

   e. No additional interlocks or guards apart from Item c are foreseen.

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f. In addition to the procedures described in c) and d), *redundancy* is implemented by displaying a flashing symbol on the computer terminal when the shutter is open.

g. The paper *label* will carry the trefoil symbol of radioactive material and will be of the standard colors as specified in §20.203,10 CFR 20. The label will be mounted on the right side of the scanner cover under a removable plexiglas plate, and will be updated at every source change.

3. The maximum *activity*, for which approval of possession is sought, amounts to 3.0 Ci. The average strength of the source ordinarily installed will be about 1 Ci, but a maximum of 2.0 Ci should be permitted. The source is normally used for about 2 halflife times, which leaves an activity of 250 to 500 mCi at source change. It is planned to keep at least the most recent replaced source for developmental work of detectors and detector electronics as well as for calibration experiments of scatter, filtration and energy spectrum. Once a year, all used sources but the last replaced source will be returned to AECL, Canada.

The label with the source particulars will be changed at the time of each source change and will contain actual activity and date of the installed source.

4. The *collimator* of the source holder is the same as the one of the device from which the radiation profiles were submitted. The arrangement of the detectors, however, is different, because it allows the placement of 16 rather than 8 detectors over the same fan width. The distance between source and detector collimator as well as the distance between source and

center of rotation are not known presently, but will be similar to those in the other scanner. New radiation profiles will be mapped out when source and detectors are installed.

5. Measured with thermo-luminescence dosimeters on a similar scanner, skin *dose* at the hot spot was 50 mrem with a 1 Ci source. This figure includes all radiation applied to the patient during one measurement procedure: one digital radiograph performed by translations of source/detector without rotation but with z-axis movement and adjacent scans at 2 mm intervals covering the same volume as the scoutscan. This dose is typically given to the forearm over a width of 10 to 15 mm and to the distal end of the leg over a similar width.

6. For a *source change*, the detector holder is removed from the scanner and handled behind lead blocks or similar shielding material. The time when the holder is open and some radiation is able to reach the hands of the operator is typically less than one minute. It is easy, in this operation, to point the source away from any human tissue so that no direct beam ever reaches the skin of the operator's hands. The source is changed about three to four times every year.

7. Based on the submitted values for *dose distribution*, the exposure dose-rate at 1 m distance with an object in the scanner is 0.7 mr/hr. It is not necessary for the operator to be closer than 2 to 3 m during the scanning procedure. This reduces the operator dose-rate to about 0.1 mr/hr. The total time during which the source is open for one patient measurement ordinarily does not exceed 15 minutes. The maximum

number of patient measurements per day is estimated to be 10. This amounts to a total exposure time of 2.5 hours. During about 20% of this time the scattered radiation is directed completely away from the operator, so that the upper limit of daily exposure-time is 2 hours. A full load of patient measurements during one work-week would produce a maximum radiation exposure to the operator of 1 mr. This is with a source of 1 Ci. With a half-life time of 60-days and a usable lifetime of 4 months, the same patient load at the end of the source life produces an operator exposure of 0.25 mr during one week.

8. *Test of Specifications on Finished Device*:

a. Dose rates at the angle of maximum exposure and at 5 cm, 30 cm and 100 cm distance from the measurement plane of a plexiglass cylinder mimicking a forearm will be documented. These measurements will be obtained with shutter open and closed and a source of 1 Ci ^{125}I, the nominal activity to be used in the scanner. The dose for the maximum activity of 2.0 Ci will be calculated from the above data.

b. The source holder will be visually inspected for cracks and tightness of fit. With the source installed and the shutter closed, dose rates will be obtained under all directions at 5 cm and 30 cm distance. If any cracks or other unwanted openings allow radiation to exit, the source holder will be modified before installation on the scanner.

c. The shutter operation with its motor-pulse interlock will be tested before installation of a source.

d. Leak tests of the source will be performed by the manufacturer of the source (AECL) before delivery and pertinent certificates will accompany the shipments. Further leak tests at 6 month intervals will be

performed in-house. At this time, the sources are ordinarily not in use for the scanner anymore.

A wipe test to measure contamination of the source capsule will be carried out before installation of the source in the source holder. Contamination of the ^{125}I source material with ^{126}I is a potential problem. Measurements of countrates through known absorbers will give us an indication about contamination with this higher-energy isotope. These measurements are performed as part of the daily calibration routine.

e. Detailed dose rates on the sides and behind the detectors will document the precise alignment of the source detector to avoid any direct radiation not stopped by the detector collimator.

9. The device can only be operated under computer control. As the user interface is currently being written, exact instructions for the operation of the system are not available as of now. The leak tests will be handled by the Radiation Safety Officer of this hospital.

10. In order to avoid over-tightening of the set screw which holds the source in place, the screw will be fitted with a plastic tip.

11. As galvanic action of the source capsule is a slow process and as the source ordinarily does not reside in the source holder for more than 4 months, we have reasonable expectations that leakage is no problem while the source is in use. A wipe test of the source at the time of removal will help us to build a track record in this respect and take action if results contrary to our assumptions are encountered.

12. At this point, we have no plans to build *another device* that uses ^{125}I and works according to the same principles.

13. All operations in connection with this device are carried out by the Biomedical Imaging Laboratory at *Miami Valley Hospital*. The hospital's NRC license covering these operations is 34-00341-06.

14. During *service operation* of mechanics and electronics of the scanner, the source is ordinarily not handled. If handling of the source should become necessary, the same procedures as for a source change will be followed. After servicing and as part of the daily control and calibration procedure, countrates are collected with the shutter open as well as with the shutter closed. This provides not only operator-accessible data about the functioning of the shutter, but also allows automatic computer evaluation and error display in the case of malfunction.

15. *Dr. Hangartner* has a degree on the master's level in experimental physics. His training pertinent to the use of radioactive sources includes:

Topic	Duration [hrs]	Institution
a. Principles and practices of radiation protection	50	Swiss Federal Institute of Technology, Zürich, Switzerland
b. Radioactivity measurements and monitoring techniques	100	
c. Mathematics and calculations basic to radioactivity	150	
d. Biological effects of radiation	20	

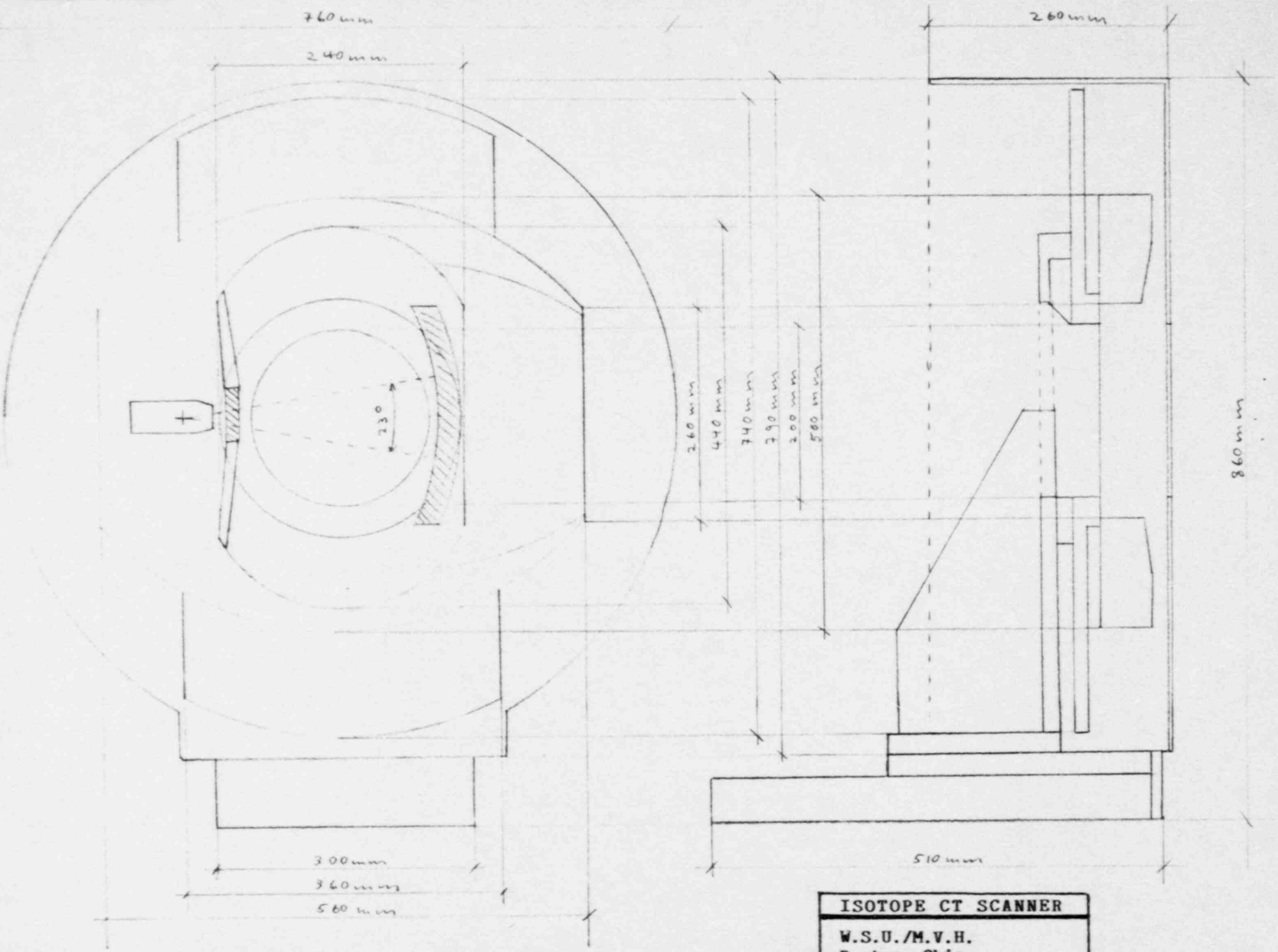
Experience:

Type of Source	Duration [y]	Location	Type of Use
^{125}I (max. 1 Ci)	4	Switzerland	CT Scanner
X-ray	4	Switzerland	CT Scanner
^{125}I (max. 2 Ci)	7	Canada	CT Scanner
X-ray	7	Canada	CT Scanner

16. This device is optimized for measuring bone density and will be used in patients referred by their physicians to do such measurements. These referrals take place if the physician established the need for bone-density assessment.

17. The *Medical Director* of the Biomedical Imaging Laboratory is Dr. Jose Quinones, and he will supervise the medical use of this device. Dr. Quinones currently is authorized to use isotopes of the groups I-V and for specific purposes as stated on the current license.

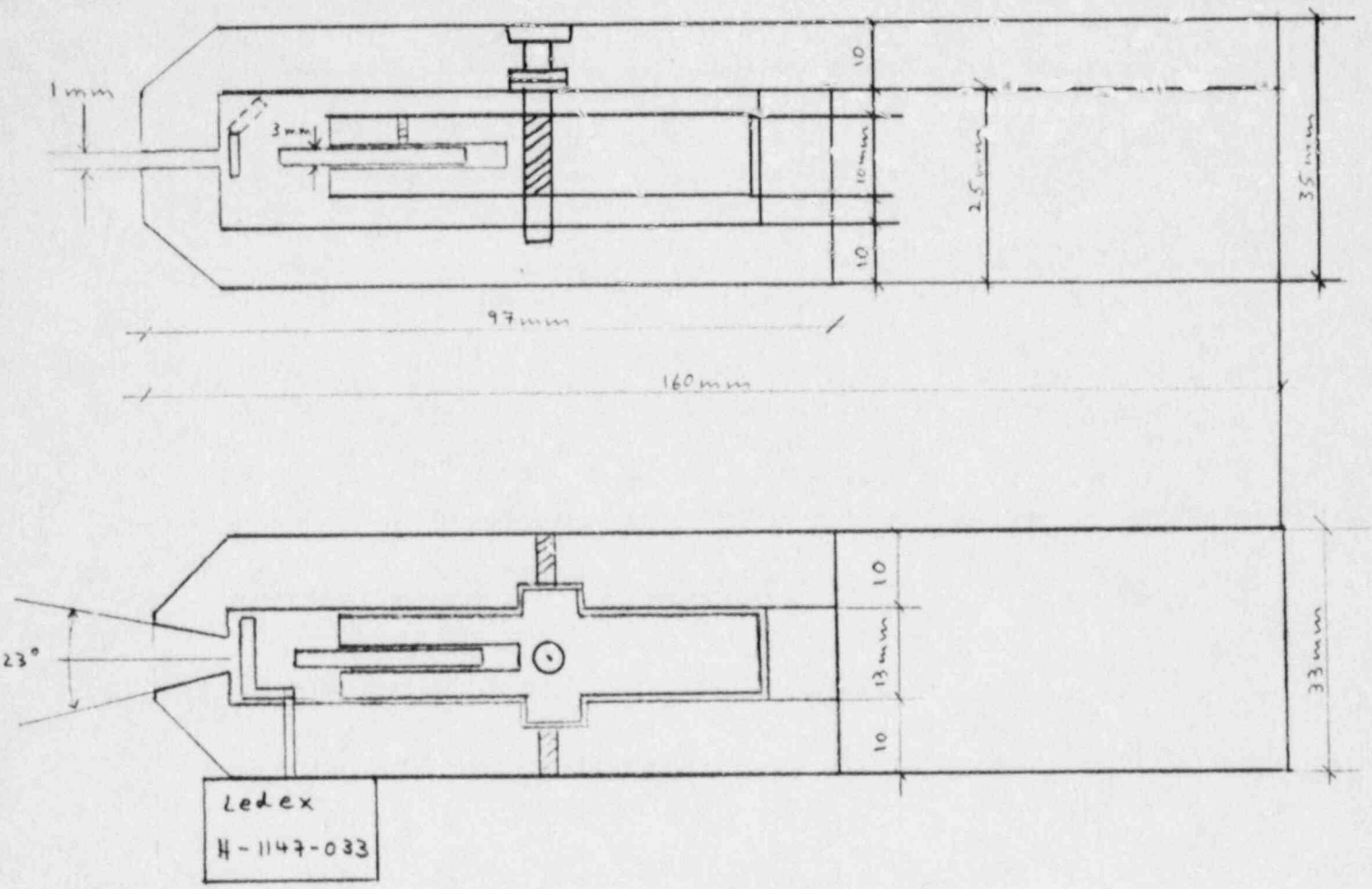
DRAWING NUMBER 1



ISOTOPE CT SCANNER

W.S.U./M.V.H.
Dayton, Ohio

DRAWING NUMBER 2



DETECTOR HOUSING WITH SHUTTER
W.S.U./M.V.H. Dayton, Ohio