388-5748

Hello Ms. Matson

This concerns the Miami Valley Hospital request to amend license number 34-00341-06 (mail control# 381304). To evaluate the request we need additional information or clarification of the following items.

A) We need a model number that can be used to uniquely identify the device. This is necessary for automated tracking and retrieval purposes.

B) We need a description and diagram of the device design and dimensions. This should include material of construction, shutter operation, on-off indicators, interlocks or guards etc. The above description should also include any computer controlled safety related operations. For example, the computer screen tells the operator that the source shutter is open or closed.

C) We will except the radiation profile for scatter submitted for a similar scanner provided they demonstrate the same geometry. We also need the dose rate from the source holder and a scenario that describes the radiation fields and times needed for a worker to exchange the source. Further, the licensee should include the dose rate around a completed device and calculate the dose to the operator.

D) Generally we require some type of prototype testing or engineering evaluation of the device. If there is such information please send it in. Else we would like to evaluate the device design prior to accepting their statement about the device is augmenting the source integrity and therefore is safe to use under the specified conditions of use.

E) They need to explain how Dr. Hangartner will determine that the device is built to the specifications and dimensional tolerances that will be submitted.

F) Location and material of construction of the label need to be explained. The label has historically contained the trefoil symbol. They should also include this information on the label. The information in the submission indicates that the source size is only 1 curie. The first page of the submission requests 2 curies, this needs to be expressed as the maximum activity that will be placed into the device.

G) The users operation procedures and leak testing procedures need to be provided. If this tool is for R&D work only then we can forgo the request for the operation manual.

H) It appears from the drawing that a set screw is used to

hold the source in place. Please describe how they plan to prevent source damage from this set screw due to over tightening. For example the set screw has a teflon tip that is secured at a given torque specification.

I) Please be aware that recent incidents involving these source design have caused concern about the possibility of moisture getting into contact with the source. If this liquid is allowed to remain this will cause a galvanic reaction and corrode the source capsule. Please explain what precaution either design in nature of written do they plan to take to prevent occurrence of this problem.

J) The servicing activity must be licensed since it will involve handling a direct source of I-125. This could be done under the above license or under Dr. Hangartners license.

K) Please note a FDA finding of premarketing, ie 510K or equivalent, only applies to a custom device used in the treatment of humans. If there are two of the devices built for that purpose then a premarketing approval is needed.

L) An approach that might be explored--AECL has just been issued an MD license. The applicants requested source falls within the AECL license. If the applicant has a group VI license it may be possible to close out this license application. Copy enclosed.

~~M) Estimated dose to patient.~~ Radiation profiles submitted

Stan Baggoo
2/3/87
427-9005

NRC FORM 374 (9-84)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93 - 438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below, to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Atomic Energy of Canada, Limited	3. License number 54-00300-16MD
2. 413 March Road P. O. Box 13500 Kanata, Ontario, Canada K2K 1X5	4. Expiration date October 31, 1991
	5. Docket or Reference No. 030-22541

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Iodine 125	A. Sealed sources (AECL Model C-324/C-236 or C-235/C-236)	A. Not to exceed 3 curies per source

9. Authorized use

A. Pursuant to Section 32.74, 10 CFR Part 32, the licensee is authorized to distribute the byproduct material described in Items 6., 7., and 8. of this license to persons licensed pursuant to Section 35.14 and Section 35.100, 10 CFR Part 35, or under equivalent licenses of Agreement States, for Group VI licensees or to persons authorized to receive the license material pursuant to the terms and conditions of specific license issued by the Nuclear Regulatory Commission or Agreement State.

CONDITIONS

10. The licensee is authorized to distribute licensed material, described in Items 6. and 7. of this license, from 413 March Road, Kanata, Ontario, Canada.

11. This license does not authorize possession or use of licensed material.

12. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

"OFFICIAL COPY"

ML18

SOURCE AND DEVICE EVALUATION TECHNICAL ASSISTANCE REQUEST

TO: Steven Baggett, Material Licensing Branch, FC/NMSS MS 396-SS

FROM: Evelyn R Matson REGION: I II (III) IV V (Circle One)

FTS PHONE NO. 388-5748 DATE: 8/8/86

LICENSEE Miami Valley Hospital LETTER/~~APPLICATION~~ DATE 5/6/86

MAIL CONTROL NO.(S) 81304 LICENSE NO.(S) 34-00341-06

REQUEST ACTION (CHECK APPROPRIATE BOX)

/✓/ SOURCE AND/OR (DEVICE) REVIEW
/ / CUSTOM/IMPORTED
/ / AMENDMENT OF REGISTRATION SHEET NO. _____
/ / OTHER: _____

****

FOR FCML USE ONLY CONTROL NO. _____ MODELS: _____

DATE RECEIVED: _____ REVIEWER: _____

TYPE OF ACTION (INDICATE NO. OF EACH ON THE LINES)

/ / SOURCE REVIEW ___ / / DEVICE REVIEW ___

/ / FORMAL____ / / AMENDMENT____ / / CUSTOM____

TOTAL REVIEWER HOURS SPENT ON EVALUATION _____ DATE COMPLETED: _____

NOTES: _____ DEFICIENCY LETTER ___ DATE SENT: _____

DEFICIENCY PHONE CALL ___ DATE MADE: _____

RESPONSE TO DEFICIENCY: _____

TYPING DRAFT___ IN___ OUT___ FINAL___ IN___ OUT___

****

FOR LFMS USE ONLY

FEES THAT HAVE BEEN PAID FOR: (INDICATE NO. OF EACH ACTION ON THE LINES)

/ / SOURCE REVIEW____ / / DEVICE REVIEW ____ / / CUSTOM____
/ / FORMAL____ / / AMENDMENT____

NOTES: _____ DATE TO LFMS: _____
DATE RETURNED: _____

SIGNED _____

DATE: _____

"EVALUATION" ON FILE10