December 1, 1992

Docket No. 50-20
Dr. John A. Bernard
Director of Reactor Operations
Nuclear Reactor Laboratory
Massachusetts Institute of Technology
138 Albany Street
Cambridge, Massachusetts 02139

Dear Dr. Bernard

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION (TAC NO. M82958)

We are continuing our review of your application for amendment of Facility Operating License No. R-37 for the Massachusetts Institute of Technology Research Reactor which you submitted on March 10, 1992. During our review of your application, questions have arisen for which we require additional information and clarification. Please provide responses to the enclosed Request for Additional Information within 30 days of the date of this letter. Following receipt of the additional information, we will continue our evaluation of your application. If you have any questions regarding this review, please contact me at (301) 504-1127.

In accordance with 10 CFR 50.30(b), your response must be executed in a signed original under oath or affirmation.

This requirement affects nine or fewer respondents and, therefore, is not subject to Office of Management and Budget review under P. L. 96-511.

Sincerely,
- original signed by -
Alexander Adams, Jr., Sr. Project Manager
Non-Power Reactors and Decommissioning
Project Directorate
Division of Operating Reactor Support
Office of Nuclear Reactor Regulation

Enclosures:
As stated

cc w/enclosures:
See next page

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[M82958.AA]

ONDD/LA	ONDD:PM	NMSS:IMAB	ONDD:D
EHylton	AAdams:dmj	JGlenn	SWeiss
11/16/92	11/17/92	11/30/92	12/1/92

with deletions marked

FOI
41

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

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As stated

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See next page

Massachusetts Institute of Technology

Docket No. 50-20

cc:

City Manager
City Hall
Cambridge, Massachusetts 02139

Assistant Secretary for Policy
Executive Office of Energy Resources
100 Cambridge Street, Room 1500
Boston, Massachusetts 02202

Department of Environmental
Quality Engineering
100 Cambridge Street
Boston, Massachusetts 02108

ENCLOSURE

REQUEST FOR ADDITIONAL INFORMATION

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

DOCKET NO. 50-20

I. The following questions concern the Technical Specifications (TS).

1. Please provide a definition of physician authorized user that includes information such that the physician authorized user is an authorized user physician on a NRC license who is specifically authorized for medical use using neutron capture therapy.

2. In TS 6.5.2 you state that the Massachusetts Institute of Technology (MIT) is only responsible for the delivery of the desired radiation fluence as requested by the certified medical physicist. Please amend this TS to state that MIT is responsible for (1) delivery of the desired radiation fluence as requested by the written directive, and (2) providing current and accurate beam characteristic parameters to the medical use licensee.

3. Does the radiation monitor discussed in TS 6.5.7 provide the ability to alert people in the medical therapy room that the beam is on?

4. TS 6.5.7(b) discusses the use of a check source 24 hours prior to patient irradiation. Please amend the specification to require the check to occur the same calendar day and prior to treatment.

5. In addition to the communication discussed in TS 6.5.8, can personnel at the medical therapy facility control panel hear the patient inside the medical therapy room?

6. Please amend TS 6.5.12(f) to remove the word "feasibility." You must be able to close the shutters from within the facility and conduct a surveillance on this function of the medical therapy facility.

7. Please amend TS 6.5.13 to make it clear that the verification of manual operation of the door involves full opening of the door and is different than opening the door to meet the requirements of TS 6.5.12.

8. TS 6.5.14 discusses when calibration checks and characterizations shall occur. In TS 6.5.14(a) you discuss performing a calibration check in the event that any component of a given beam design has been replaced or performing a calibration and functional check in the event of a design modification. In TS 6.5.14(b) you discuss performing a characterization in the event that any component of a given beam design has been modified. This wording can be confusing. Please clarify.

9. Please clarify the difference between characterization and full characterization.

10. Please amend definition 8(a) to say "A radiation treatment without a written directive; or".

11. Please amend definition 8(b) to say "A radiation treatment where a written directive is required without reporting to the medical use licensee in writing each fluence given within 24 hours of the treatment."

12. In the forth paragraph of the basis you say that the 20% level on fluence "establishes an allowable upper limit on the delivered fluence." This is actually a trigger level upper limit on the delivered fluence before NRC has to be notified of a misadministration. Please amend this section of the basis to reflect this fact.

13. In the fifth paragraph of the basis you refer to licensed personnel. Does this mean licensed reactor operators? Please clarify.

14. In the last paragraph of the basis you have information concerning the modification of the Quality Management Program. Please consider placing this information in the specification section of the TS.

II. The following questions concern the Quality Management (QM) Program.

15. The written directive for the QM program is a document that must be signed and dated by the "physician authorized user" from the medical use licensee. Please review the QM program and insure the directive is written, signed, and dated by the "physician authorized user" and physicians referred to in the program are identified as the "physician authorized users."

16. Note that all boron neutron capture therapy treatments are therapy procedures and require written directives. Therefore, references in the QM program to "diagnostic procedures" or "situations where written directives are unnecessary" can be removed.

17. MIT's responsibilities include not only delivering the directed fluence but also providing the medical use licensee with the current and accurate beam characteristic parameters. Therefore, MIT's QM program should include a commitment to provide the medical use licensee with a dated and signed statement within 24 hours of the treatment that these two specific duties were performed.

18. In item 3(e) MIT committed to determining whether the administered total "dose" and "dose" per fraction were as specified in the written directive. Since MIT is not responsible for the "dose" but the "fluence" requested in the written directive, this commitment should be for administered total fluence and fluence per fraction.