June 18, 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., Senior Project Manager
Non-Power Reactors, Decommissioning and
Environmental Project Directorate
Division of Reactor Projects - III/IV/V
Office of Nuclear Reactor Regulation

Enclosure:
As stated

cc w/enclosure:
See next page

DISTRIBUTION:

Docket File 50-20	BBoger	AAdams	Region I
NRC & Local PDRs	SWeiss	OGC	CHehl
PDNP R/F	EHylton	ACRS (10)	JGlenn

[BERNARD.AA]
*see previous concurrence

PDNP:LA*	PDNP:PD*	MAB	PDNP:D
EHylton	AAdams:lb	JGlenn	SWeiss
06/12/92	06/12/92	06/18/92	06/18/92

DF01

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

June 18, 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,

Alexander Adams, Jr., Senior Project Manager
Non-Power Reactors, Decommissioning and
Environmental Project Directorate
Division of Reactor Projects - III/IV/V
Office of Nuclear Reactor Regulation

Enclosure:
As stated

cc w/enclosure:
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

REQUEST FOR ADDITIONAL INFORMATION

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

DOCKET NO. 50-20

1. Your proposed technical specification (TS) 6.5.3 discusses the temporary use of the intercom to contact the control room to scram the reactor if the minor scram on the medical room control panel is out of service. Please put a time limit on the use of this temporary measure.

2. Please rewrite your proposed TS 6.5.5(d) in the form of a "shall" statement.

3. Your proposed TS 6.5.6 discusses the use of an alternate means of verifying shutter position in the event that the status light malfunctions. Please propose a maximum time limit on the use of this alternative means of verification.

4. Please propose a TS surveillance requirement for verification of proper indication of the control panel status lights.

5. Your proposed TS 6.5.7 discusses the radiation monitor that indicates radiation levels within the medical therapy room. TS 6.5.7(b) discusses checking the monitor for proper operation. Please propose a TS that discusses calibration frequency, alarm set points if applicable, and any required actions based on alarms, if applicable. TS 6 5.7(c) discusses the use of portable survey instruments if the radiation monitor is inoperable. Please propose a maximum time limit that this monitor can be inoperable.

6. The third sentence of TS 6.5.10 should be rewritten as a "may" statement. Please correct.

7. TS 6.5.11 specifies the criterion for a misadministration per definition 8 as a total radiation fluence delivered by the medical therapy beam, as measured by on-line monitors, which exceeds the patient treatment plan by more than 20%, or 30% for any treatment fraction. 10 CFR 35.2 also sets the criteria for a misadministration as a 10% difference between the total prescribed dose and the calculated total administered dose for treatments consisting of three treatments or fewer, or when a weekly administered dose is 30% greater than the weekly prescribed dose. Please include these criteria in your definition or provide a technical basis for omitting these criteria.

8. As discussed in Section 4 of ANS Standard 15.1-1990, "The Development of Technical Specifications for Research Reactors", the surveillance requirements of proposed TS 6.5.12 need not be performed monthly if the medical therapy facility is not to be used for human therapy in that month. However, if greater than a month has passed since the last surveillance, the surveillance would have to be performed prior to use of the facility for human therapy. Also ANS 15.1-1990 provides for maximum intervals for time based surveillance. Please insure that all time based surveillance including this TS have maximum intervals stated.

9. TS 6.5.12 lists surveillance for interlocks or channels. The interlock in TS 5(a) does not seem to appear in TS 6.5.12. TS 6.5.12(b) tests TS 5(b) which is different than TS 5(a). Please correct.

10. Other reactor scrams listed in TS 4.3.1 appear to be on a surveillance schedule of at least monthly or before reactor start-up if the reactor has been shut down more than 16 hours. Please justify not applying the same surveillance to the medical therapy room minor scram.

11. TS 6.5.12(e) requires a function check of the beam-monitoring instrumentation. Please also discuss requirements for calibration of the beam-monitoring instrumentation.

12. TS 6.5.13 discusses verification of manual operation of the shield door on a semiannual basis and refers to the monthly operability check of the automatic shutter closure interlock. Does the operability check of the automatic shutter closure interlock also verify manual door operation?

13. TS 6.5.14 discusses calibration checks of the beam on a weekly basis for any week that the beam will be used for human therapy. This calibration check should occur before humans are irradiated. Please amend this TS to state this.

14. TS 6.5.15 discusses modifications to the medical therapy facility. Please confirm that modifications to the facility will be subject to the requirements of 10 CFR 50.59.

15. TS 6.5.15 states that the operating couch, patient positioning equipment, medical instruments, and other equipment used for the direct support of the patient are not part of the medical therapy facility. Who is responsible for the possible activation or contamination of this equipment?

16. TS 6.5.17 discusses reports made to NRC. Please add to the TS that 24 hour verbal reports by telephone will be made to the NRC Operations Center and the Regional Administrator, Region I, or his designate. Please add that written reports will be sent to the NRC Document Control Desk with a copy to the Regional Administrator, Region I.

17. Is a change to the medical therapy facility beam that has the potential to significantly increase the amount of activation products in the medical therapy room a "design modification?" If so, please amend definition 5.

18. Only an authorized user physician can provide written directives for the administration of radiation to a patient. Please modify definition 9.

19. Please add to the list of information provided to the NRC in your annual report, TS 7.13.5, a summary of the use of the medical therapy facility for human therapy. If the human therapy is for investigative studies, provide the status of the studies and number of people involved. If the human therapy is for direct therapeutic benefit, provide number of patients and type of cancer treated.

20. Provide a commitment in your TS to follow the requirements of the "Quality Management Program for Generation of Medical Therapy Facility Beam for Human Therapy at the Massachusetts Institute of Technology Research Reactor."

21. Are you planning any modification to your reactor operating procedures or reactor instrumentation set points when human therapy is being conducted?

22. Please discuss what training will be required for users of the medical therapy facility for normal use and equipment failure situations (e.g. manual operation of door and shutters), and for the MIT Quality Management Program focusing on implementation and the handling of questions prior and during treatment.

23. Can the beam or reactor be shut down from inside the medical therapy room?

24. Please provide a copy of the procedures and instructions pertaining to the medical therapy facility.

25. Your Quality Management Program should consist of copies of your procedures that show how MIT will meet objectives similar to the five objectives of 10 CFR 35.32, Quality management program. The following specific questions concern your Quality Management Program:

    a. The term "Authorized Users" is too generic. Please consider replacing this term with "Authorized Medical Use Licensee" or an equivalent term. Consider changing the phase "is limited to the" to "is limited to the physician authorized users specifically authorized by" or equivalent.

    b. Please revise Section 3(a) of your program to assure MIT has the most recent written directive from the medical use licensee and for the correct patient.

    c. Please restate Section 3(c) of your program to focus on assurances that MIT's calculations, computer programs, and quality control procedures for the beam are checked and reviewed to assure that the neutron beam meets the requirements for the particular treatment (see Regulatory Guide 8.33, pages 2 and 3 for additional guidance).

    d. Please expand Section 3(e) of your program to provide procedures for meeting an objective similar to objective 5 of 10 CFR 35.32. Please focus on the on-going review process that compares delivered dose with the anticipated dose (see Regulatory Guide 8.33, pages 7 and 8 for additional guidance).

    e. Please provide addition detail on your specific sampling technique referred to in Section 4(a)(i) of your program. For your information, NRC is developing draft guidance that calls for 100% sampling up to 20 patients; a sample of 20 for 21 to 100 patients; and 20% sampling for more than 100 patients.

f. Because MIT is part of a total treatment team, Section 4(b)(iv) should be amended to provide information to the medical use licensee. This is particularly important for the information in Sections 3(e), 5, and 7.