April 2, 2001

Dr. John A. Bernard, Director
Nuclear Reactor Laboratory
Massachusetts Institute of Technology
138 Albany Street
Cambridge, MA 02139-4296

SUBJECT: ISSUANCE OF AMENDMENT NO. 32 TO AMENDED FACILITY OPERATING LICENSE NO. R-37 - MASSACHUSETTS INSTITUTE OF TECHNOLOGY (TAC NO. MA6085)

Dear Dr. Bernard:

The Commission has issued the enclosed Amendment No. 32 to Amended Facility Operating License No. R-37 for the Massachusetts Institute of Technology Research Reactor. The amendment consists of changes to the technical specifications (TSs) in response to your letter of June 30, 1999, as supplemented on March 17, August 15, November 9, and December 6, 2000.

The amendment updates TS 6.5 concerning generation of the medical therapy facility beams for human therapy and allows the use of the fission converter beam and medical therapy room for human irradiations.

You proposed a change to TS 6.5.12 to increase the period that the reactor would have to be shutdown to require a test of the minor scram for each medical therapy facility from 16 to 24 hours. The basis of this change was consistency with other changes to the TSs you proposed, as part of a separate application for license renewal. You noted in answer 17 of your letter of March 17, 2000, that this change could be deferred until the license renewal was approved. This change will be reviewed as part of the license renewal request from MIT and will not be reviewed at this time.

A copy of the safety evaluation supporting Amendment No. 32 is also enclosed.

Sincerely,

/RA/

Alexander Adams, Jr., Senior Project Manager
Events Assessment, Generic Communications and
Non-Power Reactors Branch
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

Docket No. 50-20

Enclosures:
1. Amendment No. 32
2. Safety Evaluation

cc w/enclosures:
Please see next page

Massachusetts Institute of Technology

Docket No. 50-20

cc:

City Manager
City Hall
Cambridge, MA 02139

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

Department of Environmental Quality Engineering
100 Cambridge Street
Boston, MA 02202

April 2, 2001

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MASSACHUSETTS INSTITUTE OF TECHNOLOGY

DOCKET NO. 50-20

AMENDMENT TO AMENDED FACILITY OPERATING LICENSE

Amendment No. 32
License No. R-37

1. The U.S. Nuclear Regulatory Commission (the Commission) has found that

   A. The application for an amendment to Amended Facility Operating License No. R-37 filed by the Massachusetts Institute of Technology (the licensee) on June 30, 1999, as supplemented on March 17, August 15, November 9, and December 6, 2000, conforms to the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the regulations of the Commission as stated in Chapter I of Title 10 of the *Code of Federal Regulations* (10 CFR);

   B. The facility will operate in conformity with the application, the provisions of the Act, and the rules and regulations of the Commission;

   C. There is reasonable assurance that (i) the activities authorized by this amendment can be conducted without endangering the health and safety of the public and (ii) such activities will be conducted in compliance with the regulations of the Commission;

   D. The issuance of this amendment will not be inimical to the common defense and security or to the health and safety of the public;

   E. This amendment is issued in accordance with the regulations of the Commission as stated in 10 CFR Part 51, and all applicable requirements have been satisfied; and

   F. Prior notice of this amendment was not required by 10 CFR 2.105, and publication of notice for this amendment is not required by 10 CFR 2.106.

2. Accordingly, the license is amended by changes to the Technical Specifications as indicated in the enclosure to this license amendment, and paragraph 2.C.(2) of Amended Facility Operating License No. R-37 is hereby amended to read as follows:

   (2) Technical Specifications

   The Technical Specifications contained in Appendix A, as revised through Amendment No. 32, are hereby incorporated in the license. The licensee shall operate the facility in accordance with the Technical Specifications.

3. This license amendment is effective as of the date of issuance.

FOR THE NUCLEAR REGULATORY COMMISSION

/RA/

Ledyard B. Marsh, Chief
Events Assessment, Generic Communications and
Non-Power Reactors Branch
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

Enclosure:
Appendix A, Technical
Specifications Changes

Date of Issuance: April 2, 2001

ENCLOSURE TO LICENSE AMENDMENT NO. 32

AMENDED FACILITY OPERATING LICENSE NO. R-37

DOCKET NO. 50-20

Replace the following pages of Appendix A, "Technical Specifications," with the enclosed pages. The revised pages are identified by amendment number and contain vertical lines indicating the areas of change.

Remove	Insert
6-21 to 6-33	6-21 to 6-33b

6.5 Generation of Medical Therapy Facility Beams for Human Therapy

Applicability

This specification applies solely to the generation of medical therapy facility beams for the treatment of human patients. It does not apply to any other use of the medical therapy facilities and/or their beams. Surveillances listed in this specification are only required if human therapy is planned for the interval of the surveillance. However, in the event of a hiatus in the scheduled performance of any given surveillance, that surveillance shall be performed prior to the initiation of human therapy during the interval in question.

Objective

To provide for the protection of the public health and safety by ensuring that patients are treated in accordance with the treatment plan established by the BNCT physician authorized user and that the ALARA principle is observed for all non-therapeutic radiation exposures.

Specification

1. Patients accepted for treatment shall have been referred by written directive from a BNCT physician authorized user from a medical center with an NRC or Agreement State medical use license that contains BNCT specific conditions and commitments for BNCT treatment on humans conducted at the Massachusetts Institute of Technology Research Reactor's Medical Therapy Facilities.
2. All medical treatments, including irradiations and analyses of the neutron capture agents in the patients, are the responsibility of the BNCT physician authorized user in charge of the therapy and the medical physicists from the NRC-licensed or Agreement State-licensed medical center. The Massachusetts Institute of Technology is only responsible for providing current and accurate beam characteristic parameters to the medical use licensee and for delivery of the desired radiation fluence as requested in the written directive. Before the start of a therapy, both the certified medical physicist and the BNCT Principal Investigator, or designate, must agree that the therapy can be initiated. The BNCT physician authorized user is responsible for

monitoring the therapy and can direct its termination. Because MIT is responsible for delivery of the prescribed fluence, the BNCT Principal Investigator, or designate, will under normal circumstances terminate the irradiation whenever the prescribed fluence is attained. However, a radiation therapy can also be terminated at any time if either the BNCT physician authorized user or the BNCT Principal Investigator, or their designates, judge that the therapy should be terminated.

3. It shall be possible to initiate a minor scram of the reactor from a control panel located in each medical therapy facility area.

4. Access to each medical therapy facility shall be controlled by means of the shield door located at its entrance.

5. The following features and/or interlocks shall be operable:

   a) An interlock shall prevent opening of the shutters that control beam delivery unless the medical therapy facility's shield door is closed.

   b) The shutters that control beam delivery shall be interlocked to close automatically upon opening of the medical therapy facility's shield door.

   c) Except for the fission converter mechanical shutter, the shutters that control beam delivery shall be designed to close automatically either upon failure of electric power, or upon reduced air pressure if the shutter is operated pneumatically. For the fission converter mechanical shutter, the reactor will be scrammed automatically upon loss of electric power to that shutter.

   d) Shutters that control beam delivery and that are normally pneumatically-operated shall, in addition, be designed for manual closure.

   e) It shall be possible to close the shutters that control beam delivery from within the medical therapy facility.

   f) The fission converter mechanical shutter, which is normally operated electrically, shall also allow manual closure.

6. Each of the shutters that controls beam delivery shall be equipped with a light that indicates the status of the shutter. These lights shall be visible at each medical

therapy facility's local control panel. In the event of a status light malfunction, it shall be acceptable to use the affected shutter provided that an alternate means of verifying position is available. Use of this alternate means of shutter position verification is limited to seven consecutive working days.

7. Each medical therapy facility shall be equipped with a monitor that provides a visual indication of the radiation level within the facility, that indicates both within the facility and at the local control panel, and that provides an audible alarm both within the facility and at the local control panel.
   a) This radiation monitor shall be equipped with a backup power supply such as the reactor emergency power system or a battery.
   b) This radiation monitor shall be checked for proper operation by means of a check source on the calendar day of and prior to any patient irradiation.
   c) This radiation monitor shall be calibrated quarterly.
   d) The audible alarm shall be set at or below 50 mR/hr. This monitor and/or its alarm may be disabled once the medical therapy room has been searched and secured, such as is done immediately prior to initiation of patient therapy. If this is done, the monitor and/or its alarm shall be interlocked so that they become functional upon opening of the medical therapy facility's shield door.
   e) In the event that this monitor is inoperable, personnel entering the medical therapy facility shall use either portable survey instruments or audible alarm personal dosimeters as a temporary means of satisfying this provision. These instruments/dosimeters shall be in calibration as defined by the MIT Research Reactor's radiation protection program and shall be source-checked daily prior to use on any day that they are used to satisfy this provision. Use of these instruments/dosimeters as a temporary means of satisfying this provision is limited to seven consecutive working days.
8. An intercom or other means of two-way communication shall be operable both between each medical therapy facility control panel and the reactor control room, and

also between each medical therapy facility control panel and the interior of the facility. The latter is for the monitoring of patients.

9. It shall be possible for personnel monitoring a patient to open each medical therapy facility's shield door manually.

10. It shall be possible to observe the patient through both a viewing port and by means of a closed-circuit TV camera. Both methods of patient visualization shall be operable at the outset of any patient irradiation. Should either fail during the irradiation, the treatment may be continued at the discretion of the BNCT physician authorized user. Adequate lighting to permit such viewing shall be assured by the provision of emergency lighting.

11. The total radiation fluence delivered by the medical therapy facility beam as measured by on-line beam monitors shall not exceed that prescribed in the patient treatment plan by more than 20%. The treatment is normally delivered in fractions in accordance with standard practice for human therapy. The 20% criterion applies to the sum of the radiation fluences associated with all fractions in a given treatment plan. A criterion of 30% applies to the difference between the administered and prescribed fluence for any given week (seven consecutive days). Finally, if the treatment consists of three or fewer fraction, then a criterion of 10% shall apply.

12. The following interlocks or channels shall be tested at least monthly and prior to treatment of human patients if the interlock or channel has been repaired or deenergized:

	Interlock or Channel	Surveillance
a)	Medical therapy facility minor scram	Scram test
b)	Shutters will not open unless shield door is closed	Operational test
c)	Shutters close upon both manual and automatic opening of shield door	Operational test

c)	Shutters close or the reactor is automatically scrammed on loss of electrical power, and shutters close upon reduction of pressure to pneumatic operators, if applicable	Operational test	
d)	Manual closure of pneumatic shutters	Operational test	
e)	Shutters can be closed manually from within the facility	Operational test	
f)	Shutter status lights	Operational test	
g)	Radiation monitor alarm	Operational test	
h)	Radiation monitor and/or alarm enabled upon opening of shield door	Operational test	
i)	Intercoms	Operational test	
k)	Manual closure of fission converter mechanical shutter	Operational test	
l)	Availability of emergency power for beam monitor systems	Operational test	

In addition to the above, each medical therapy facility minor scram shall be tested prior to reactor startup if the reactor has been shut down for more than sixteen hours.

13. Manual operation of each medical therapy facility's shield door in which the door is opened fully shall be verified semi-annually.

14. a) Use of the basement medical therapy facility beam shall be subject to the following:

    (i) A functional check of the beam monitors that are described in provision 11 of this specification shall be made weekly for any week that the beam will be used for human therapy. This check shall be made prior to any patient irradiation for a given week. In addition, a functional check shall be performed prior to any patient irradiation in the event of a component replacement or a design modification.

    (ii) A calibration check of the beam shall be performed every six months for any six-month interval that the beam will be used for human therapy.

This six-month calibration check shall be made prior to any patient irradiation for a given six-month interval. In addition, a calibration check shall be performed prior to any patient irradiation in the event of a component replacement or a design modification.

(iii) A characterization of the beam shall be performed every twelve months for any twelve-month interval that the beam will be used for human therapy. This twelve-month characterization shall be made prior to any patient irradiation for a given twelve-month interval. A characterization shall also be performed prior to any patient irradiation in the event of a design modification. As part of the characterization process, the proper response of the beam monitors that are described in provision 11 of this specification shall be established.

(iv) The instruments (e.g., tissue-equivalent chamber and either a graphite or a magnesium wall ionization chamber or the equivalent) that are to be used to perform both calibration checks and characterization of the beam shall be calibrated by a secondary calibration laboratory. This calibration shall be performed at least once every two years for any two- year interval that the beam will be used for human therapy. The two-year calibration shall be made prior to any patient irradiation during any given two-year interval. (Note: If a method (e.g., foil activation) other than these checks is used for the calibration and or the characterization, then the devices (e.g., foils) used in that method shall either be traceable to the National Institute of Standards and Technology or be selected in accordance with the relevant ANSI/ANS standards.)

(v) There shall be a minimum of two neutron-sensitive beam monitors to initiate a patient irradiation. Once initiated, a patient irradiation may be continued at the discretion of both the certified medical physicist and

the BNCT Principal Investigator, or designate, provided that at least one neutron-sensitive beam monitor is operable.

(vi) A calibration of the beam monitors that are described in provision 11 of this specification shall be performed at least once every two years for any two-year interval that the beam will be used for human therapy. The two-year calibration shall be made prior to any patient irradiation during any given two-year interval.

b) Use of the fission converter medical therapy facility beam shall be subject to the following:

(i) Functional checks: the same requirements as provision 14(a)(i) above.

(ii) Calibration checks: the same requirements as provision 14(a)(ii) above except that all frequencies are weekly instead of six months.

(iii) Characterization: the same requirements as provision 14(a)(iii) above except that all frequencies are six months instead of twelve months.

(iv) Instrument calibration: the same requirements as provision 14(a)(iv).

(v) Number of beam monitors: the same requirements as provision 14(a)(v).

(vi) Calibration of beam monitors: the same requirements as provision 14(a)(vi).

15. Maintenance, repair, and modification of the medical therapy facilities shall be performed under the supervision of a senior reactor operator who is licensed by the U.S. Nuclear Regulatory Commission to operate the MIT Research Reactor. The 'medical therapy facility' includes the beam, beam shutters, beam monitoring equipment, medical therapy facility shielding, shield door, and patient viewing equipment. All modifications will be reviewed pursuant to the requirements of 10 CFR 50.59. The operating couch, patient positioning equipment, medical instruments, and other equipment used for the direct medical support of the patient

are not considered part of the medical therapy facility for purposes of this provision, except insofar as radiation safety (i.e., activation and/or contamination) is concerned.

16. Personnel who are not licensed to operate the MIT Research Reactor but who are responsible for either the medical therapy or the beam's design including construction and/or modification may operate the controls for the corresponding medical therapy facility beam provided that:

    a) Training has been provided and proficiency satisfactorily demonstrated on the design of the facility, its controls, and the use of those controls. Proficiency shall be demonstrated annually.

    b) Instructions are posted at the medical therapy facility's local control panel that specify the procedure to be followed:

        (i) to ensure that only the patient is in the treatment room before turning the primary beam of radiation on to begin a treatment;

        (ii) if the operator is unable to turn the primary beam of radiation off with controls outside the medical therapy facility, or if any other abnormal condition occurs. A directive shall be included with these instructions to notify the reactor console operator in the event of any abnormality.

    c) In the event that a shutter affects reactivity (e.g., the D_2O shutter for the medical room below the reactor and the converter control shutter for the fission converter beam), personnel who are not licensed on the MIT Research Reactor but who have been trained under this provision may operate that shutter provided that verbal permission is requested and received from the reactor console operator immediately prior to such action. Emergency closures are an exception and may be made without first requesting permission.

    Records of the training provided under subparagraph (a) above shall be retained in accordance with the MIT Research Reactor's training program or at least for three

years. A list of personnel so qualified shall be maintained in the reactor control room.

17. Events defined as 'recordable' under definition 8 of this specification shall be recorded and the record maintained for five years. Events defined as 'misadministrations' under definition 9 of this specification shall be reported to the U.S. Nuclear Regulatory Commission (24 hours verbal, 15 day written report). The 24 hour verbal reports will be made to the Headquarters Operation Center, or designate. The 15 day written reports will be sent to the NRC Document Control Desk, or designate.

18. The requirements of the Quality Management Program (QMP) for the Generation of Medical Therapy Facility Beams for Human Therapy at the Massachusetts Institute of Technology Research Reactor shall be observed for any human therapy. (Note: The presence of this commitment to observe the QMP in these specifications does not preclude modifying the QMP as provided in that document. Any such modifications are not considered to be a change to the MITR Technical Specifications.)

19. Reactor facilities (e.g., prompt gamma for the determination of boron concentration in blood or tissue) that are used to perform measurements associated with the conduct of medical therapy shall be calibrated every twelve months for any twelve-month interval that the beam will be used for human therapy. This twelve-month calibration shall be made prior to any patient irradiation for a given twelve-month interval. This calibration could be done by measuring a series of standards that span the anticipated range of boron in blood or tissue. In addition, a single point check, (e.g., verification that a single standard is measured ±10% of its true value) shall be performed prior to any patient irradiation.

20. An emergency power source shall be available for the beam monitor systems.

Definitions

1. The medical therapy facilities are equipped with shutters that are used (i) to control beam delivery and (ii) to adjust the neutron energy spectrum of the beam. The former currently include lead, boral, and light water shutters as described in Reference 6.5-1. The heavy water blister tank, which is also described in Reference 6.5-1, is an example of the latter. For the fission converter, the shutters that control beam delivery are a water shutter and a fast-acting mechanical shutter. It is conceivable that these designations may change should it be found desirable to alter the beam configuration. Accordingly, the phrase "shutters that control beam delivery" refers either to the aforementioned existing shutters or to any future shutter or group thereof that provides an equivalent or greater reduction in beam intensity. Shutter-effect analyses shall be documented through the standard safety review process including, where appropriate, an SAR revision and submission to NRC under 10 CFR 50.59.
2. The term 'calibration check' refers to the process of checking the beam intensity and quality via one or more of the following: foil activation; use of a fission chamber; use of an ion chamber; or an equivalent process. The purpose of a calibration check is to ensure that the beam has not changed in a significant way (e.g., energy spectrum or intensity) from the beam that was characterized.
3. The term 'functional check of the beam monitors' shall consist of verifying that system output is consistent (± 10%) with previously measured values upon normalization to a common neutronic power level.
4. The term 'characterization' refers to the process of obtaining the dose-versus-depth profile in phantoms as described in Reference 6.5-2 or an equivalent process. The dose-versus-depth profile from the surface of the phantom to a depth at least equivalent to the total thickness of the body part to be treated on a central axis is deemed adequate for a characterization. Fast neutron, thermal neutron, and gamma

ray components are determined in a characterization and monitors are normalized by this characterization.

5. The term ‘component replacement’ means the replacement of a component in the beam with an identical unit or the re-installation of a component in the beam for which a characterization has already been performed. For example, the latter may be a change of collimators.

6. The term ‘design modification’ as applied to a medical therapy facility beam refers (a) to a change that is shown to alter the dose-versus-depth profile of the fast neutrons, thermal neutrons, or gamma rays in the beam as sensed by the calibration check and (b) to a change that has the potential to increase significantly the amount of activation products in the medical therapy facility when the beam is to be used for the treatment of human patients.

7. The term ‘radiation fluence’ means the total fluence of neutrons and gamma radiation that is emitted in a medical therapy facility beam. The determination of the ratios of gamma, fast neutron, and thermal neutron fluences is part of the beam characterization. Knowledge of these ratios allows the total radiation fluence to be monitored by the on-line detectors, which are neutron-sensitive. Compliance with the limits specified on radiation fluence by this specification is determined by reference to the fluence monitored by these detectors.

8. The term ‘recordable event’ means the administration of:
   a) A radiation treatment without a written directive; or
   b) A radiation treatment where a written directive is required without reporting to the medical use license in writing each fluence given within 24 hours of the treatment; or
   c) A treatment delivery for which the administered radiation fluence for any given fraction is 15% greater than prescribed.

9. The term ‘misadministration’ means the administration of a radiation therapy:
   a) Involving the wrong patient, wrong beam (basement or fission converter), or wrong treatment site; or
   b) When the treatment delivery is not in accordance with provision 11 of this specification.
10. The term ‘written directive’ means an order in writing for a specific patient, dated and signed by a BNCT physician authorized user prior to the administration of radiation and which specifies the treatment site, the total radiation fluence, radiation fluence per fraction, the medical facility (basement medical therapy facility beam or fission converter medical therapy facility beam) and collimator, if any, to be used, and overall treatment period.
11. The term ‘human therapy’ means radiation treatments that are of direct therapeutic benefit to the patient and/or part of investigatory studies that involve humans.
12. The term ‘BNCT physician authorized user’ means a medical physician authorized by the medical use licensee’s radiation safety committee to act as an authorized user for BNCT on humans.
13. The term ‘certified medical physicist’ means a medical physicist certified in either radiological physics or therapeutic radiation physics by the American Board of Radiology, or in therapeutic radiation physics by the American Board of Medical Physics and who also has specific training in neutron dosimetry and neutron capture therapy.
14. The term ‘BNCT Principal Investigator’ means a person representing MIT who holds an advanced degree in science or engineering and who has two or more years of experience in BNCT.
15. The term ‘basement medical therapy facility beam’ means the beam emanating from the MIT Research Reactor into the medical therapy room that is physically located below the reactor on the building’s lower level.

16. The term 'fission converter medical therapy facility beam' means the beam emanating from the MIT Research Reactor's fission converter into the medical therapy facility that is physically located adjacent to the reactor on the building's main floor.

17. The term 'calibration of the beam monitors' refers to the process whereby the beam monitors that are described in provision 11 of this specification are calibrated against instruments that measure dose including a tissue-equivalent chamber and either a graphite- or magnesium-wall ionization chamber (or the equivalent to any of these three) that have in turn been calibrated by a secondary calibration laboratory.

Basis

The stipulation that patients only be accepted from a medical use licensee that has an NRC or an Agreement State medical use license that contains BNCT specific conditions and commitments for BNCT treatment of humans conducted at the Massachusetts Institute of Technology Research Reactor's Medical Therapy Facilities ensures that medical criteria imposed by NRC or the Agreement State on such licensees for the use of the MIT Research Reactor's medical therapy facility beams for human therapy will be fulfilled. The second provision delineates the division of responsibilities between the Massachusetts Institute of Technology and the medical licensee that refers the patient. Also, it establishes administrative authority and protocol for initiating and terminating a radiation therapy.

The requirement that it be possible to initiate a minor scram from control panels located in the medical therapy facility areas assures the attending physician and/or medical physicist of the capability to terminate the treatment immediately should the need arise. The provision that access to each medical therapy facility be limited to a single door ensures that there will be nor inadvertent entries. The various interlocks for the shutters that control beam delivery ensure that exposure levels in the medical therapy facility will be minimal prior to entry by personnel who are attending the patient. The shutter-indication lights serve to notify personnel of the beam's status. The provision for a radiation monitor ensures that personnel will have information available on radiation levels in the medical therapy facility prior to entry. The purpose of this monitor's audible alarm is to alert personnel to the presence of

elevated radiation levels, such as exist when the shutters that control beam delivery are open. This monitor and/or its alarm may be disabled once the medical therapy facility has been searched and secured so that it will (1) not disturb a patient and (2) not distract attending personnel. The monitor and/or its alarm are interlocked with the shield door so that they are made functional upon opening that door, and hence prior to any possible entry to the medical therapy facility. One intercom provides a means for the prompt exchange of information between medical personnel and the reactor operator(s). The second intercom is for monitoring the patient.

The provision for manual operation of each medical therapy facility's shield door ensures access to any patient in the event of a loss of electrical power. The presence of a viewing window and a closed-circuit TV camera provide the attending BNCT physician authorized user and/or medical physicist with the opportunity to monitor the patient visually as well as through the use of various instruments. The viewing window will function even during an electric power failure because of the provision for emergency lighting.

The specification that the total radiation fluence for a therapy (i.e., the radiation fluences for the sum of all fractions specified in a given treatment plan) not exceed that prescribed in the patient treatment plan by 20% establishes a trigger limit on the delivered fluence above which NRC has to be notified of a misadministration. The 20% criterion is based on the definition of misadministration (clause 4(iv)) as given in 10 CFR 35.2. The criterion that the difference between the administered and prescribed fluence for any seven consecutive days is set at 30%. This is also in accordance with the definition of misadministration (clause 4(iii)) as given in 10 CFR 35.2. Finally, if a treatment involves three or fewer fractions, then a more stringent criterion, 10%, applies to the difference between the total radiation fluence for a therapy and that prescribed in the treatment plan (10 CFR 35.2(4(ii)). The surveillance requirements for the functional checks as well as those for the beam calibration checks and characterizations provide a mechanism for ensuring that each medical therapy facility and its beam will perform as originally designed. Similarly, the surveillance requirements on the instruments used to perform these checks and

characterizations ensure that these instruments are calibrated by a means traceable to the National Institute of Standards and Technology. The chambers specified (tissue-equivalent, and graphite or magnesium-wall) were chosen because they measure dose as opposed to fluence. Finally, the requirement on the number of beam monitors is in keeping with standard practice for gamma-ray sources.

The specification on maintenance and repair of the medical therapy facilities ensures that all such activities are performed under the supervision of personnel cognizant of quality assurance and other requirements such as radiation safety. The provision on the training and proficiency of non-licensed personnel ensures that all such personnel will receive instruction equivalent to that given to licensed reactor operators as regards use of the medical therapy facility beams. (Note: Licensed reactor operators may, of course, operate the medical therapy facility beams.) Also, this provision provides for the posting of instructions to be followed in the event of an abnormality.

The specification on 'recordable events' and 'misadministrations' provides for the documentation and reporting to the U.S. Nuclear Regulatory Commission of improper events regarding the generation and use of medical therapy facility beams. The requirement that the Quality Management Program (QMP) be observed ensures that radiation treatments provided by a medical therapy facility beam will be administered as directed by the BNCT physician authorized user.

The specification on calibration of reactor facilities that are used to measure the concentration of boron in blood or tissue ensures that these measurements are accurate.

References

6.5-1 MITR Staff, "Safety Analysis Report for the MIT Research Reactor (MITR-II)," Report No. MITNE-115, 22 Oct. 1970, Section 10.1.3.

6.5-2 Choi, R.J., "Development and Characterization of an Epithermal Beam for Boron Neutron Capture Therapy at the MITR-II Research Reactor," Ph.D. Thesis, Nuclear Engineering Department, Massachusetts Institute of Technology, April 1991.

SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

SUPPORTING AMENDMENT NO. 32 TO

AMENDED FACILITY OPERATING LICENSE NO. R-37

THE MASSACHUSETTS INSTITUTE OF TECHNOLOGY

DOCKET NO. 50-20

1.0 INTRODUCTION

By letter dated June 30, 1999, as supplemented on March 17, August 15, November 9, and December 6, 2000, the Massachusetts Institute of Technology (MIT or the licensee) submitted a request for amendment of Appendix A, "Technical Specifications (TSs) for the MIT Research Reactor," to Amended Facility Operating License No. R-37 for the MIT Research Reactor (MITR). The requested changes would update TS 6.5 concerning generation of the medical therapy facility beams for human therapy and would allow the use of the fission converter beam and medical therapy room for human irradiations.

2.0 BACKGROUND

The Atomic Energy Act of 1954, as amended (the Act) authorizes the issuance of class 104 licenses for medical therapy (Section 104.a. of the Act) and for research and development facilities (Section 104.c. of the Act). All non-power reactors (NPRs) currently licensed by the Nuclear Regulatory Commission (NRC or the Commission) hold class 104.c. licenses in accordance with 10 CFR 50.21(c). MIT also holds an 104.a. license in accordance with 10 CFR 50.21(a). MIT is the only NPR licensee to hold a 104.a. license. This license was issued in 1958 when the original MIT reactor was licensed by the Atomic Energy Commission.

A potential medical therapy use for NPRs that was identified in the 1950s is the use of neutron beams to treat the cancers glioblastoma multiforme and metastasized melanoma. Called Boron Neutron Capture Therapy (BNCT), the treatment consists of a patient ingesting a boron compound that concentrates boron in the tumors. The patient is then exposed to a neutron beam from the NPR which causes the boron to fission into lithium and an alpha particle, which are heavy charged particles. These particles cause secondary ionization that kills the tumor cells.

MIT conducted patient trials during 1960-1962 with no success. Improved boron compounds and the use of epithermal neutron beams lead researchers to the conclusion that another attempt should be made to treat cancers using BNCT. This lead to MIT approaching NRC in 1991 about a resumption of BNCT patient trials.

The existing regulations authorize the issuance of licenses for human therapy but places no requirements or restrictions on the irradiation of humans with neutron beams from NPRs. Because NRC has not issued any other 104.a. licenses, regulations for the use of special nuclear material for medical therapy at NPRs had not been developed. However, regulations for the medical use of byproduct material have been developed in 10 CFR Part 35, "Medical Use of Byproduct Material." The use of neutron beams for medical therapy has many similarities to teletherapy. Because of this, the NRC staff decided to use the criteria of 10 CFR Part 35, Subpart I, Teletherapy, as a model for the requirements for neutron beams for the treatment of human patients. The requirements were placed in the MIT technical specifications.

The requirements of Part 35 were modified to account for the differences between teletherapy and BNCT. For regulatory purposes, BNCT is divided into two components: beam generation and beam use. MIT is responsible for the regulatory aspects beam generation and the hospital providing treatment to the patient is responsible for the regulatory aspects of beam use.

A February 19, 1992, letter to MIT from NRC outlined the following commitments and information that MIT was requested to submit to NRC:

(1) A commitment to limit the delivery of neutrons only to human subjects pursuant to a written directive from NRC medical use licensee No. 20-03857-06 (New England Medical Center). This commitment was broadened by Amendment No. 30 to the MIT reactor license issued on April 3, 1997, to include subjects from NRC and Agreement State medical use licensees whose licenses contain BNCT-specific conditions and commitments for BNCT treatments on humans conducted at MIT.

(2) A commitment to record events equivalent to "recordable events" in 10 CFR 35.2, report events equivalent to "misadministrations" in 10 CFR 35.2, and establish a written quality management program using the criteria specified in 10 CFR Part 35 for teletherapy (the neutron beam).

(3) The methodology to ensure that the neutron flux, fluence, and spectrum delivered to the patient are as requested by the medical use of byproduct material licensee.

(4) The design aspects of the neutron beam delivery system that are important to patient or user safety such that these aspects cannot be changed without license amendment.

(5) The reactor operator and physician communication system and the method for terminating the treatment exposures.

(6) A list of the anticipated activities that may alter beam characteristics and may require spot-checks before the beam use and the spot-checks that will be performed in these situations.

(7) The interlock systems and safety precautions used to prevent personnel from being accidentally exposed to the beam in the treatment room and the safety precautions to be followed before, during, and after treatment exposures to limit occupational exposure to ionizing radiation. Include information on surveillances, if required.

Each of these areas was addressed by MIT and the NRC issued Amendment No. 27 to the MIT license on February 16, 1993, adding requirements to the TSs for the use of the MITR-II medical facility beam for human therapy.

3.0 EVALUATION

Since Amendment No. 27 was issued, MIT has gained experience with the use of the beam and facility for human irradiations. Based on this experience, the licensee has requested changes to TS 6.5, "Generation of Medical Therapy Beams for Human Therapy."

The original beam and therapy room was built during initial facility construction in the 1950s (basement beam). The licensee has recently added a second fission converter beam and medical therapy room (converter beam). Amendment No. 31, issued on December 21, 1999, allowed operation of the second beam and medical therapy room, but did not allow human irradiations with the new beam. The proposed amendment would allow the second beam to be used for irradiation of humans. The new converter beam meets the requirements of TS 6.5 that are not modified by this license amendment. The licensee presented an analysis of the converter beam and existing TS 6.5. The NRC staff reviewed the analysis and found it acceptable. The NRC staff also concludes that the original 1992 commitments and information that formed the basis for issuance of Amendment No. 27 should remain in effect.

In addition to proposed changes to TS 6.5 to reflect experience gained by the licensee in the use of beams for medical therapy, the licensee has also proposed changing a number of TSs to reflect the addition of the new beam and therapy room. Single references were changed to plural references to reflect the existence of two beams. Because this change reflects the physical condition of the facility, it is acceptable to the staff.

It has been proposed that in TS 6.5.2 and 14 (a)(v) the reference to the Director of the Nuclear Reactor Laboratory (NRL) be replaced with BNCT Principal Investigator and that the responsibilities of the persons involved in human therapy be clarified. The affected section of TS 6.5.2 currently reads:

> Before the start of a therapy, both the certified medical physicist and the Director of the Nuclear Reactor Laboratory, or his designate, must agree that the therapy can be initiated. The BNCT physician authorized user is responsible for monitoring the therapy and for directing its termination. However, a radiation therapy can also be terminated at any time if either the BNCT physician authorized user or the NRL Director, or their designates, judge that the therapy should be terminated.

The proposed amended TS would read:

> Before the start of a therapy, both the certified medical physicist and the BNCT Principal Investigator, or designate, must agree that the therapy can be initiated. The BNCT physician authorized user is responsible for monitoring the therapy and can direct its termination. Because MIT is responsible for delivery of the prescribed fluence, the BNCT Principal Investigator, or designate, will under normal circumstances terminate the irradiation whenever the prescribed fluence is attained. However, a radiation therapy can also be terminated at any time if either the BNCT

> physician authorized user or the BNCT Principal Investigator, or their designates, judge that the therapy should be terminated.

When this TS was originally issued the Director of the NRL was the BNCT Principal Investigator. This is not currently the case. To ensure that the BNCT Principal Investigator is qualified for the responsibility given in the TSs, the licensee has proposed a new definition in the TSs (definition 14) and the Quality Management Program (QMP) (definition 9.c). The proposed definition reads as follows:

> The term 'BNCT Principal Investigator' means a person who holds an advanced degree in science or engineering and who has two or more years experience in BNCT.

In a discussion between the NRC MIT Project Manager and the Director of the MIT Nuclear Reactor Laboratory on January 30, 2001, it was agreed to add the words "representing MIT" to the definition to make it clear that the decisions the BNCT Principal Investigator makes with reference to the TSs, are made for the licensee. The amended definition reads as follows:

> The term 'BNCT Principal Investigator' means a person representing MIT who holds an advanced degree in science or engineering and who has two or more years experience in BNCT.

The proposed changes to TS 6.5.2 are acceptable to the staff because they clarify the responsibilities for initiating and terminating human therapy. The staff concludes that the combination of education and experience proposed for the BNCT Principal Investigator is sufficient to carry out the responsibilities of the TSs and this change is, therefore, acceptable.

The licensee has requested a change to TS 6.5.3 concerning the operability of the minor scram during patient irradiations. The TS currently reads:

> It shall be possible to initiate a minor scram of the reactor from a control panel located in each medical therapy area. In the event that the medical facility minor scram is inoperable, it shall be acceptable to use one of the control room scrams via communication with the reactor operator as a temporary means of satisfying this provision. Use of this temporary provision is limited to seven consecutive working days.

The licensee has proposed to change this TS to read:

> It shall be possible to initiate a minor scram of the reactor from a control panel located in each medical therapy area.

The licensee has decided that in case of a failure of the minor scram system in either medical therapy area, a substitute scram could be installed and tested without significant delay. Because this proposed change to the TS is more conservative than the existing TS (eliminating the provision for a temporary measure), it is acceptable to the staff.

The licensee proposed changes to TS 6.5.5(c) and 6.5.12(d), which concern failures of the shutters that control beam delivery. TS 6.5.5(c) currently reads:

> (c) The shutters that control beam delivery shall be designed to close automatically upon failure of either electric power or on low air pressure if the shutter is operated pneumatically.

The licensee has proposed changing this TS to read:

> (c) Except for the fission converter mechanical shutter, the shutters that control beam delivery shall be designed to close automatically either upon failure of electric power, or upon reduced air pressure if the shutter is operated pneumatically. For the fission converter mechanical shutter, the reactor will be scrammed automatically upon loss of electric power to that shutter.

The shutters for the basement beam are designed to close automatically if electricity or compressed air (if the shutters are pneumatically operated) is lost. This is a conservative design feature to make the shutters fail safe. The convertor beam has a fast-acting mechanical shutter (it takes about 15 seconds to close) and a water shutter (which takes about 100 seconds to fill with water). An additional shutter (converter control shutter) is used to control the neuronic coupling between the reactor core and the fission converter. Although this shutter also closes at the end of a patient irradiation, it is not considered part of the beam delivery system and is not subject to the requirements of TS 6.5. The licensee has discussed the consequences of the failure of the converter control shutter to close at the end of a patient treatment. With the mechanical and water shutters closed and the reactor in operation, the patient would have to remain in the irradiation position for over 25 hours to experience a medical overexposure of 10 percent (which is the most restrictive of the TS 6.5.11 criteria for the amount delivered radiation fluence can exceed prescribed fluence). The staff has reviewed the licensee's discussion and concludes that the converter control shutter need not be part of the requirements of the proposed TS.

Because of the design of the MIT emergency power system, it would be very difficult to design a system that would close the converter beam mechanical shutter using emergency power. A general power failure to the reactor facility would stop treatment because the reactor, which is the source of neutrons, would automatically shut down. The mechanical shutter can then be manually closed from outside the therapy room. The purpose of the beam shutters is to allow a controlled end to a patient irradiation and to reduce radiation levels in the medical treatment facility at the end of the irradiation so that the treatment staff can safely enter the medical therapy facility. It is noted by the licensee that the performance of the basement beam shutters has been excellent with no failures to close.

The licensee has analyzed various failures of the beam shutter system for the converter beam. The worse case is a failure of the mechanical shutter such that it cannot be closed either electrically or manually. The beam would have to be controlled by reactor shutdown and closing the water shutter. The beam monitoring system, which monitors the dose (counts) to the patient during therapy, scrams the reactor if the counts exceed what is planned by 2 percent. This type of failure would result in a maximum patient medical overexposure of

about 2.7 percent (which is within the most restrictive TS 6.5.11 criteria of 10 percent that the amount of delivered radiation fluence can exceed prescribed fluence).

Radiation levels in the therapy room would not prevent therapy staff from entering and removing the patient from the therapy room. The licensee calculates that the dose rate in the beam 5 minutes after reactor shutdown, with the converter control and the water shutter closed, is about 1 Rem/hr. It would take about 1 minute to remove the patient, which would result in a maximum exposure to a staff member of 20 mRem. Even in the highly unusual case where the mechanical shutter would fail when called upon to close during an medical emergency, staff entering the room as soon as possible when the therapy door is opened would receive exposures within occupational limits.

The staff has reviewed the various failure scenarios for the shutters in the converter beam and has concluded that patients will not experience unacceptable medical over-exposures and that the therapy staff can safely remove patients from the converter beam therapy room following the various failures. Therefore, it is acceptable to the staff to dispense with emergency power for the mechanical shutter and to scram the reactor if the mechanical shutter does not automatically close when required.

The licensee has proposed a new requirement (TS 6.5.5 f) that the converter beam mechanical shutter be capable of being manually closed. The proposed TS reads as follows:

f) The fission converter mechanical shutter, which is normally operated electrically, shall also allow manual closure.

The shutter can be manually closed in about 30 seconds. The shutter would be closed manually after a power failure with a shutter closure time not significantly greater than for automatic closure. Manually closing the shutter and scramming the reactor if the mechanical shutter loses electric power ensure patient and staff safety during therapy and are therefore acceptable to the staff.

TS 6.5.12(d) contains the surveillance requirement for TS 6.5.5(c), to conduct a monthly operational test to confirm that the shutters close on loss of electrical power (reduction of pressure for pneumatic operators). The licensee has proposed changing this surveillance to an operational test to confirm that the shutters close or the reactor automatically scrams on loss of electrical power (or that shutters close upon reduction of pressure to pneumatic operators). Because the proposed surveillance tests the new reactor scram function, it is acceptable to the staff.

The licensee has proposed adding a new surveillance requirement to the TS, 6.5.12(k), to conduct a monthly operational test of the manual closure of the fission converter mechanical shutter to ensure that TS 6.5.5.f is met. Because this new surveillance ensures that the manual mechanical shutter closure system is regularly tested for proper operation, it is acceptable to the staff.

The licensee has proposed changes to TS 6.5.14 to clarify the TS requirements, modify the surveillance frequencies for the basement beam based on experience gained through use of the existing beam, and establish surveillance frequencies for the new converter beam.

Current TS 6.5.14 a. discusses calibration checks of the beam and functional checks of the beam monitors and reads as follows:

> a) A calibration check of the beam and a functional check of the beam monitors that are described in provision 11 of this specification shall be made weekly for any week that the beam will be used for human therapy. These checks shall be made prior to any patient irradiation for a given week. In addition, a calibration check shall be performed prior to any patient irradiation in the event that any component of a given beam design has been replaced. Finally, a calibration and a functional check shall be performed prior to any patent irradiation in the event of a design modification.

To clarify the requirements for the basement beam, the licensee has proposed that this TS be split into two specifications, one for functional checks and one for calibration checks, which read as follows:

> 14. a) Use of the basement medical therapy facility beam shall be subject to the following:
>
> (i) A functional check of the beam monitors that are described in provision 11 of this specification shall be made weekly for any week that the beam will be used for human therapy. This check shall be made prior to any patient irradiation for a given week. In addition, a functional check shall be performed prior to any patient irradiation in the event of a component replacement or a design modification.
>
> (ii) A calibration check of the beam shall be performed every six months for any six-month interval that the beam will be used for human therapy. This six-month calibration check shall be made prior to any patient irradiation for a given six-month interval. In addition, a calibration check shall be performed prior to any patient irradiation in the event of a component replacement or a design modification.

The licensee has added a requirement in proposed TS 6.5.14 a. for a functional check of the beam monitor in the case of a “component replacement” (a newly defined term, see discussion below). Other aspects of the functional check are not changed. The licensee also adds the newly defined term, “component replacement,” to proposed TS 6.5.14 b, which concerns calibration checks of the beam (the concept of a component existed in the TS, but it was not referred to as a component replacement). Because this proposed change expands the use of the functional checks of beam monitors, it is acceptable to the staff.

The licensee has requested that the frequency of calibration checks of the beam be changed from weekly to every 6 months if the beam will be used for human therapy during that time. This was a first-of-a-kind beam when the original TSs became effective in 1993. The purpose of the calibrations was to ensure the stability of the beam over time. The beam parameters have remained stable over time. Therefore, the staff finds the increase in the interval between calibration checks of the basement beam to be acceptable.

For the converter beam the licensee has proposed the same functional checks as for the basement beam and weekly calibration checks. Proposed TS 6.14.b reads as follows:

14. b) Use of the fission converter medical therapy facility beam shall be subject to the following:

(i) Functional checks: the same requirements as provision 14(a)(i) above.

(ii) Calibration checks: the same requirements as provision 14(a)(ii) above except that all frequencies are weekly instead of six months.

Because the proposed surveillance requirements for the converter beam are based on the original intervals for the basement beam, the proposed surveillance requirements for beam functional and calibration checks of the converter beam are acceptable to the staff.

TS 6.5.14 b. concerning beam characterization currently reads as follows:

b) A characterization of the beam shall be performed every six months for any six-month interval that the beam will be used for human therapy. This six-month characterization shall be made prior to any patient irradiation for a given six-month interval. A characterization shall also be performed prior to any patient irradiation in the event of a design modification. As part of the characterization process, the proper response of the beam monitors that are described in provision 11 of this specification shall be verified.

For the basement beam, the licensee has numbered its proposed TS 6.5.14 (a)(iii). It reads as follows:

14. a) Use of the basement medical therapy facility beam shall be subject to the following:

(iii) A characterization of the beam shall be performed every twelve months for any twelve-month interval that the beam will be used for human therapy. This twelve-month characterization shall be made prior to any patient irradiation for a given twelve-month interval. A characterization shall also be performed prior to any patient irradiation in the event of a design modification. As part of the characterization process, the proper response of the beam monitors that are described in provision 11 of this specification shall be established.

The licensee has proposed that the frequency of the beam characterization for the basement beam be increased from 6 to 12 months if the beam will be used for human therapy in that time. The reason for this requested change is that the beam characteristics have not changed since 1994. Reducing the frequency of the characterizations will also reduce radiation exposure to the MITR staff. Therefore, the staff finds the increase in the intervals between characterizations of the basement beam to be acceptable.

The licensee has proposed retaining the 6-month interval for characterization of the converter beam:

> 14. b) Use of the fission converter medical therapy facility beam shall be subject to the following:
>
> (iii) Characterization: the same requirements as provision 14(a)(iii) above except that all frequencies are six months instead of twelve months.

Because this proposed TS maintains the shorter characterization interval for the new converter beam, it is acceptable to the staff.

TS 6.5.14 c. concerning calibration of the beam monitors has been renumbered 14(a)(vi) and a corresponding identical requirement for the converter beam has been added to the TS as TS 14(b)(vi). The corresponding Definition 5 of TS 6.5 has been renumbered as Definition 17. These renumberings are administrative and are therefore acceptable to the staff. The added requirement for calibration of the beam monitors for the new converter beam is identical to the requirement for the basement beam and, is therefore, acceptable to the staff.

The licensee has a new TS 6.5.14 (a)(iv) for the basement beam:

> 14. a) Use of the basement medical therapy facility beam shall be subject to the following:
>
> (iv) The instruments (e.g., tissue-equivalent chamber or graphite-magnesium wall ionization chamber or the equivalent) that are to be used to perform both calibration checks and characterization of the beam shall be calibrated by a secondary calibration laboratory. This calibration shall be performed at least once every two years for any two-year interval that the beam will be used for human therapy. The two-year calibration shall be made prior to any patient irradiation during any given two-year interval. (Note: If a method (e.g., foil activation) other than these checks is used for the calibration and or the characterization, then the devices (e.g., foils) used in that method shall either be traceable to the National Institute of Standards and Technology or be selected in accordance with the relevant ANSI/ANS standards.)

The licensee has also proposed a new TS 6.5.14 (b)(iv), which states that the converter beam has the same requirements as the basement beam. The licensee has proposed this new TS to clarify the requirements for the instruments used for calibration checks and beam characterizations. The licensee has been following these requirements but has not stated them in the TSs. Because the proposed changes add a new requirement and clarify the TS, the changes are acceptable to the staff.

The licensee has proposed a new TS, 6.5.14 (a)(v) on the number of beam monitors required to perform a patient irradiation. The proposed TS reads as follows:

14. a) Use of the basement medical therapy facility beam shall be subject to the following:

    (v) There shall be a minimum of two neutron-sensitive beam monitors to initiate a patient irradiation. Once initiated, a patient irradiation may be continued at the discretion of both the certified medical physicist and the BNCT Principal Investigator, or designate, provided that at least one neutron-sensitive beam monitor is operable.

The licensee has proposed a new TS, 6.5.14 (b)(v), which states that the same requirements apply to the converter beam. Normally four beam monitors sample the beam. The beam monitors are used to determine when the patient has received the prescribed amount of radiation. Based on the symmetry of the beam, the characterization and calibration of the beam, and the reliability of the beam monitors and associated electronics, starting an irradiation with two monitors in operation gives sufficient information to the beam operators and the persons supervising the irradiations. If an irradiation that is started with two beam monitors in operation experiences the failure of a monitor, one monitor is sufficient to complete the irradiation. Because the proposed TSs add requirements to the TSs for monitor operability and experience has shown that an irradiation can be started with two monitors and finished with one monitor operable, the proposed TSs are acceptable to the staff.

The licensee has proposed a change to TS 6.5.16 (c) about operation of shutters that may affect reactivity of the reactor. The convertor control shutter is added to the TS because its movement may affect reactivity. Because the proposed change to this TS reflects the addition of the convertor beam, the change is acceptable to the staff.

The licensee has proposed changes to the reporting requirements in TS 6.5.17 to eliminate the requirement to report misadministrations to the Region I Administrator. Full responsibility for the regulation of non-power reactors has been transferred to NRC Headquarters. Verbal reports are made to the Headquarters Operations Officer and written reports are submitted to the Document Control Desk. Because these changes clarify reporting requirements to reflect the current NRC organizational structure, these changes are acceptable to the staff.

The licensee has proposed a new TS, 6.5.19 concerning other reactor facilities involved in medical therapy. The proposed TS reads as follows:

19. Reactor facilities (e.g., prompt gamma for the determination of boron concentration in blood or tissue) that are used to perform measurements associated with the conduct of medical therapy shall be calibrated every twelve months for any twelve-month interval that the beam will be used for human therapy. This twelve-month calibration shall be made prior to any patient irradiation for a given twelve-month interval. This calibration could be done by measuring a series of standards that span the anticipated range of boron in blood or tissue. In addition, a single point check, (e.g., verification that a single standard is measured ±10% of its true value) shall be performed prior to any patient irradiation.

This proposed TS adds a requirement that reactor facilities involved in measurements used in medical therapy be calibrated at a 12-month interval and a single point check be performed prior to any patient irradiation. This proposed TS helps to ensure that measurements performed using other reactor facilities in support of providing medial therapy will be accurate. The licensee has been performing these calibrations and checks for over 4 years without problem. Because the proposed TS adds requirements for calibration for reactor facilities used in medical therapy, and because the proposed surveillances at the proposed intervals have historically showed the equipment to be operating properly, the change is acceptable to the staff.

The licensee has proposed a new TS, 6.5.20, and an associated surveillance requirement, 6.5.12 (l), for the beam monitoring systems, which are composed of the beam monitors and data recorders for patient dose. The TS requires the beam monitoring system to have an emergency power source and the power source to undergo a operational test at least monthly and prior to treatment if the equipment has been repaired or deenergized. Because this proposed TS helps to ensure that patient dose data will continue to be acquired in the event of a power failure, it is acceptable to the staff.

The licensee has proposed a change to Definition 1, which defines “shutters that control beam delivery.” The converter beam water shutter and fast-acting mechanical shutter are added to the definition to reflect the addition of the converter beam to the TSs. Because the change describes the new converter beam, it is acceptable to the staff.

The licensee has proposed a change to Definition 3, which defines “functional check of the beam monitors.” The phrase “normalization to a common reactor neutronic power level” is changed to “normalization to a common neutronic power level” to reflect the addition of the fission convertor. Because the change describes the new converter beam, it is acceptable to the staff.

The licensee has proposed a new definition for the term “component replacement”:

> 5. The term 'component replacement' means the replacement of a component in the beam with an identical unit or the re-installation of a component in the beam for which a characterization has already been performed. For example, the latter may be a change of collimators.

The definition clarifies the use of the term in other parts of TS 6.5. This concept of component replacement was used in other parts of TS 6.5 but was never defined. The proposed definition clarifies this concept and is acceptable to the staff.

A change has been proposed to Definition 9, “misadministration,” to add the administration of radiation therapy with the wrong beam (basement or fission converter) as a misadministration. A similar change has been proposed for the “Quality Management Program for Generation of MITR Medical Therapy Facility Beams for Human Therapy” (QMP). These changes are acceptable to the staff because they reflect the addition of the new beam.

A change has been proposed to Definition 10, “written directive,” to specifically state in the written directive the medical facility and collimator (if any) to be used. This helps to ensure that

therapy will be performed using the proper beam (either the basement or converter beam). Because this change reflects the addition of the new converter beam, it is acceptable to the staff.

The licensee has proposed two new definitions to differentiate between the basement and converter beams as follows:

15. The term 'basement medical therapy facility beam' means the beam emanating from the MIT Research Reactor into the medical therapy room that is physically located below the reactor on the building's lower level.

16. The term 'fission converter medical therapy facility beam' means the beam emanating from the MIT Research Reactor's fission converter into the medical therapy facility that is physically located adjacent to the reactor on the building's main floor.

These new definitions are acceptable to the staff because they clarify the TSs and describe the difference between the two beams used for human therapy at MIT.

The licensee has proposed changes to the basis of TS 6.5 that are consistent with the changes discussed above. The staff has reviewed the changes to the basis and finds that they reflect the proposed changes to TS 6.5 and are therefore acceptable.

The licensee provided a copy of proposed changes to the QMP. The staff notes that these proposed changes are similar to the changes proposed for the TSs. Although the QMP is required pursuant to the TSs, the QMP is not part of the TSs and may be changed by the licensee without license amendment. The requirements for changing the QMP are given in the QMP. The staff reviewed the QMP and finds that it assures that the requirements of the TSs as related to the QMP will continue to be met.

4.0 ENVIRONMENTAL CONSIDERATION

This amendment involves changes in the installation or use of a facility component located within the restricted area as defined in 10 CFR Part 20 or changes in inspection and surveillance requirements. The staff has determined that this amendment involves no significant increase in the amounts, and no significant change in the types, of any effluents that may be released off site, and no significant increase in individual or cumulative occupational radiation exposure. Accordingly, this amendment meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). Pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the issuance of this amendment.

This amendment involves changes in recordkeeping, reporting, or administrative procedures or requirements. Accordingly, the amendment meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(10). Pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the issuance of this amendment.

5.0 CONCLUSION

The staff has concluded, on the basis of the considerations discussed above, that (1) because the amendment does not involve a significant increase in the probability or consequences of accidents previously evaluated, or create the possibility of a new or different kind of accident from any accident previously evaluated, and does not involve a significant reduction in a margin of safety, the amendment does not involve a significant hazards consideration; (2) there is reasonable assurance that the health and safety of the public will not be endangered by the proposed activities; and (3) such activities will be conducted in compliance with the Commission's regulations and the issuance of this amendment will not be inimical to the common defense and security or the health and safety of the public.

Principal Contributor: A. Adams, Jr.

Date: April 2, 2001