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December 6, 2000

Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20555

Subject: Further Response to Request for Additional Information (TAC No. MA6134), Docket No. 50-20, License No. R-37

Gentlemen:

On June 30, 1999, the Massachusetts Institute of Technology submitted a request to amend MIT Research Reactor Technical Specification No. 6.5, "Generation of Medical Therapy Facility Beam for Human Therapy." On December 23, 1999, we received a request from NRC for additional information. That response was provided on March 17, 2000. On July 21, 2000, we received a further request for information. That response was provided on August 15, 2000. On November 9, 2000, some additional changes that were either administrative in nature or served to improve clarity were provided. Enclosed are several additional such changes.

Also enclosed is a copy of the proposed wording of MITR Technical Specification No. 6.5 and its associated QMP. This wording supersedes that of our submission of November 9, 2000.

Sincerely,

Thomas H. Newton, Jr.
Reactor Engineer

Lin Wen Hu, Ph.D.
Reactor Relicensing Engineer

John A. Bernard, Ph.D.
Director

JAB/koc

Enclosure

cc: USNRC - Senior Project Manager, NRR/ONDD

USNRC - Region I - Project Scientist
Effluents Radiation Protection Section (ERPS)
FRSSB/DRSS

A020

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

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 no 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

## 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 fractions, 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 |

| | | |
|---|---|---|
| d) | 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 |
| e) | Manual closure of pneumatic shutters | Operational test |
| f) | Shutters can be closed manually from within the facility | Operational test |
| g) | Shutter status lights | Operational test |
| h) | Radiation monitor alarm | Operational test |
| i) | Radiation monitor and/or alarm enabled upon opening of shield door | Operational test |
| j) | 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 twenty-four 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 licensee 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 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 no 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(4ii)). 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.

# Quality Management Program

for

Generation of MITR Medical Therapy Facility Beams

for Human Therapy

Quality Management Program: Generation of MITR Medical Therapy Facility Beams for Human Therapy

1. Purpose: The objective of this quality management program is to ensure that radiation treatments provided by the MIT Research Reactor's (MITR) Medical Therapy Facility beams will be administered as directed by a BNCT physician authorized user.

2. Authorized Medical Use Licensees: Use of the MIT Research Reactor's Medical Therapy Facility beams, for the treatment of human subjects, is limited to the BNCT physician authorized users from medical centers 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.

3. Program Requirements: The following requirements are established as part of this quality management program:

   a) A written directive will, except as noted in subparagraph (iv) below, be prepared by a BNCT physician authorized user of either the NRC or Agreement State medical use licensee prior to the administration of any radiation therapy. This directive shall be written, signed, and dated by the BNCT physician authorized user and it shall include the following information:

      (i) Name and other means of identifying the patient.

      (ii) Names of the BNCT physician authorized user and certified medical physicist in charge of the therapy.

      (iii) The medical facility (basement medical therapy facility beam or fission converter medical therapy facility beam) to be used and the collimator, if any, the total radiation fluence to be administered, the radiation fluence per fraction, the treatment site, and the overall treatment period.

      (iv) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided the oral revision is documented immediately in the patient's record and a revised written directive is signed by a BNCT physician authorized user within 48 hours of the oral revision.

      Also, a written revision to an existing written directive may be made for any therapeutic procedure provided that the revision is dated and signed by a BNCT physician authorized user prior to the administration of the next fraction.

      If, because of the emergency nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

(v) In order to ensure that the Staff of the MIT Research Reactor has the most recent written directive from the medical use licensee and the correct directive for the patient in question, a copy of that directive shall be hand-delivered to the MITR Staff by the Staff of the medical use licensee who accompany the patient to MIT. This copy shall then be checked against the most recent previous transmission. Any discrepancy shall be resolved by the medical use licensee prior to the initiation of patient irradiation.

(vi) The BNCT Principal Investigator, or designate, will date and sign the written directive to verify that current and accurate beam characteristic parameters were provided to the NRC or Agreement State medical use licensee as appropriate and that the radiation fluence desired in the written directive was delivered. A copy of this signed directive shall be provided to the medical use licensee within twenty-four hours of a treatment.

b) Prior to each administration of any radiation, the patient's identity will be verified by more than one method as the individual named in the written directive. The MIT Nuclear Reactor Laboratory will use any two or more of the following acceptable methods of identification:

(i) Self-identification by patients who are conscious upon arrival at the MIT Research Reactor. Information provided by the patient shall include any two of the following: name, address, date of birth, or social security number. The information provided by the patient is to be compared to the corresponding information in the patient's record.

(ii) Hospital wrist band identification with the wrist band information to be compared to the corresponding information in the patient's record.

(iii) Visual identification against photographs provided with the written directive.

(iv) Other methods as specified in U.S. Nuclear Regulatory Commission Regulatory Guide 8.33, "Quality Management Program."

c) The plan of treatment is certified by the certified medical physicist to be in accordance with the written directive. In this regard, the Massachusetts Institute of Technology is responsible for calibrating the output of the beam monitoring instrumentation versus dose in phantom and for providing a central axis dose versus depth profile for the identified beam. This information will then be used by personnel at either the NRC or the Agreement State medical use licensee as appropriate to generate a plan of treatment. Conformance of the beam to its design characteristics is confirmed through the measurements specified in MITR Technical Specification #6.5, "Generation of Medical Therapy Facility Beams for Human Therapy." Functional checks are made of the beam monitors at least weekly for any week that the beam will be used for human therapy (provisions 14(a)(i) and 14(b)(i)). Calibration checks are performed every six months for any six-month interval that the basement medical beam will be used for human therapy (provision 14(a)(ii)) and every week for any week that the fission converter medical beam will be used for human therapy (provision 14(b)(ii)). The basement medical beam is characterized

dosimetrically every twelve months (provision 14(a)(iii)). The fission converter medical beam is characterized dosimetrically every six months (provision 14(b)(iii)). The instruments that are used to perform calibration checks and characterizations of the beams are calibrated every two years by a secondary calibration laboratory (provisions 14(a)(iv) and 14(b)(iv)).

d) Each administration of radiation is in accordance with the written directive subject to the tolerances established in provision 11 of MITR Technical Specification #6.5, "Generation of Medical Therapy Beams for Human Therapy."

e) Any unintended deviations from the written directive shall be identified and evaluated, and appropriate action taken. Such action shall include informing the medical use licensee of the deviation. These reviews shall be performed monthly for any month in which human therapy was conducted. For each patient case reviewed, it shall be determined whether the administered total fluence, fluence per fraction, treatment site, treatment beam (basement or fission converter), and overall treatment period were as specified in the written directive. In the event of any deviation from the written directive, the licensee (MIT) shall identify its cause and the action required to prevent recurrence. These actions may include new or revised policies, new or revised procedures, additional training, increased supervisory review of work, or other measures as deemed appropriate. Corrective actions shall be implemented as soon as practicable.

4. Program Implementation: The following practices shall be observed in order to ensure proper implementation of the quality management program:

a) A review shall be conducted of the quality management program. This review shall include, since the last review, an evaluation of:

(i) A representative sample of patient administrations,

(ii) All recordable events, and

(iii) All misadministrations.

The objective of this review is to verify compliance with all aspects of the quality management program. For purposes of this review, the term 'representative' in statement (i) above is defined as 100% sampling up to twenty patients; a sample of twenty for twenty-one to one hundred patients, and 20% sampling for more than one hundred patients. In order to eliminate any bias in the sample, the patient cases to be reviewed should be selected randomly.

b) The procedure for conducting the above review is as follows:

(i) The review shall be performed by the Director of the MIT Radiation Protection Program or designate.

(ii) The review shall be performed annually.

(iii) Patient administrations selected for review shall be audited to determine compliance with each of the requirements listed in paragraph (3) above.

(iv) The review shall be written and any items that require further action shall be so designated. Copies of the review shall be provided to the NRL Director and to the MIT Reactor Safeguards Committee who will evaluate each review and, if required, recommend modifications in this quality management program to meet the requirements of paragraph (3) above. A copy of these reviews will also be provided to each medical use licensee.

c) Records of each review, including the evaluations and findings of the review, shall be retained in an auditable form for three years.

d) The licensee (MIT) shall reevaluate the Quality Management Program's policies and procedures after each annual review to determine whether the program is still effective or to identify actions required to make the program more effective.

5. Response to Recordable Event: Within thirty days after the discovery of a recordable event, the event shall be evaluated and a response made that includes:

a) Assembling the relevant facts, including the cause;

b) Identifying what, if any, corrective action is required to prevent recurrence; and

c) Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.

A copy of any recordable event shall be provided to the affected medical use licensee.

6. Records Retention: The following records shall be retained:

a) Each written directive for three years; and

b) A record of each administered radiation therapy where a written directive is required in paragraph (3(a)) above, in an auditable form, for three years after the date of administration.

7. Program Modification: Modifications may be made to this quality management program to increase the program's efficiency provided that the program's effectiveness is not decreased. All medical use licensees shall be notified of any modifications and provided with a copy of the revised program. The licensee (MIT) shall furnish the modification to the NRC Document Control Desk within 30 days after the modification has been made.

8. Report and Surveillance Frequency: Any report or other function that is required to be performed in this Quality Management Program at a specified frequency shall be performed within the specified time interval with:

a) a maximum allowable extension not to exceed 25% of the specified surveillance interval, unless otherwise stated in this Quality Management Program;

b) a total maximum combined interval time for any three consecutive surveillance intervals not to exceed 3.25 times the specified surveillance interval.

9. Definitions:

a) 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.

b) 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 beam capture therapy.

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

d) 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.

e) 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.

10. Applicability: This Quality Management Program applies solely to the generation of medical therapy facility beams for the treatment of human subjects. It does not apply to any other use of the medical therapy facilities and/or their beams. Reports and surveillances listed in this specification are only required if human therapy was conducted during the referenced interval.