6.5 Generation of Medical Therapy Facility Beam for Human Therapy

Applicability

This specification applies solely to the generation of the medical therapy facility beam for the treatment of human patients. It does not apply to any other use of the medical therapy facility and/or its beam.

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 their physician 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 NRC Medical Use Licensee No. 20-03857-06 or from any other medical use licensee that has been similarly authorized by NRC to utilize the MIT Research Reactor's Medical Therapy Facility beam for human therapy.

2. All medical treatments, including irradiations and analyses of the neutron capture agents in the patients, are the responsibility of the licensed physician in charge of the therapy and the medical physicists from the NRC-licensed medical center. The Massachusetts Institute of Technology is only responsible for delivery of the desired radiation fluence as requested by the medical physicist in charge of the therapy. Before the start of a therapy, both a certified medical physicist and the Director of the Nuclear Reactor Laboratory, or his designate, must agree that the therapy can be initiated. A certified medical physicist 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 physician or the NRL Director, 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 the medical therapy facility 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.**

4. Access to the 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) 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.

   (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.

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 the 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. The medical therapy facility shall be equipped with a monitor that provides a visual indication of the radiation level within the facility, **that** indicates at the local control panel, **and that provides a local, audible alarm.**

(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 within 24 hours prior to any patient irradiation.

(c) **This radiation monitor shall be calibrated quarterly.**

(d) **The audible alarm shall be set so as to alert personnel if radiation levels in the medical therapy facility exceed that which exists with the reactor at full power and with the shutters that control beam delivery in the closed position by more than a factor of three. 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. **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 between the medical therapy facility and the reactor control room.

9. It shall be possible for personnel monitoring a patient to open the 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 either the patient's physician or medical physicist. 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 on loss of electrical power and reduction of pressure in pneumatic operators, if applicable	Operational test
e)	Manual closure of pneumatic shutters	Operational test
f)	Feasibility of shutter closure from within the facility	Operational test
g)	Shutter status lights	Functional check
h)	Radiation monitor alarm	Operational test
i)	Radiation monitor and/or alarm enabled upon opening of shield door	Functional check

In addition to the above, the 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 the medical therapy facility's shield door shall be verified semi-annually.

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

    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 patient irradiation in the event of a design modification.

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 that any component of a given beam design has been modified. 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.

c) 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.

15. Maintenance, repair, and modification of the medical therapy facility 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 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), 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 7 of this specification shall be recorded and the record maintained for five years. Events defined as 'misadministrations' under definition 8 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 Regional Administrator, Region I, or his designate. The 15 day written reports will be sent to the NRC Document Control Desk with a copy to the Regional Administrator, Region I, or his designate.**

18. **The requirements of the Quality Management Program for the Generation of Medical Therapy Facility Beam for Human Therapy at the Massachusetts Institute of Technology Research Reactor shall be observed for any human therapy.**

Definitions

1. The medical therapy facility is 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. 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 three 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 reactor 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 full characterization and monitors are normalized by this characterization.

5. **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 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.

6. The term 'design modification' as applied to the 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 the 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 where a written directive is required and where the treatment is appropriate; or

   (b) A radiation treatment where a written directive is required without the per treatment recording of administered radiation fluence in the appropriate record; 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 mode of treatment, 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 an authorized user **physician** prior to the administration of radiation and which specifies **the treatment site,** the total radiation fluence, radiation fluence per fraction, 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 '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.

Basis

The stipulation that patients only be accepted from NRC Medical Use Licensee No. 20-03857-06 or from any other medical use licensee that has been similarly authorized by NRC to utilize the MIT Research Reactor's Medical Therapy Facility beam for human therapy, ensures that medical criteria imposed by NRC on such licensees for the use of the MIT Research Reactor's medical therapy facility beam 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 a control panel located in the medical therapy facility area 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 the 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.** The intercom provides a means for the prompt exchange of information between medical personnel and the reactor operator(s).

The provision for manual operation of the medical therapy facility's shield door ensures access to any patient in the event of a loss of electrical power. The presence of the viewing window and a closed-circuit TV camera provide the attending physician 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 an allowable upper limit on the delivered fluence. 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 beam calibration checks **and characterizations** provide a mechanism for ensuring that the medical therapy facility and its beam will perform as originally designed. **Similarly, the surveillance requirements on the beam monitors 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.**

The specification on maintenance and repair of the medical therapy facility 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 beam. (Note: Licensed personnel may, of course, operate the medical therapy facility beam.) 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 the medical therapy facility beam. **The requirement that the Quality Management Program (QMP) be observed**

ensures that radiation treatments provided by the medical therapy facility beam will be administered as directed by an authorized user. (Note: The presence of this committment 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.)

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.