Quality Management Program

for

Generation of MITR-II Medical Therapy Facility Beam for Human Therapy

Quality Management Program: Generation of MITR-II Medical Therapy Facility Beam 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-II) Medical Therapy Facility beam will be administered as directed by a *physician* authorized user.

2. Authorized Medical Use Licensees: Use of the MIT Research Reactor's Medical Therapy Facility beam, for the treatment of human subjects, is limited to the physician authorized users authorized under:

   (a) NRC Medical Use Licensee No. 20-03857-06.

   (b) 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.

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 physician authorized user of the NRC-approved* medical use licensee prior to the administration of any radiation therapy. This directive *shall be written, signed, and dated by the physician authorized user and it* shall include the following information:

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

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

      (iii) 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 *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 *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 Director of the MIT Nuclear Reactor Laboratory, or his designate, will date and sign the written directive to verify that current and accurate beam characteristic parameters were provided to the NRC-approved medical use licensee 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 shall include name, address, date of birth, and social security number. *The social security number 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. This information *will then be used by personnel at the NRC-approved medical use licensee 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 Beam for Human Therapy." The beam is characterized dosimetrically every six months (provision 14(b)), the beam monitors are calibrated every two years by a secondary calibration laboratory and their proper operation is verified semi-annually (provision 14(c)), and calibration checks are made of the beam at least weekly for any week that the beam will be used for human therapy (provision 14(a)).

(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 Beam 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, 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 his 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 (Region I) 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 'physician authorized user' means a medical physician approved for neutron capture therapy by an NRC-approved medical use licensee.*

(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.

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