NUCLEAR REACTOR LABORATORY

AN INTERDEPARTMENTAL CENTER OF
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J. A. BERNARD, JR.
Director of Reactor Operations

January 22, 1993

U.S. Nuclear Regulatory Commission,
ATTN: Document Control Desk
Washington, D.C. 20555

Subject: Further Response to Request Dated 12/01/92 for Additional Information (TAC No. M82958) Concerning Generation of Medical Therapy Facility Beam for Human Therapy, License No. R-37, Docket No. 50-20

Gentlemen:

On 12/22/92, the Massachusetts Institute of Technology submited, in their entirety, revised copies of proposed MITR Technical Specification No. 6.5, "Generation of Medical Therapy Facility Beam for Human Therapy" and "Quality Management Program for Generation of MITR-II Medical Therapy Facility Beam for Human Therapy." Also enclosed was the last page of existing Specification No. 7.13, "Plant Reporting Requirements." The revisions in those documents, which were denoted by italicized print, were made in response to the letter of 1 December 1992 from Mr. Alexander Adams, Jr. (Project Manager NRR/PDNP) to Dr. John A. Bernard (Director of Reactor Operations, MIT). All changes requested in that letter were made. On 12/30/92, three further changes were requested. Revised copies of the above documents were therefore submitted at that time. One additional change in the Quality Management Program has since been identified as desirable. Accordingly, page 2 of that document is hereby resubmitted.

Sincerely,

John A. Bernard, Ph.D.
Director of Reactor Operations
MIT Research Reactor

JAB/gw

Enclosure: Revision to paragraph 3(b)(i) of the proposed Quality Management Program

cc: MITRSC (with enclosures)
USNRC - Project Manager,
NRR/PDNP
USNRC - Region I - Chief,
Effluents Radiation Protection Section (ERPS)
FRSSB/DRSS
USNRC - Director,
NRR/PDNP

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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 *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. 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."