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March 17, 2000

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555

Re: 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. Enclosed is our response to that request. Please note that, as a result of further design considerations, our proposed revision of specifications 6.5.5(c) and 6.5.12(d) has been further modified. The new wording provides for a fail-safe mode of operation. This wording is given in our response to question #2 of the TAC.

In addition to the changes in Technical Specification No. 6.5 that are necessitated by our response to the TAC, we have made some additional changes that provide clarification. These are delineated as Item No. 17 in our response to the TAC.

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 June 30, 1999.

Sincerely,

John A. Bernard, Ph.D.
Director

JAB/koc

A020

Response to TAC No. MA6134

1. The fission converter beam and its associated medical therapy room conform to the requirements of MITR Technical Specification No. 6.5, as proposed for revision by MIT. In order to demonstrate this, each provision of the proposed technical specification is listed below together with an explanation of the design feature of the fission converter (FC) beam and its associated medical therapy room that establishes conformance. Certain provisions of the technical specification, such as the first one (No. 6.5.1) are administrative requirements on the conduct of an irradiation for human therapy and do not pertain to system design. In such cases, an entry of "N/A" is given below under the column "Design Feature." It is both MIT's understanding and intent that the administrative procedures be followed during the conduct of patient irradiations using either the FC beam or the original beam.

Provision No.	Design Feature
6.5.1	N/A
6.5.2	N/A
6.5.3	Refer to Table 6.6.2.5-1 of Technical Specification 6.6.2.5. For both operation with forced convection and operation without forced convection of flow, a minor scram of the reactor is required at the FC medical control panel which is located in the FC Medical Therapy Facility area.
6.5.4	Access to the FC Medical Therapy Facility will be controlled by means of a shield door located at its entrance.
6.5.5	For the existing beam (the one below the reactor), the shutters that control beam delivery are the water, lead, and boral shutters. All are electrically controlled. Closure of the water shutter is achieved by an electric signal that controls a solenoid valve that in turn positions an air-operated valve that allows water to fill the shutter by gravity. On loss of electric power, the shutter fills. The lead and boral shutters are pneumatically driven. Both close automatically on reduction of pneumatic pressure. Hence, these three shutters are fail-safe. For the FC, the shutters that control beam delivery are a water shutter and a fast-acting mechanical shutter. (Cont.)

6.5.5 Cont.	Both are electrically controlled. Closure of the water shutter is achieved by an electric signal that controls a solenoid valve that in turn positions an air-operated valve that allows water to fill the shutter by gravity. On loss of electric power, the shutter fills. Closure of the fast-acting mechanical shutter is achieved by an electric signal that applies power to operate the shutter drive. The following will be installed: a) An interlock to prevent opening of the FC shutters that control beam delivery unless the medical therapy facility's shield door is closed. b) An interlock to close the FC shutters that control beam delivery automatically upon opening of the medical therapy facility's shield door. c)) An interlock or passive (i.e., fail-safe) design will be utilized so that: (i) The FC water shutter will close automatically on loss of either air pressure or electrical power, or both. (ii) Loss of electrical power to the FC mechanical shutter will result in an automatic reactor scram. d) Not applicable for fission converter shutters. e) It will be possible to close the FC shutters that control beam delivery from within the medical therapy facility.
6.5.6	The shutters that control beam delivery are, as noted above, the water shutter and the fast-acting mechanical shutter. Both will be equipped with lights that indicate the status of the shutter's position. These lights will be visible at the FC Medical Therapy Facility's local control panel. An alternate means of indication for the water shutter would be the level in its storage tank. An alternate means of indication for the fast-acting mechanical shutter would be the beam monitoring system readout.
6.5.7	The FC Medical Therapy Facility will be equipped with the same complement of radiation monitors as are used in the existing medical therapy facility (the one located below the reactor). These will include an area monitor that is located outside the facility and which indicates in the control room, an area monitor that is located within the facility and which indicates both inside the facility and in the control room, and a third monitor that satisfies the provisions of MITR Technical Specification 6.5.7. This third monitor will be located inside the Fission Converter Medical Therapy Room. It will indicate both within that room and at the local control panel, and it will provide an audible alarm both within the facility and at the local control panel. In addition, it will be equipped with a battery backup power supply. (Note: The other provisions of MITR Technical Specification 6.5.7 are administrative.)

6.5.8	The FC Medical Therapy Facility will be equipped with two intercoms. The first will allow communication between the FC Medical Therapy Facility control panel and the reactor control room. The second will allow communication between the FC Medical Therapy Facility control panel and the interior of the facility. It is for the monitoring of patients. (Note: There also will be a telephone servicing the fission converter medical therapy area.)
6.5.9	It will be possible to operate the FC Medical Therapy Facility door manually. This will be done by use of a winch of a design similar to the one for the door of the existing medical therapy facility room.
6.5.10	The FC Medical Therapy Facility room will be equipped with both a viewing port and a closed-circuit TV camera. Lighting for the room will be picked up by reactor emergency power in the event of loss of off-site power.
6.5.11	N/A
6.5.12	N/A
6.5.13	N/A
6.5.14	Provisions (a)-(d) are administrative only. For provision (e), the fission converter beam will be equipped with the same complement of beam monitors as are used is the existing medical therapy facility beam. These include four neutron and one gamma detector. For the existing beam, the neutron detectors consist of two thermal and two epithermal detectors. For the FC beam, all four neutron detectors will be epithermal. Please refer to our answer to TAC question No. 5 for further information.
6.5.15	This provision is largely administrative in nature. However, we note that equipment installed in the FC Medical Therapy Facility will be selected with radiation safety (i.e., minimization of activation and ease of removal of contamination) as part of the criteria.
6.5.16	N/A
6.5.17	N/A
6.5.18	N/A
6.5.19	N/A

2. We have made a further design change that obviates the proposed changes (wording as of June 30, 1999) to Technical Specification 6.5.5(c) and 6.5.12(d) and ensures fail-safe operation so that there is no need for human intervention to assure shutter closure upon

failure of electric power or air pressure. Accordingly, the following wording is now proposed:

a) Technical Specification No. 6.5.5(c):

> Except for the fission converter mechanical shutter, shutters that control beam delivery shall be designed to close automatically either upon failure of electric power, or upon lower 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.

b) Technical Specification No. 6.5.12(d):

	Interlock or Channel	Surveillance
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

Automatic closure of the mechanical shutter on loss of electrical power is not necessary because the reactor is scrammed automatically. Also, it is not practical because there is a 12-second time delay before the emergency power system (battery that supplies a motor-generator set) picks up loads.

We believe that the above changes in the proposed wording of MITR Technical Specification No. 6.5.5(c) and 6.5.12(d) obviate the issues raised by the many sub-questions in Question #2 of the TAC. However, we note the following relative to the operational history of the existing beam shutters. The automatic closure of the existing shutters is checked monthly whenever a subject irradiation is planned. The shutters have never failed to close in over five years of testing. There has never been an inadvertent failure resulting in a shutter not closing during a human subject irradiation. A review of available work history records (last five years) indicates that there have not been any such failures during irradiations that did not involve human subjects.

3. There was no precedent for the regulation of neutron beams for human therapy when MIT first proposed MITR Technical Specification No. 6.5. Accordingly, after both extended internal review and lengthy discussion with the U.S. Nuclear Regulatory Commission, it was decided to adopt very conservative frequencies for the beam checks described in Provision 14 of the aforesaid specification. It was recognized at the time (1994) that these frequencies would be subject to revision once some operational experience had been gained. The original frequencies were weekly for functional and calibration checks and semi-annual for characterizations. The objective of these tests was to detect changes in the beam parameters. No such changes have been detected during either the characterizations, calibration checks, or functional checks performed for the patient trials that were on-going continuously from September 1994 to May 1999. Accordingly, for both reasons of ALARA and staff time, it is appropriate to revise these frequencies. A weekly frequency is retained for functional tests. Semi-annual and annual are proposed for calibration checks and characterizations, respectively.

We anticipate that the fission converter beam's parameters will be as stable as those of the existing facility (the one under the reactor). We say this based on a detailed technical understanding of both systems. However, as a conservatism, the original frequencies are retained for the FC beam at this time.

4. The typographical error in Proposed TS 6.5.14(d) has been corrected.

5. The beam monitors are located on the periphery of the epithermal neutron beam where they sample the beam intensity without significantly perturbing the beam. The count rates of these detectors are calibrated against the dose delivered to an ellipsoidal water-filled head phantom based on the Snyder head model. This calibration is obtained during the dosimetric characterization of our medical beams for both the FC beam and the beam in the basement medical room. This information is made available to our medical partners and they use it in their treatment planning systems to specify the integrated monitor counts that

are required for each subject irradiation. This is one of the items contained in the written medical directives. During an actual irradiation, the total counts from each monitor are recorded. The objective is to match the actual integrated counts to the figures specified in the written directive.

Four detectors are used to provide redundancy and to check the symmetry of the beam. (Note: We have found from experience that symmetry changes are not an issue unless modification has been made to the beam. If modifications are made, our TS require recharacterization.) The use of two epithermal neutron detectors and two thermal neutron detectors was initially chosen out of both conservatism and a desire to obtain as much information as possible about the basement medical beam (M-67). The use of two detectors that are more sensitive to thermal than epithermal neutrons (thermal neutron monitors) and two others that are relatively more sensitive to epithermal than thermal neutrons (epithermal neutron monitors) provides coarse information about the energy distribution of the neutrons in the beam. Based on several years of experience, we do not feel that the use of thermal and epithermal monitors is sufficiently advantageous to warrant this approach in the new FC beam. We have, therefore, decided to use four epithermal monitors for the FC beam.

For the existing beam (the one below the reactor) the signals from the four neutron monitors and the gamma monitor are redundantly displayed. These displays are monitored by the persons in charge of the subject irradiation, and these individuals give the instruction to close the shutters that terminate an irradiation. For the FC beam, the same detector arrangement will be utilized and two independent programmable logic controllers (PLCs) will monitor integrated counts. The PLCs will normally initiate shutter closure. However, the shutters can also be closed manually at any time.

Supervision of a subject irradiation is conducted by three senior individuals. These are the Physician Authorized User, the MIT BNCT Principal Investigator, and the Medical Physicist or their designates. The latter two pay particular attention to delivery of the

prescribed fluence. Delivery of the prescribed fluence is ultimately MIT's responsibility. Two monitors provide an adequate level of redundancy for starting an irradiation. The rationale for completing an irradiation with only one operable monitor is based on our experience that these detectors and their associated electronics are highly reliable. It is highly unlikely that we will have two monitors out of commission and be required to start an irradiation with only two monitors. It is even more unlikely that if we start an irradiation with two monitors operative that we will lose one during the short time required for a patient irradiation. However, one monitor is fully capable of accurately providing the information needed to control an irradiation.

6. Technical Specification No. 6.5.19 was written in response to a new NRC requirement that is contained in NUREG-1537. That requirement had in turn been suggested to NRC by MIT as an item that NRC might wish to consider. We note that the proposed MITR wording for TS 6.5.19 requires both an annual calibration and a one-point check prior to each subject irradiation. This approach has been our practice since 1994. It has worked well. In particular, the one-point check would identify any sudden malfunction of the facility. The annual calibration would detect any slow trends. For the five years for which we have experience, no problems have been noted with the use of these frequencies.

7. The selected facility and beam will be specified as part of the written directive. Please see revised definition 10 and revised QMP Section 3(a)(iii). Treatment in the wrong room and beam would fall under the definition of a "misadministration" (definition 3(a) of the technical specification) because the wrong mode of treatment would be involved. This would require a 24-hour verbal and a 15-day written report to NRC, as specified in TS 6.5.17. These requirements are more restrictive than those for a recordable event. Accordingly, we do not feel that the definition of a recordable event should be revised.

8. The typographical error in QMP Section 3(c) has been corrected.

9. QMP Section 7 has been changed to submit modifications to the NRC Document Control Desk, in accordance with current NRC organizational structure.

10. Possible alternate means for the verification of shutter position include, but are not limited to, the following:

a) CCS - The primary means of position indication are the sensors for the full-open and full-closed positions. Alternate means include (1) a continuous position readout system and (2) neutron detectors in the fission converter beam line. (Note: The converter control shutter (CCS) does not control beam delivery, and does not fall under TS 6.5.6.)

b) Water Shutter - The primary means of position indication are the status lights for its full-open and full-closed positions. Alternate means include (1) the water level in the shutter's storage tank which can be viewed by means of a sight glass and (2) radiation levels in the FC Medical Therapy Room.

c) Mechanical Shutter - The primary means of position indication are the status lights for its full-open and full-closed positions. Alternate means include: (1) radiation levels in the FC Medical Therapy Room and (2) beam monitor readouts.

All of the above primary and alternate means for the verification of shutter position are visible from the FC medical room control panel with the exception of the water shutter storage tank level. The latter is viewable via closed-circuit TV from the control room or by walking a short distance from the FC medical room control panel.

11. Appendix A to this response is entitled, "Information on Patient Safety During Use of FCB Facility." These calculations were prepared by Professor Harling and the senior staff of the fission converter project. It provides information on the fission converter irradiation control logic, anticipated radiation levels (rad/minute) for both 5 and 30 minute patient irradiations, and an analysis of various failure scenarios including failure of both the mechanical and water shutters. Note that both the 5 and 30 minute irradiations assume the delivery of a tolerance dose of 1200 RBE-cGy. Listed below are responses to the subitems requested on TAC No. 11.

a) In the event of a power failure, the reactor will scram and the water shutter will close. These two actions shut off the fission converter beam (no neutrons), thus terminating the irradiation and greatly reducing the radiation levels in the room. The mechanical shutter will be manually closed to allow

personnel to enter the room. The mechanical shutter can be fully closed manually from outside the room within 30 seconds. During closure the room radiation levels will drop rapidly and are expected to be greatly reduced in 10-15 seconds as the shutter closes. Please refer to Appendix A for information on dose levels.

b) The mechanical shutter does not need to be on emergency power because its closure is not needed to ensure safety in the event of a power outage. Two scenarios could occur. These are loss of off-site power and loss of power to the mechanical shutter. For both situations, the reactor scrams. Also, the water shutter will close either on loss of power or upon opening the medical room door.

c) The beam monitoring equipment is provided with an uninterruptible power supply, and will continue to function in the event of a loss of off-site power.

d) Data recorders for the fluence delivered to a subject are provided with an uninterruptible power supply. Hence, records will not be lost if off-site power is interrupted. Also, patient data is written to disk every few seconds. Hence, the information would not be lost even if there were no uninterrupted power supply (UPS) and power were lost.

e) The equipment in question (beam monitors, data recorders for dose to subjects) will be, as noted in parts (c) and (d) above, on an emergency power source. Technical Specification 6.5.20 has been added to require that the beam monitors and the data recorders for patient dose be equipped with a UPS or other form of emergency power. Technical Specification 6.5.12(l) specifies a corresponding periodic test frequency (monthly).

(i) Technical Specification 6.5.20

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

(ii) Technical Specification 6.5.12(l)

Interlock or Channel	**Surveillance**
l) Availability of emergency power for beam monitor systems.	Operational Test

f) The door for the fission converter medical therapy facility will open in about the same time as the existing door for the medical therapy room now located below the reactor. Those times are ~10 seconds under electrical power and ~60 seconds under manual operation.

12. The requirements of Technical Specification No. 6.5 do not apply to the converter control shutter (CCS) because it is not used to control beam delivery. The dose delivered to

patients is determined and/or limited by the mechanical shutter and the water shutter. In the case of the former, a reactor scram is initiated in the event of failure. In the case of the latter, the design is inherently fail-safe.

A typical tolerance dose to a patient is 1200 rads, which can be delivered in 5 minutes assuming that the highest theoretically available intensity of the FCB were used. The normal means to terminate an irradiation is to close the mechanical and water shutters. This action reduces the in-beam dose rate to an estimated ~7.6 mrad/min if the CCS remains open and if the reactor continues to operate at full power. Without any further action the patient would have to remain in the irradiation position for a total of about 26 hours for an over-exposure of 10%. It should be noted any one of several subsequent actions would significantly lessen the patient's exposure. These actions are: closure of the CCS, removal of the patient from the beam, or reduction of reactor power. For the above reasons, the CCS is not required to assure patient safety.

13. The sequence to turn the fission converter beam on and off is given below. It is important to realize that the mechanical shutter, which will require less than 15 seconds to cycle, alters beam intensity by three or more orders of magnitude.

a) To Turn the Beam On: The start button is manually operated. The water shutter begins to empty and the CCS begins to rise. Both water shutter and CCS will be fully open in about 100 seconds. The mechanical shutter, which is the component with the most control over beam intensity, is then opened. This requires less than 15 seconds.

(b) To Turn the Beam Off: This action is normally initiated by the programmable logic controllers (PLCs) but can also be initiated manually. Either way, the decision is based upon the integrated counts of the beam monitors. The mechanical shutter, the water shutter, and the CCS will all close automatically when the signal is given. Full closure of the mechanical shutter will take ~15 seconds, and this will effectively terminate the irradiation. The water shutter will close by gravity in ~100 seconds. (Note: Close signals always override open signals.)

(Note: The speed of the CCS opening/closing may be determined by its reactivity effect on the MITR. This issue is addressed fully in TS. 6.6.)

14. Drawings of the components listed in TAC Question Nos. 14(a) - 14(f) are included as an attachment to this response. Please refer to Appendix B. There are no common components to the two shutters that control beam delivery with the exception of electrical power. As described in our response to TAC Questions No. 1, 2, and 11, fail-safe provisions exist to ensure both patient and staff safety in the event of loss of electrical power. The staff would become aware of a loss of motive power to a shutter by the occurrence of the associated fail-safe action (shutter-closure or reactor scram). Failure of a shutter for other reasons (e.g., foreign material precluding movement) would be detected by the redundant beam monitor system which would generate an automatic reactor scram. The indicator lights would also show a failure when shutter closure was attempted and did not give the desired result. If electrical power were lost to the facility as a whole, the activation of the emergency power system would be a further indication.

15. We do not feel that it is necessary to include "epithermal" in the definitions of TS 6.5. The terms "thermal," "epithermal," and "fast" are routinely used in the literature to refer to neutrons of a specific energy range. The ranges are not precisely defined but are understood to correspond to the three distinct regions of certain microscopic cross-sections. These are the "1/v," resonance capture, and fast absorption regions. The dose to a patient is the integral of all components including fast neutron, thermal neutron, gamma, and of course, that resulting from the boron capture reaction.

16. Technical Specifications 6.5.5(f) and 6.5.12(k) have been added to include both a requirement for the capability to close the mechanical shutter manually and to verify that capability via a periodic surveillance (monthly). The following wording is proposed:

a) <u>Technical Specification 6.5.5(f)</u>

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

b) Technical Specification No. 6.5.12(k)

Interlock or Channel	Surveillance
k) Manual closure of fission converter mechanical shutter.	Operational Test

17. In addition to the changes in Technical Specification No. 6.5 that are necessitated by the response to the TAC, several other changes have been identified as desirable. These are listed below together with a justification.

a) The terms "Director of the Nuclear Reactor Laboratory and NRL Director" have been replaced with the term, "BNCT Principal Investigator." When Technical Specification No 6.5 was first issued, the NRL Director and the BNCT Principal Investigator were the same person. At present they are different people and the responsibilities stated in the Technical Specification are those of the latter.

b) The time requirement for performing surveillance listed in Technical Specification 6.5.12 if the reactor has been shut down has been changed from 16 to 24 hours. This change is made to achieve consistency with similar requirements in the MITR-III SAR that was submitted in July 1999 as part of the relicensing package for the MIT Research Reactor. The 24-hour figure was selected based on NUREG-1537 and various ANSI standards. (Note: This change could be deferred until such time as the MITR-III SAR is approved.)

c) Definition 1: Language is added to define the shutters that control beam delivery for the fission converter.

d) Definition 3: The last sentence is changed to read, "...normalization to a common neutronic power level." The word, "reactor." has been deleted because the definition now applies to both the MITR and the fission converter.

e) Definition 10: The items to be contained in the written directive have been expanded to include the medical facility room and the collimator (if any). This change was made at the suggestion of NRC.

f) Definition 13: A typographical error has been corrected. The end of the last sentence should read, "...and neutron capture therapy," as opposed to, "...and neutron beam capture therapy."

g) Quality Management Program:

(i) The word MITR-II has been changed to MITR throughout the document.

(ii) Item 3(a)(iii) which specifies the content of the written directive has been modified to include medical facility room and the collimator (if any). This change was made at the suggestion of NRC.

Appendix A

Information on Patient Safety During Use of FCB Facility

Prepared by

Professor Otto K. Harling
MIT Department of Nuclear Engineering
February 2000

Description of Attached Material

The information provided here focuses on patient safety during neutron irradiation with the fission converter-based epithermal neutron beam (FCB) at the MIT Research Reactor. Included are:

- Cover or title page.
- Isometric of MITR and FCB facility.
- A simplified schematic of the control logic for a patient irradiation.
- A table showing the maximum possible consequences of equipment failures. A careful review of possible failure scenarios has been performed. Our analysis shows that the scenario with maximum possible consequences, to the patient, is scenario A. Note that we have removed all reference to the converter control shutter (CCS) because this system is not needed to assure patient safety and is therefore excluded in these analyses. We have also assumed that the FCB is operating at its maximum licensed power of 250 kW. In this case the shortest, single-fraction irradiation is expected to be five minutes.
- Dose control for a five minute irradiation at maximum (250 kW) FCB power. The effects of the shutters and reactor scram are summarized in this table.
- Scenario A, "Mechanical Shutter Failure, " is described in more detail.
- The time dependence of patient dose during scenario A is presented.
- Scenario B, "Loss of Power to the Mechanical Shutter," is described in more detail.
- Scenario C, "Emergency Medical Room Entry," is described in more detail.
- Scenario D, "Water Shutter Failure," is described in more detail.

Note: There is no discussion of the Converter Control Shutter (CCS) because this system is not required to assure patient safety.

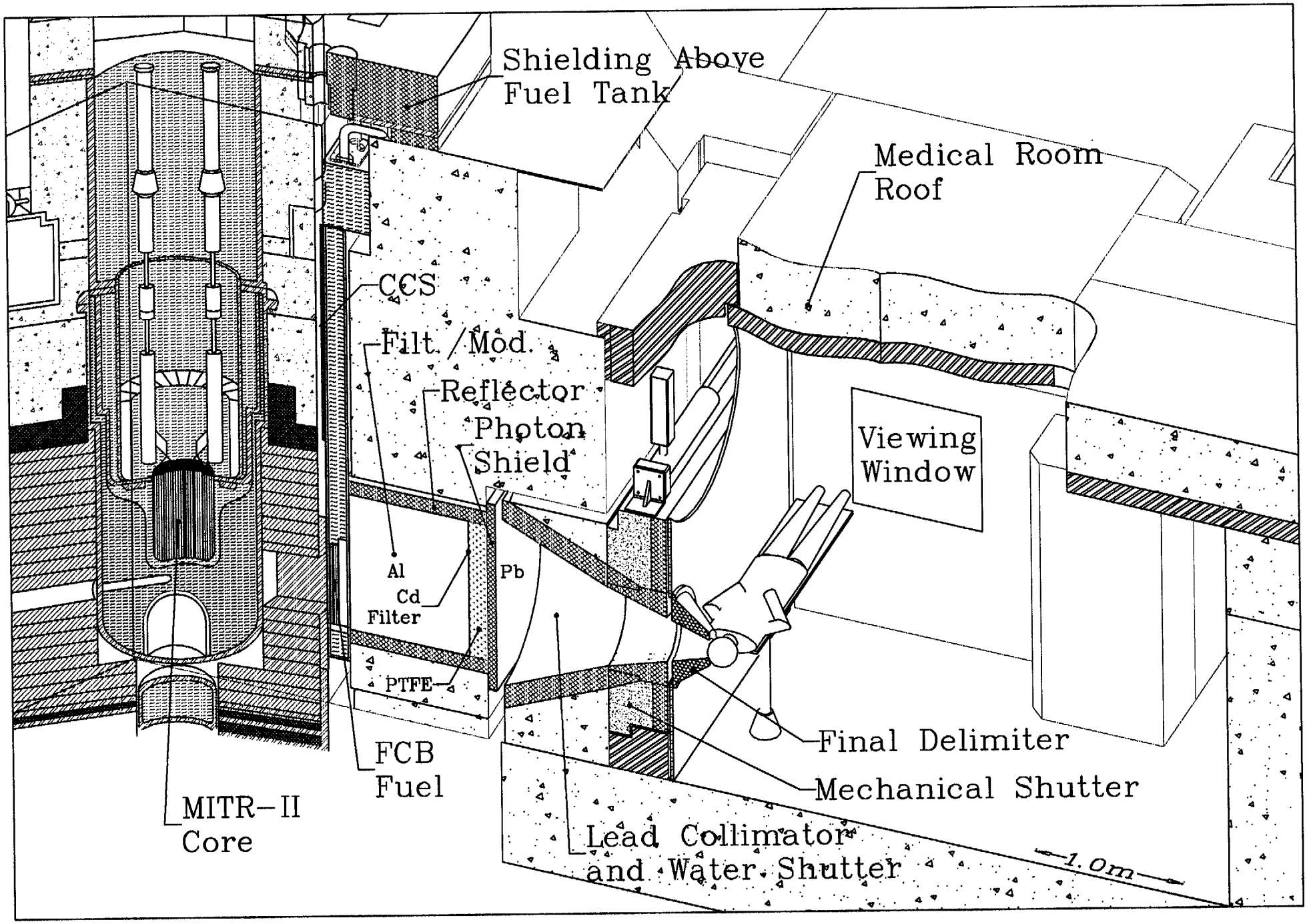
FISSION CONVERTER IRRADIATIONS

PATIENT SAFETY

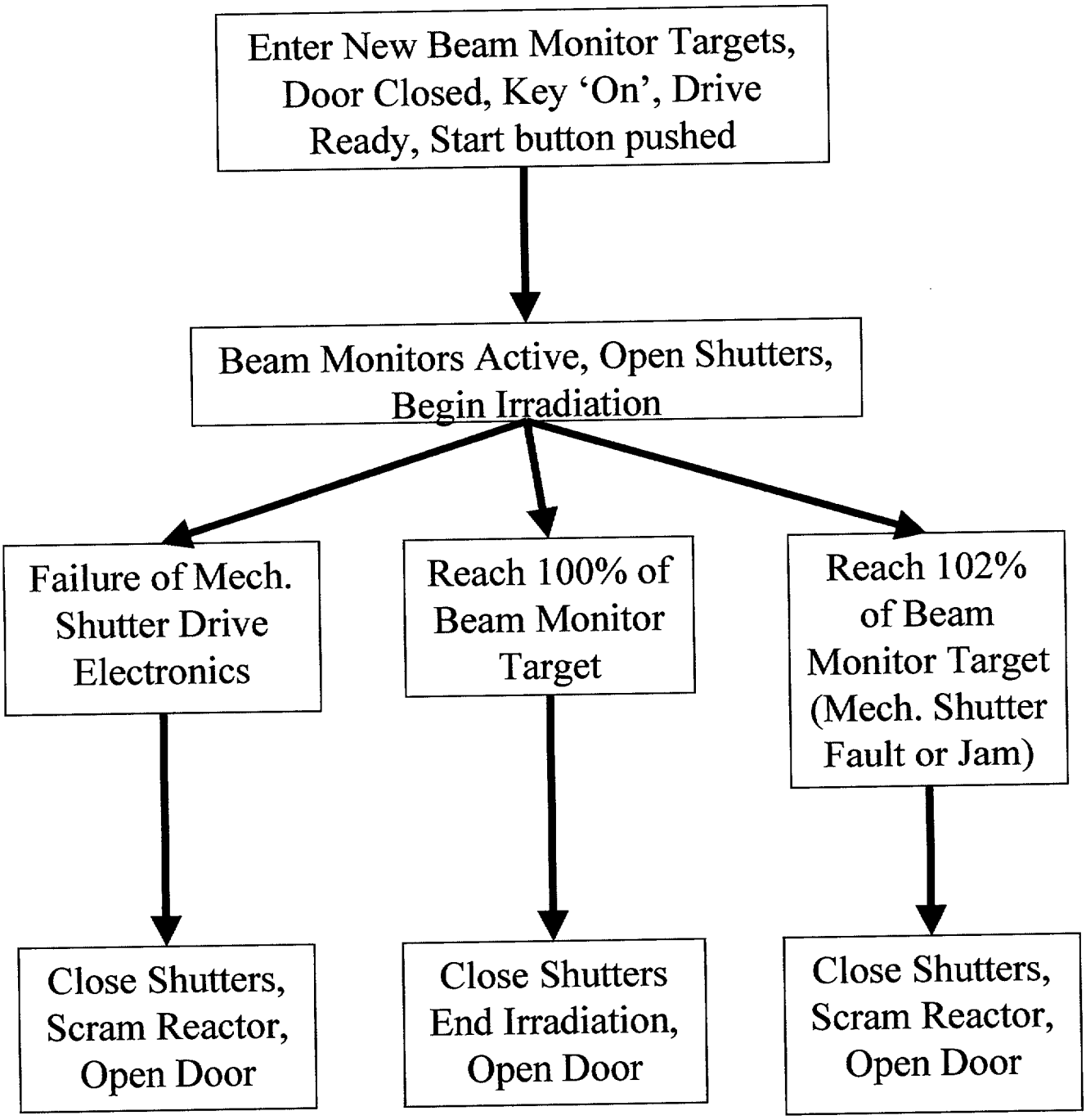
by

Professor Otto K. Harling
Principal Investigator
Fission Converter Irradiation Facility

MIT Fission Converter Facility



Fission Converter Irradiation Control Logic



MIT NRL Fission Converter Project

Consequences of Failure Scenarios for a 5 Minute Irradiation in the MIT FCB Facility

Scenario	Description	Consequences
A	Mechanical Shutter Failure	Maximum patient overexposure* of 2.7%.
B	Loss of power to Mechanical Shutter	Maximum patient overexposure* of 0.7%.
C	Emergency Medical Room Entry	No significant consequences.
D	Water Shutter Failure	No significant consequences.

* - Overexposure refers to dose delivered above the target dose of 1200 RBE cGy

Dose Control for 5 Minute Patient Irradiations in the Fission Converter Beam*

Converter Operating at Maximum Licensed Power of 250 kW

Shutters Status	Equivalent Rad/min†
All open	240
Mechanical and Water Shutters Closed	0.0076
Only Mechanical Shutter Closed	0.024
Reactor Scram Only	2.2 - 0.19**
Failure Scenarios	
Mechanical Shutter Fails Reactor Scrams, Water Shutter Closes	2.2 - 0.019‡
Water Shutter fails Mechanical Shutter Closes	0.024

* - For a single fraction, 5 minute irradiation to MTD (1200 RBE cGy). Dose rates determined in the main beam at the target position. Dose rates outside the main beam are much lower.

† - Equivalent Rad/min, RBE=1 for gammas, 3.2 for neutrons, 1.35 for $^{10}B(n,\alpha)$ reaction, normal tissue ^{10}B concentration of 30 ppm.

** - 2.2 Rad/min immediately after scram. This value rapidly decreases due to decay of delayed neutrons. 0.19 Rad/min arises from gamma dose delivered from fission product activity and beamline activation.

‡ - 2.2 Rad/min immediately after scram. This value rapidly decreases due to decay of delayed neutrons and water shutter closure. 0.019 Rad/min arises from gamma dose delivered from fission product activity and beamline activation.

MIT NRL Fission
Converter Project

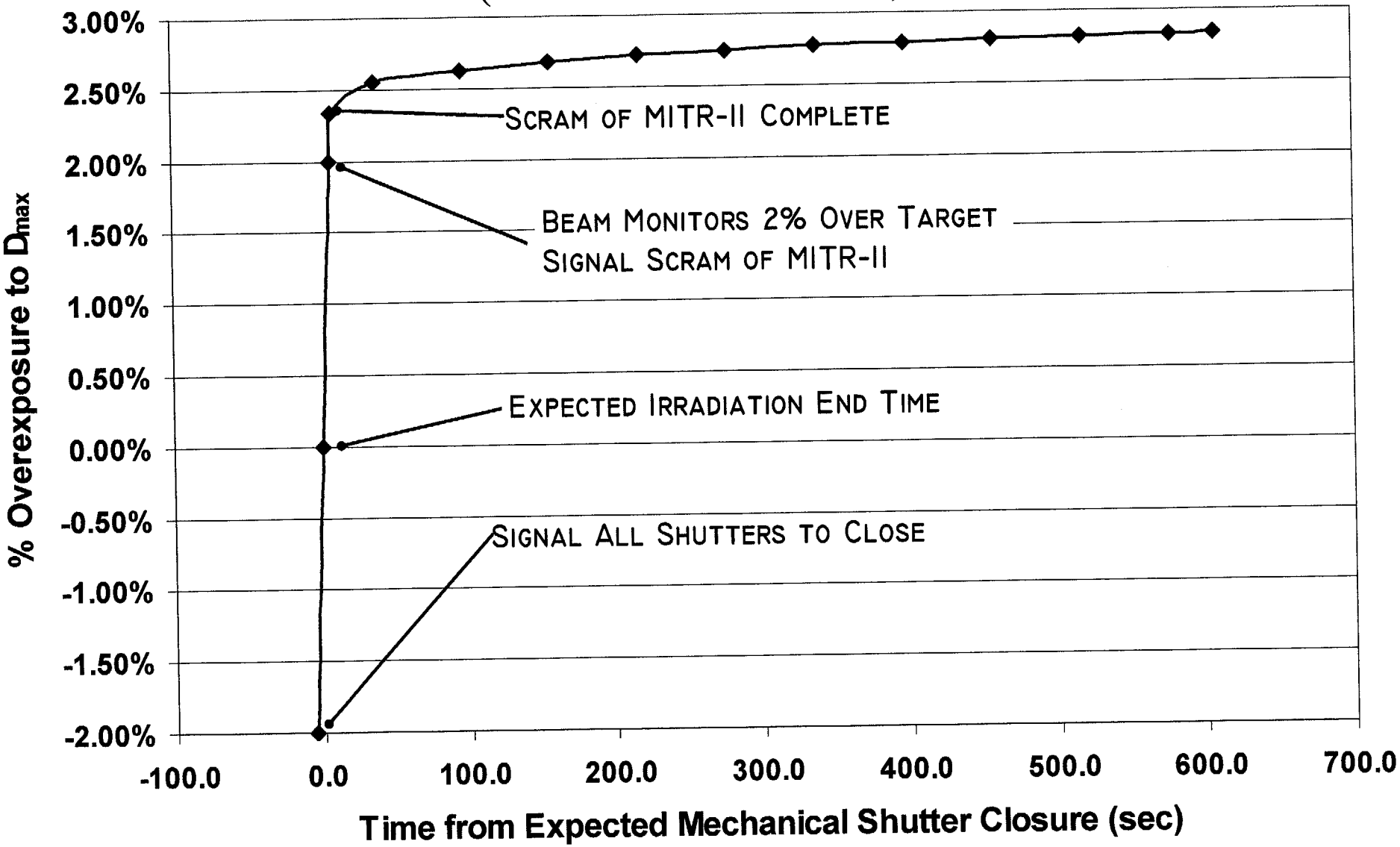
Scenario A

(Mechanical Shutter Failure)

- This worst case scenario leads to a maximum patient overexposure of 2.7%
- In this worst case scenario, the mechanical shutter fails such that it cannot be closed
- The Beam Monitoring System (BMS) accumulates 2% excess counts (6 seconds for a 5 minute irradiation) and then automatically scrams the MITR, reducing the dose rate by two orders of magnitude. The BMS has redundant, independent circuits and is backed up by separate uninterruptible power supplies.
- The water shutter closes in 100 seconds which provides another factor of 10 in gamma attenuation. Delayed neutrons have also decayed to negligible levels during this time. At this point the dose rate in the direct beam is ~ 0.019 Eq. Rad/min.
- Once the reactor has scrammed and the water shutter has filled, the patient could remain in the room up to 0.1*1200/0.019 = 6300 minutes before approaching a 10% overexposure.

Overexposure During Mechanical Shutter Failure

(5 minute FCB Irradiation)



Scenario B

(Loss of Power to Mechanical Shutter)

- <u>This scenario results in a maximum overexposure to the patient of 0.7%</u>
- In this scenario, the power supply to the mechanical shutter is lost, preventing the shutter from closing.
- In the worst case, this incident would occur at exactly the time the shutter was to be closed.
- A scram of the MITR is automatically initiated as soon as the loss of power is identified (via an electronic status indicator on the mechanical shutter drive). This reduces the dose rate by two orders of magnitude.
- The water shutter closes in 100 seconds which provides another factor of 10 in gamma attenuation. During this time delayed neutrons have also decayed to negligible levels. At this point the dose rate in the direct beam is ~ 0.019 Eq. Rad/min.
- Once the reactor has scrammed and the water shutter has filled, the patient could remain in the room up to 0.1*1200/0.019 = 6300 minutes before approaching a 10% overexposure.
- The mechanical shutter can be closed with the manual drive system prior to entry into the room, and no significant personnel exposures result.

Scenario C

(Emergency Medical Room Entry)

- The patient can be attended to for their medical emergency in less than half a minute.
- In this scenario, a medical emergency is assumed to occur. This emergency requires immediate access to the patient.
- All shutters are told to close via the control console and medical personnel immediately enter the room.
- A reactor scram can also be initiated from the control panel.
- In the time required to open the door and enter the medical room, the mechanical shutter will be closed and dose rates in the medical room have been greatly reduced (by a factor of 10^4). The water shutter is completely closed within 100 seconds, reducing dose rates in room to ~ 20 mrem/hr.

Scenario D

(Water Shutter Failure)

- No significant consequences to the patient result from this scenario.
- In this scenario, the water shutter is assumed to fail precisely at the point in time when all shutters are signaled to close. Note that this is not an impossible scenario, but it is very unlikely due to the fail safe design of the shutter system. Also, a large water leak, which could interfere with proper shutter function, would be easy to detect.
- The mechanical shutter will close, reducing the dose rate to the patient to ~ 0.024 Eq. Rad/min. This effectively terminates the therapeutic irradiation, preventing any significant overexposure to the patient.
- Once the mechanical shutter closes, the patient could remain in the room for (0.1)x1200/0.024 = 5000 minutes before approaching a 10% overexposure.

Appendix B

Drawings of FCB Shutters

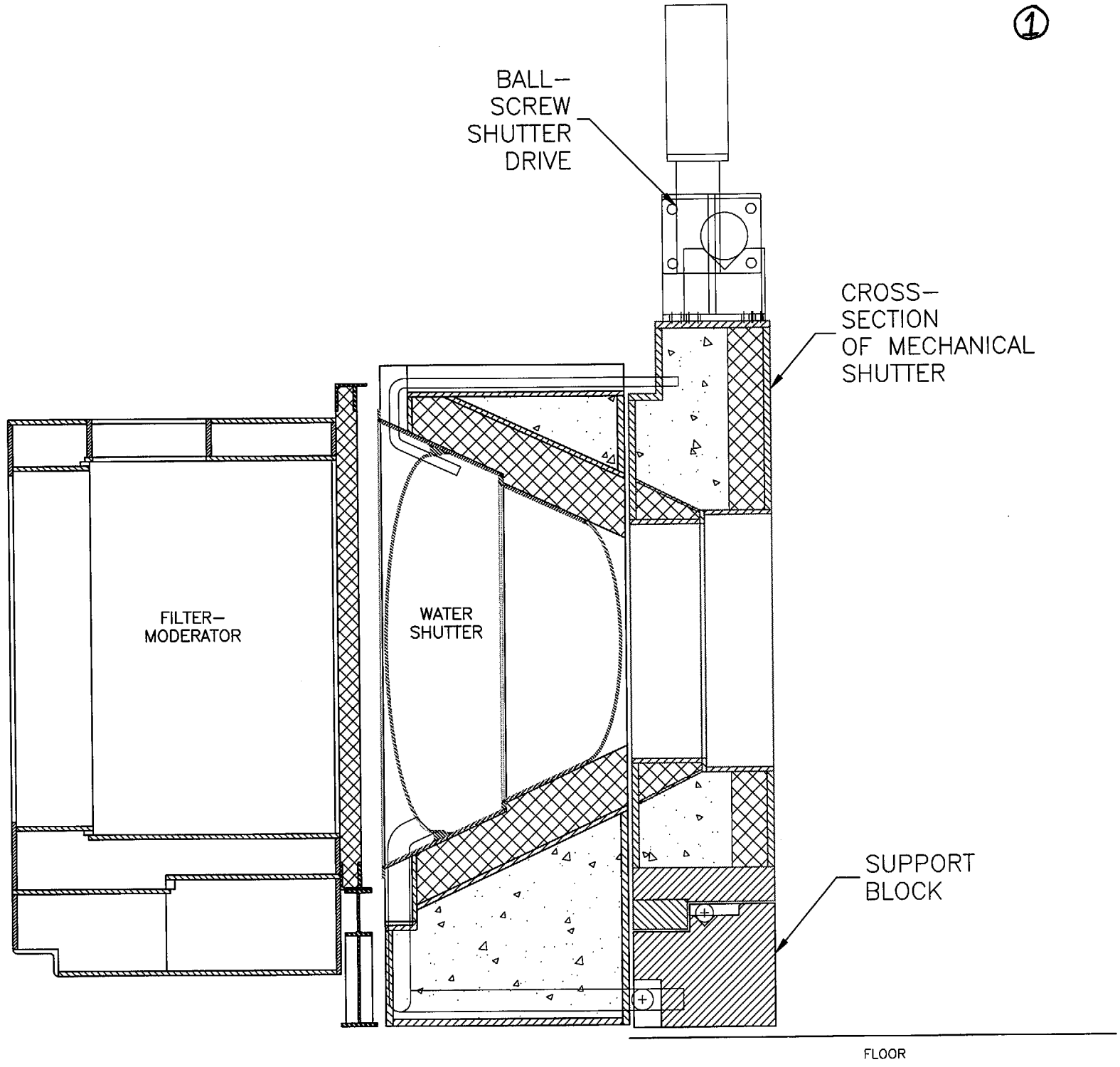
Prepared by

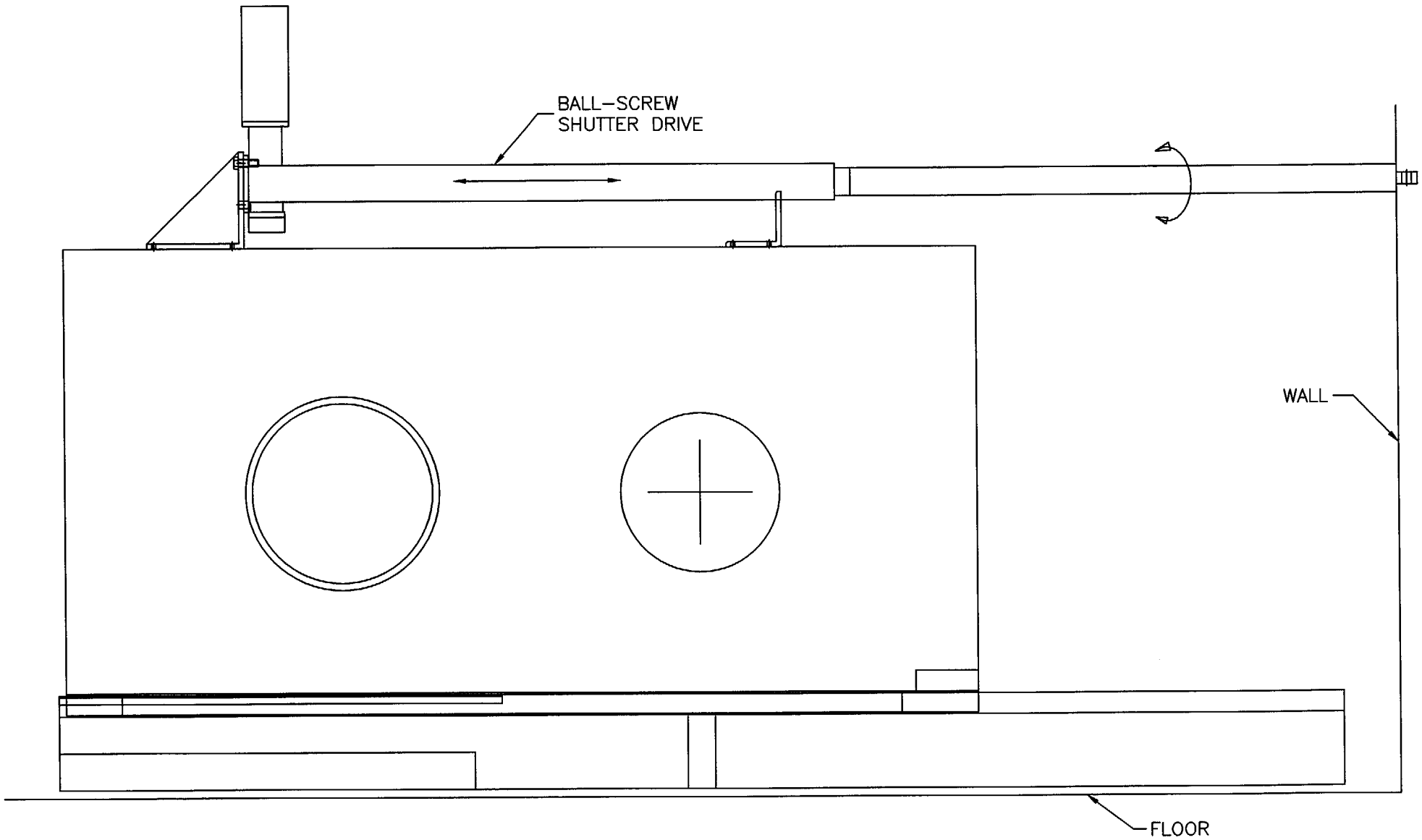
Fission Converter Project Staff
February 2000

Description of Attached Material

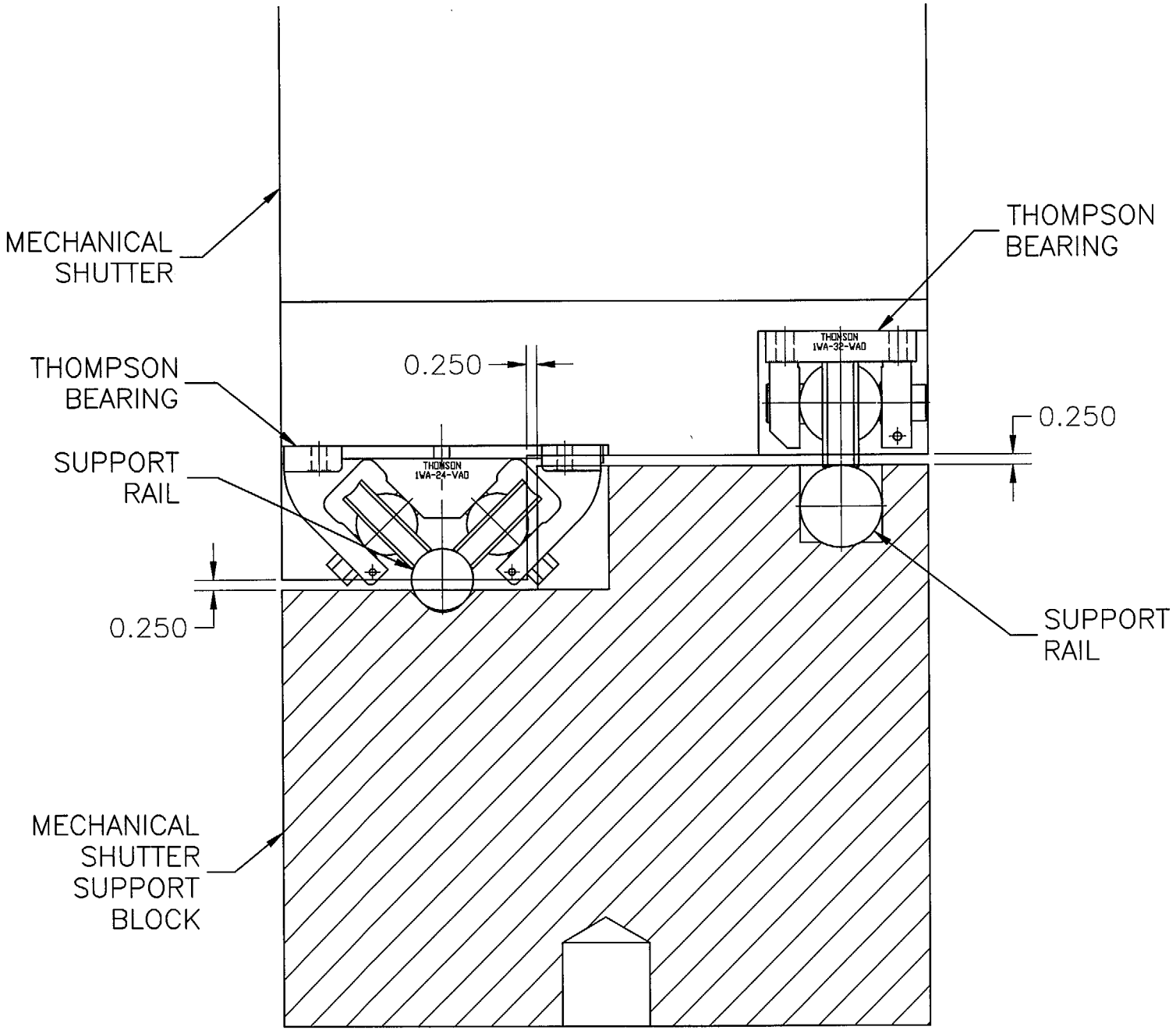
Engineering and schematic drawings of the water shutter and the mechanical shutter are attached pursuant to NRC's request. Also attached is a schematic and engineering drawing of the converter control shutter (CCS). The CCS drawings are included at NRC's request. However, the CCS is not required for patient safety. The drawings are numbered in the upper right-hand corner and are listed here.

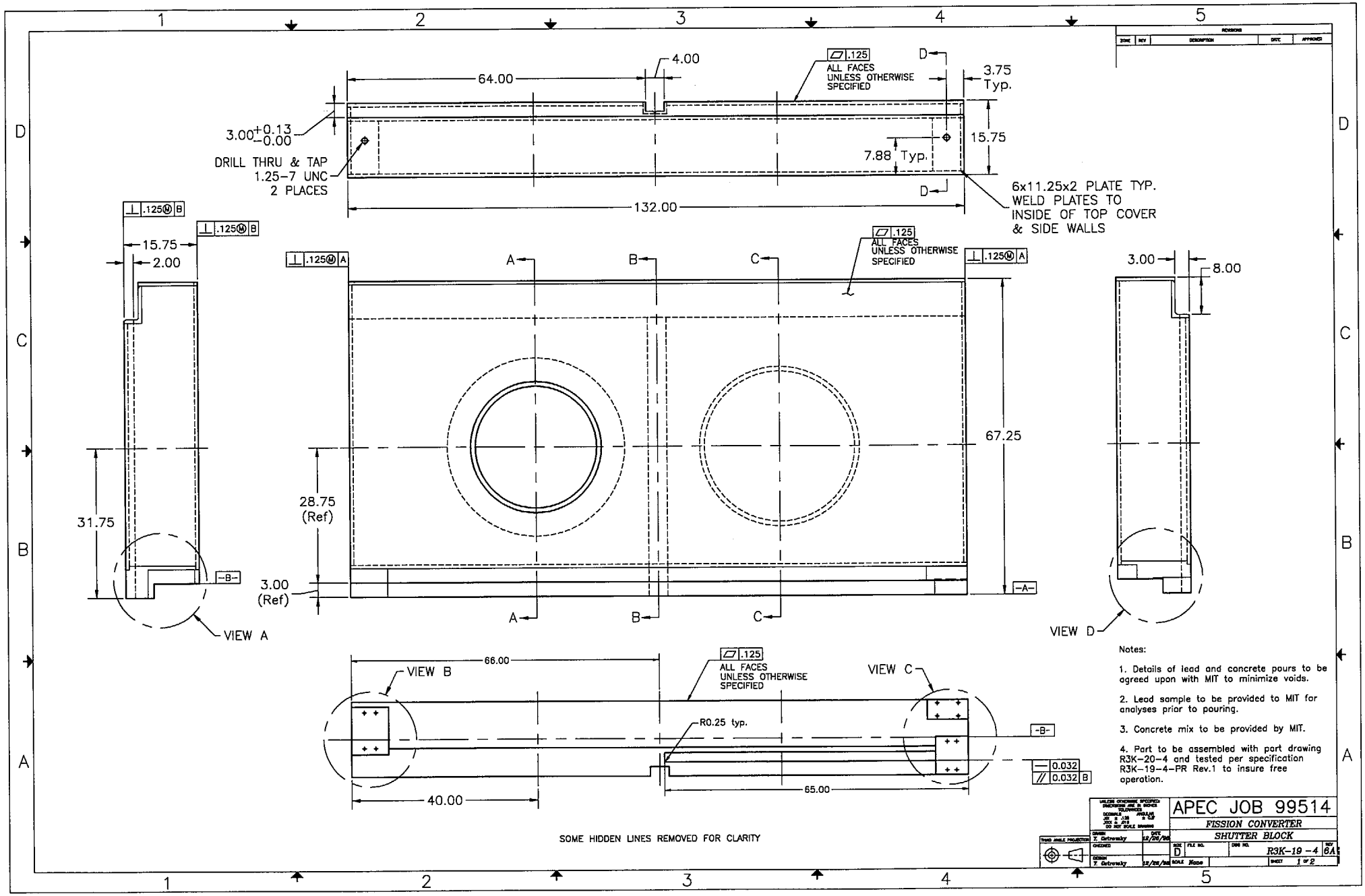
1) Cross-section of the water shutter and mechanical shutter.
2) Front, patient-side view of the mechanical shutter and its ball screw drive system.
3) Cross-section detail showing the mechanical shutter, its support block with rails and Thompson bearings with important clearances.
4) Construction drawing of the mechanical shutter, front view.
5) Construction drawing of the mechanical shutter, side view.
6) Construction drawing of the support block for the mechanical shutter.
7) Schematic isometric of the water shutter.
8) Schematic isometric of the fuel tank, upper shield blocks, CCS and winch for raising and lowering the CCS.
9) Construction drawing of CCS.


BALL–
SCREW
SHUTTER
DRIVE
CROSS–
SECTION
OF MECHANICAL
SHUTTER
FILTER–
MODERATOR
WATER
SHUTTER
SUPPORT
BLOCK
FLOOR



FRONT VIEW OF MECHANICAL SHUTTER


MECHANICAL SHUTTER
THOMPSON BEARING
THOMPSON BEARING
SUPPORT RAIL
0.250
0.250
0.250
SUPPORT RAIL
MECHANICAL SHUTTER SUPPORT BLOCK
THOMSON IWA-24-VAO
THOMSON IWA-32-VAO

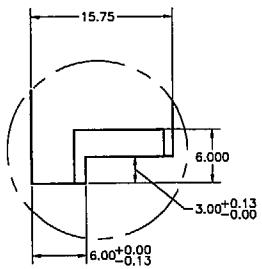


SOME HIDDEN LINES REMOVED FOR CLARITY

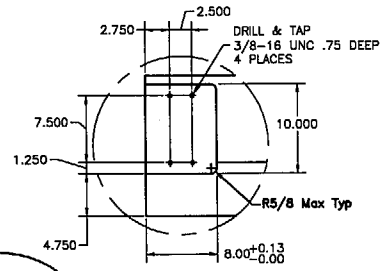
Notes:

1. Details of lead and concrete pours to be agreed upon with MIT to minimize voids.
2. Lead sample to be provided to MIT for analyses prior to pouring.
3. Concrete mix to be provided by MIT.
4. Part to be assembled with part drawing R3K-20-4 and tested per specification R3K-19-4-PR Rev.1 to insure free operation.

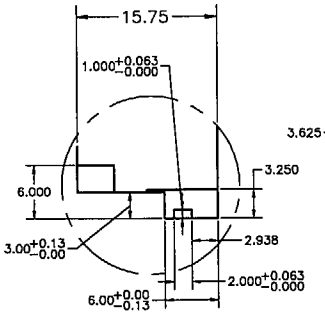
APEC JOB	99514
	FISSION CONVERTER
	SHUTTER BLOCK
DESIGN	Y. Gotowsky
CHECKED	
DRAWN	Y. Gotowsky
SIZE	D
DWG NO.	R3K-19-4
REV	6A
SCALE	None
SHEET	1 of 2



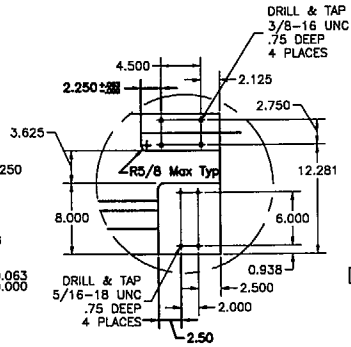
VIEW A

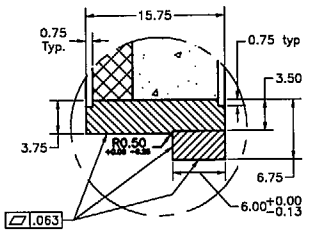


VIEW B

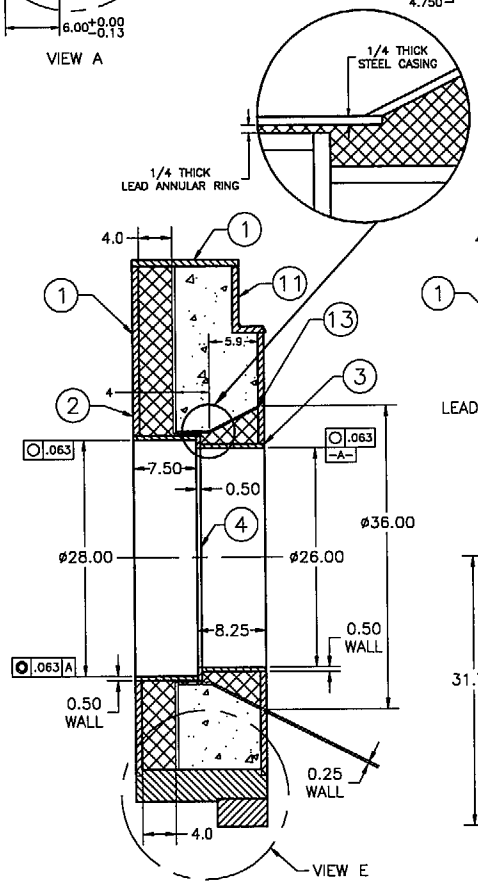


VIEW D

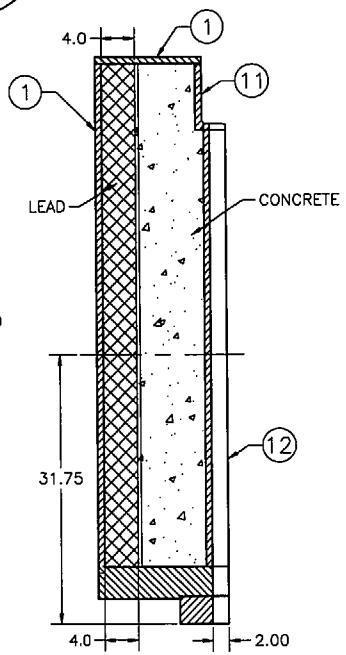




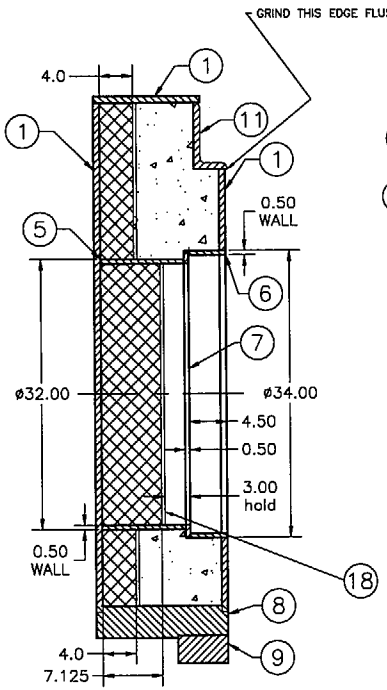
VIEW E



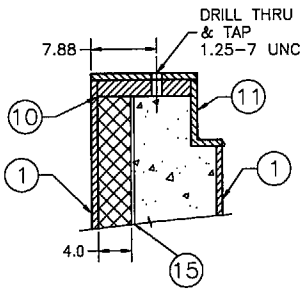
SECTION A–A



SECTION B–B



SECTION C–C



SECTION D–D

Notes:

1. Details of lead and concrete pours to be agreed upon with MIT to minimize voids.
2. Lead sample to be provided to MIT for analyses prior to pouring.
3. Concrete mix to be provided by MIT.
4. Part to be assembled with part drawing R3K-20-4 and tested per specification R3K-19-4-PR Rev.1 to insure free operation.

SOME HIDDEN LINES REMOVED FOR CLARITY

Ref	Description	Qty	Material	Stock
18	PLATE	1	Steel	3/8" THICK
15	PLATE	1	Steel	3/8" THICK
13	Cone	1	Steel	.25" Plate
12	C-Shape	2	Steel	2.5x2.5x.5 angle
11	L-Shape	1	Steel	L 8"x4"x.75"
10	Lifting Plate	2	Steel	6"x11.25"x2" Plate
9	Lower Block	1	Steel	Bar 5"x6"x132.5"
8	Base	1	Steel	Bar 4"x16"x132.5"
7	Ring 2	1	Steel	.75" Plate
6	Holder 2	1	Steel	Tube 34"ODx.5"wall
5	Holder 1	1	Steel	Tube 32"ODx.5"wall
4	Ring 1	1	Steel	.75" Plate
3	Collimator 2	1	Steel	Tube 27"ODx.5"wall
2	Collimator 1	1	Steel	Tube 29"ODx.5"wall
1	Shell	Qty	Steel	.75" Plate

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES TOLERANCES DECIMALS .XX ± .125 .XXX ± .013 DO NOT SCALE DRAWING ANGULAR ± 0.5°

THIRD ANGLE PROJECTION

DRAWN Y. Ostrovsky 12/20/96
CHECKED
DESIGN Y. Ostrovsky 12/20/96

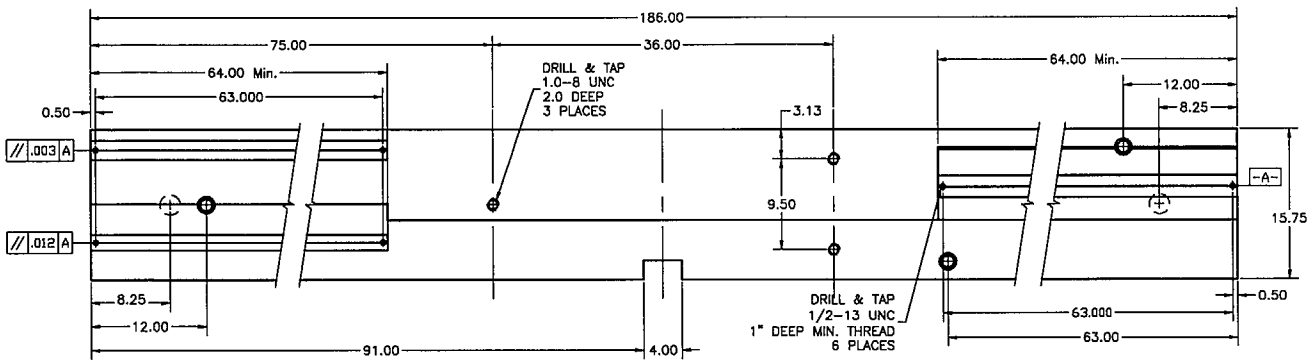
APEC JOB 99514

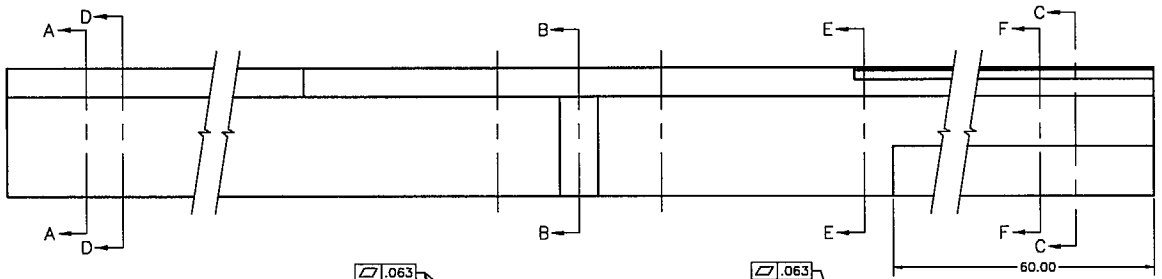
FISSION CONVERTER

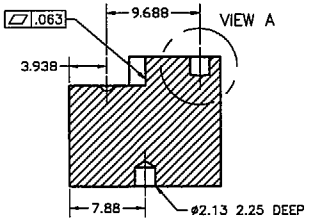
SHUTTER BLOCK

SIZE D FILE NO. DWG NO. R3K-19-4 REV 6A

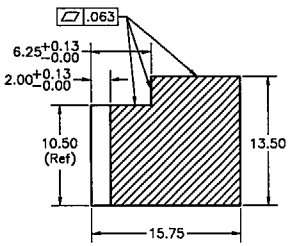
SCALE None SHEET 2 OF 2



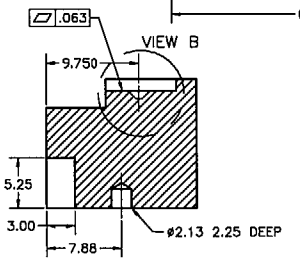




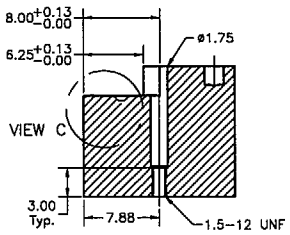
SECTION A-A



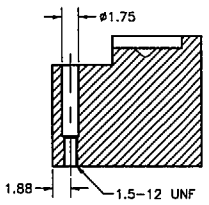
SECTION B-B



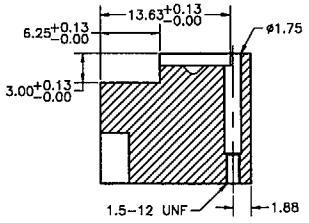
SECTION C-C



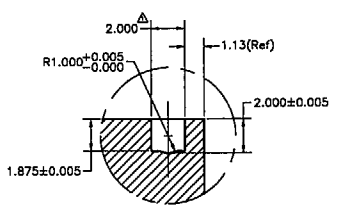
SECTION D-D



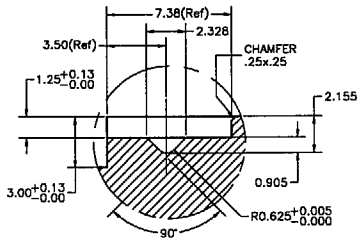
SECTION E-E



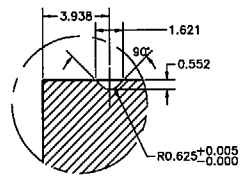
SECTION F-F



VIEW A



VIEW B



VIEW C

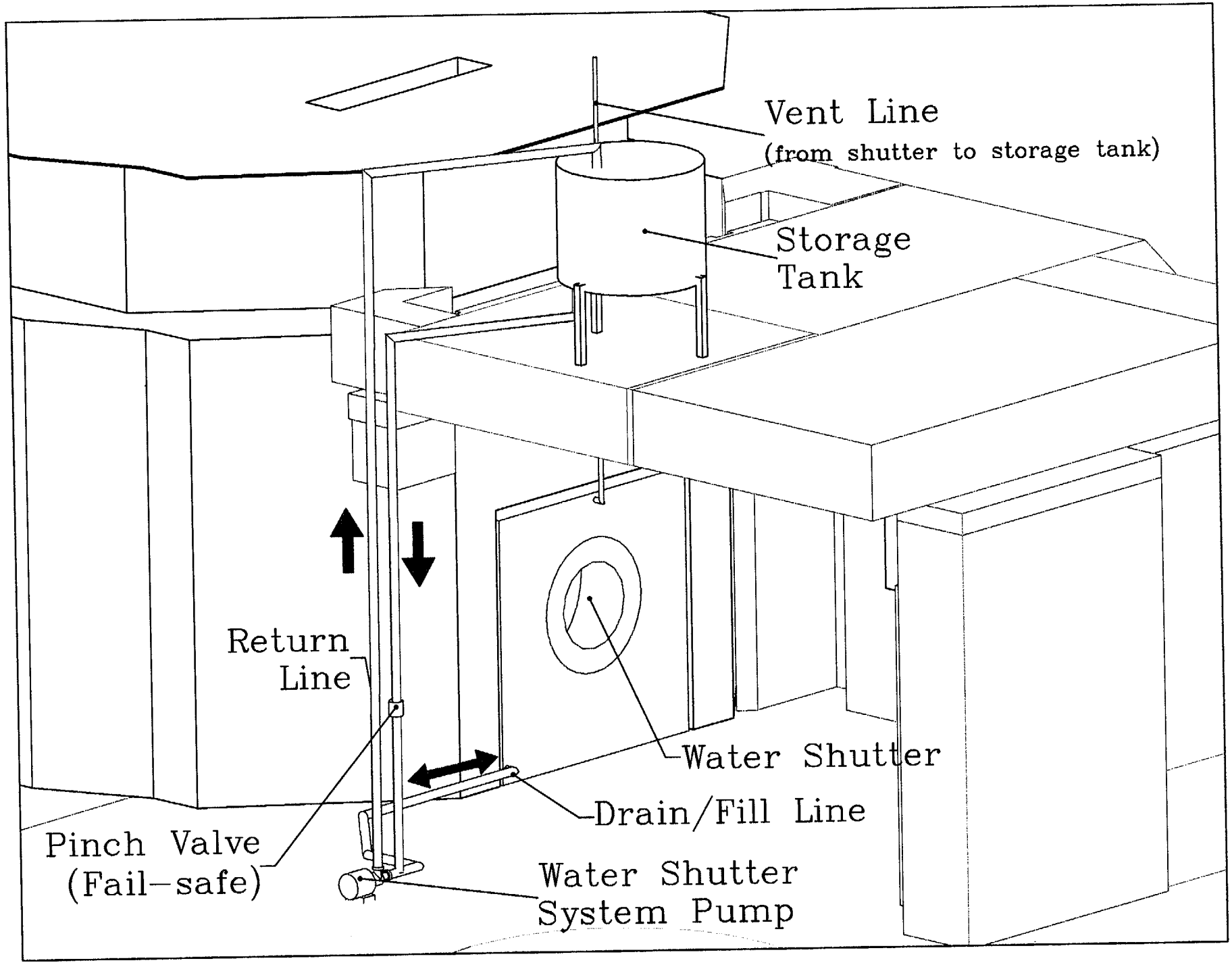
SOME HIDDEN LINES REMOVED FOR CLARITY

Notes:

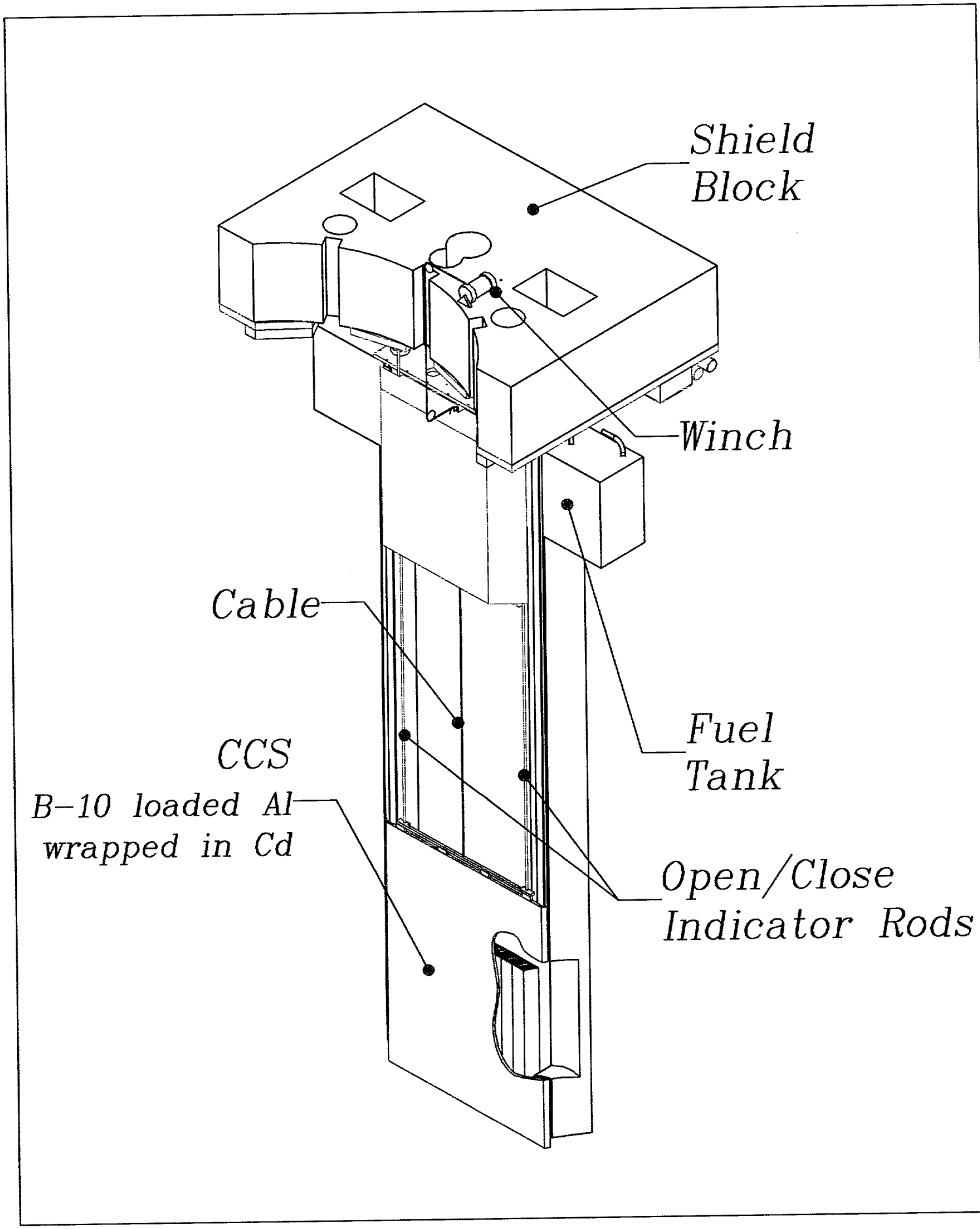
1. Machine grove to fit Thomson 60 Case Shafting (2" Dia. x 64" Long) model T22735. Maximum gap between Shafting and grove side not to exceed 0.003".

APEC JOB 99514	
FISSION CONVERTER	
SHUTTER SUPPORT	
DRAWN: T. Detrenky 12/29/98	SIZE: D FILE NO. DWG NO. R3K-20 -4 REV 4
CHECKED	
DESIGN: T. Detrenky 12/29/98	SCALE: None SHEET 1 of 1
THIRD ANGLE PROJECTION	

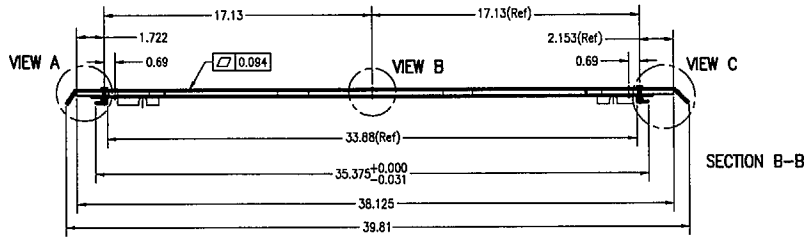
Schematic of FCB Water Shutter System



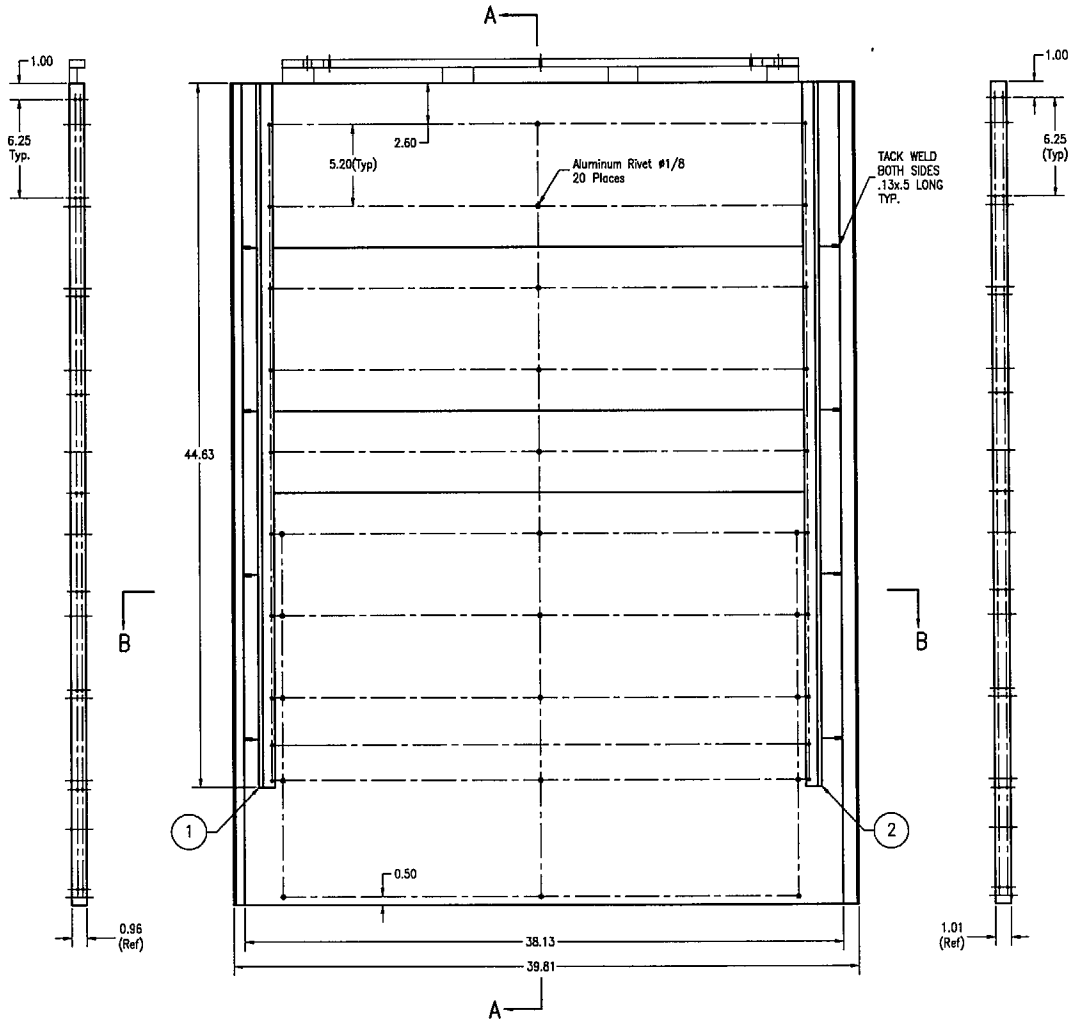
FCB Fuel Tank and CCS

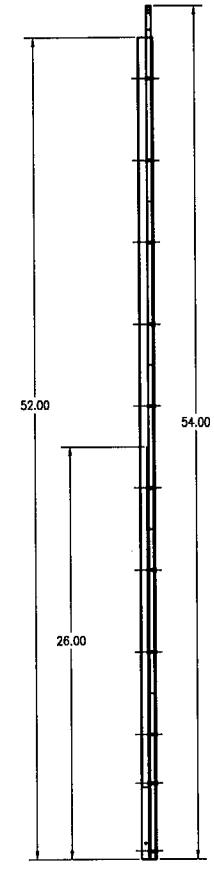


(9)

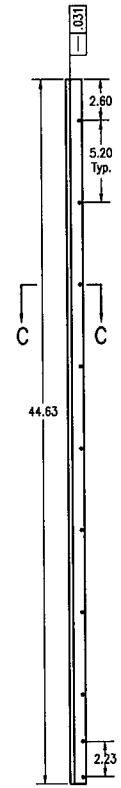


SECTION B–B

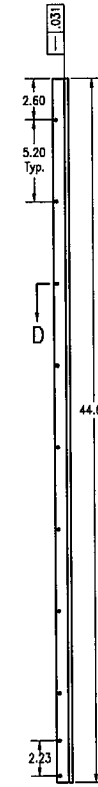




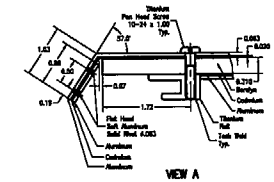
SECTION A–A

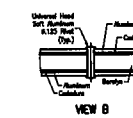


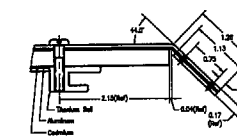
DETAIL 1

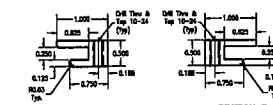


DETAIL 2









				MASSACHUSETTS INSTITUTE OF TECHNOLOGY REACTOR	
				FISSION CONVERTER	
				CADMIUM CONTROL SHUTTER	
				SIZE E	REV. NO. R3K-22-5
				SCALE None	SHEET 1 OF 1

Converter Control Shutter (CCS)

Appendix C

Summary of changes to MITR Technical Specification No. 6.5 and the Quality Management Program.

A. Changes to TS 6.5

1. TS 6.5.2 fifth line from bottom: changed to "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."

2. TS 6.5.5 (c): changed to "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."

3. Added TS 6.5.5 (f): The fission converter mechanical shutter, which is normally operated electrically, shall also allow manual closure.

4. TS 6.5.12 (d): changed to "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.

5. Added TS 6.5.12 (k): Manual closure of fission converter mechanical shutter. Operational Test.

6. Added TS 6.5.12 (l): Availability of emergency power for beam monitor systems. Operational Test.

7. TS 6.5.12 last line: sixteen is changed to twenty-four.

8. TS 6.5.14(a)(iv) first line changed to, "... (e.g., tissue-equivalent chamber and either a graphite or a magnesium wall ionization chamber or the equivalent)," last line added close bracket.

9. Added TS 6.5.14 (b) for fission converter medical beam.

10. Added TS 6.5.20 "An emergency power source shall be available for the beam monitor systems."

11. Definition 1 fifth line from top: added "For the fission converter, the shutters that control beam delivery are a water shutter and a fast-acting mechanical shutter." Changed "...refers either to the aforementioned three existing shutters..." to "...refers either to the aforementioned existing shutters..."

12. Definition 3: changed "...a common reactor neutronic power level." to "...a common neutronic power level."

13. Definition 10: changed "...which specifies the treatment site, the total radiation fluence, radiation fluence per fraction, and overall treatment period." to "...which specifies the treatment site, the total radiation fluence, radiation fluence per fraction, the medical facility and collimator (if any) to be used, and overall treatment period."

14. Definition 13 last sentence: changed "...neutron beam capture therapy." to "...neutron capture therapy."

B. Changes to QMP

1. Cover page: changed MITR-II to MITR.

2. Page 1: changed MITR-II in first line to MITR.

3. Item 1 second line: changed MITR-II to MITR.

4. Item 3(a)(ii), changed to "Name" to "Names."

5. Item 3(a)(iii): changed "The total radiation fluence to be administered, ..." to "The medical facility to be used and the collimator (if any), the total radiation fluence to be administered, ..."

6. Item 3(a)(vi): changed "The Director of the MIT Nuclear Reactor Laboratory..." to "The BNCT Principal Investigator..."

7. Item 3(c) third line from bottom: changed "The instruments that used to perform ..." to "The instruments that are used to perform ..." Added requirements for the fission converter medical beam.

8. Item 7 second line from bottom: changed "NRC (Region I)" to "NRC Document Control Desk".

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

Director of the Nuclear Reactor Laboratory, or designate, provided that at least one neutron-sensitive beam monitor is operable.

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) Beam monitors: the same requirements as provision 14(a)(v).

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 Regional Administrator, Region I, or 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 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 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 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 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.

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 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. 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, 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.

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.