Washington State University
Nuclear Radiation Center

P O Box 641300
Pullman, WA 99164-1300
509-335-8641
FAX 509-335-4433

Thursday, May 15, 1997

Marvin M. Mendonca
Senior Project Manager
U.S. Nuclear Regulatory Commission
MS OWFN 11-B-20
Washington, D.C. 20555

50-27

Ref: Dock~t 50-27

Dear Mr. Mendonca:

This letter is in response to a request for additional information (TAC NO. M79607) dated March 25, 1997. I will address each item in the order in which they are listed in the request.

1. All of the proposed changes to our Technical Specifications could be made under the provisions of the current license. These changes are being made in order to establish a record of our ability to achieve a standard of performance that is appropriate for medical therapy in the future.

2. All of the suggested changes in this item have been done in the enclosed draft, namely;
   a. the applicability and objective sections have been changed.
   b. specifications which deal solely with medical therapy have been temporarily deleted
   c. references to patients, human therapy etc. have been temporarily deleted

3. Some of the provisions specified in the TS 3.15 (e.g., (8) and (11)) refer to definitions that are later in the TS. Provide clarification to ensure understanding of the application of the definitions and terms.

Answer: TS 3.15 (8) has become TS 3.15 (6). It has also been abbreviated. The purpose of TS 3.15 (6) is to require adequate communication amongst the experimenters and the reactor control room personnel.

TS 3.15 (11) has been deleted as suggested in item 2. b. of the request for more information.

4. Provide a description of the independence and redundancy of the reactor scram and bridge movement functions related to the treatment room shield door opening in TS 3.15 (3)(b).

Answer: We presume that the reference was intended for TS 3.15 (5)(b) which read: "The reactor shall scram and the bridge shall move to the retracted position automatically upon opening the treatment room's shield door."

A020

TS 3.15 (5)(b) has become TS 3.15 (3)(b). "shield door" has been changed to "access gate." We will have some redundancy in the gate interlock by having two micro switches on the gate. One switch will be part of the scram chain. A scram by any switch opening in the scram chain will cause the bridge to retract. The second microswitch on the gate will send an independent logic signal to an OR logic gate whose output controls the bridge retraction. This OR gate will cause the

bridge to retract when it gets a logic signal either from any scram or from the second microswitch on the access gate. These two independent interlocks will be tested by holding the switches closed by hand and then releasing them independently to test that they independently retract the bridge

5. For manual movement of the bridge in accordance with TS 3.15 (5)(d), provide verification and analyses that

a. this is in addition to the automatic movement and can not interfere with the automatic function, and

b. the speed of the manual movement provides an acceptable backup to the automatic function.

answer: TS 3.15 (5)(d) is now TS 3.15 (3)(d)

a) the manual backup to the "electronic" bridge retraction will override any electronically activated movement because the manual backup involves disengaging the electric motor with a foot pedal and then hand cranking the currently installed bridge moving mechanism. The electric motor, whether stalled or rotating incorrectly, would not be able to interfer with this hand and foot action.

b) the electronically controlled bridge movement speed design criterion was specifically matched to the speed with which we ordinarily move the bridge by hand.

6. Provide description of indication of reactor condition (e.g. criticality and power) in and around the facility for the medical therapy facility. Provide verification that these functions can be monitored from and around the medical therapy facility.

answer: We have inserted the following TS 3.15 (5) to cover this item:

"The BNC facility shall be equipped with a readout display of the reactor log-power and the linear-power on the BNC facility control console just outside of the shielding."

7. The proposed TS 3.15 (10) discusses cameras but does not discuss monitors or the fact that the emergency lighting provides backup to normal lighting. Provide verification of the monitors that are required for visualization of the treatment room and the backup function of the emergency lighting.

answer: We have inserted the following TS 3.15 (10) items:

l) BNC facility TV cameras, monitors and their backup power	Operational test
m) BNC facility emergency lighting	Operational test

8. TS 3.15 (14) (d) should be clarified to establish if the reduction in dose includes consideration of bridge movement or not.

answer: TS 3.15 (14) (d) has become TS 3.15 (12) (d)

add the phrase "and bridge retraction" at the end of the last sentence of TS 3.15 (12) (d)so that it is understood that the dose reduction includes both the scram and the bridge movement.

9. TS 3.15 (16) (c) specifies "closures." This term should be made consistent with other definitions in the TS (e.g.) scrams or shutdowns).

answer: TS 3.15 (16) (c) has become TS 3.15 (14) (c)

substitute "scrams causing a bridge retraction" for the single word "closures".

10. The bases discuss a viewing window which should also be specified in TS as an alternate observation point.

answer: We propose the substitution of

"The emergency lighting and the backup power for a TV camera and monitor will permit visual surveillance of the target area in the event of a power failure." for the sentence in the basis with:

"The viewing window will function even during an electric power failure because of the provision for emergency lighting."

Note the verifications added to the TS, described in item 7. above.

11. Additional information about the facility will be provided when explicit design features and a quality management program has been created.

Please find enclosed the fourth draft of the changes we are proposing to our WSU reactor Technical Specifications in order to provide a Boron Neutron Capture (BNC) facility beam. The number of differences between this draft and the preceding one (February 23, 1996) are sufficiently numerous that it didn't seem useful to try to identify them all with sidebars.

Sincerely,

G E Tripard

Gerald E. Tripard
Director

enclosure: Draft-4 of the Proposed Technical Specification Changes
to Accommodate a Boron Neutron Capture Facility at Washington State University

cc: R. H. Filby, WSU
Jim Venhuizen, INEL
D.W. Nigg, INEL
R.J. Wiersema, Neutron Therapies Incorporated
W.R. Rayburn, WSU
P.R. Gavin, WSU

3.15 GENERATION OF BORON NEUTRON CAPTURE FACILITY BEAM

Definitions:

1. For the purpose of this technical specification, the term 'BNC facility' shall refer to the boron neutron capture facility which includes the beam, bridge moving system, beam monitoring equipment, beam shielding room, access gate and experimental area viewing equipment. The experimental bench, positioning equipment, and other equipment used for the beam targets are not considered part of the BNC facility for purposes of this provision, except insofar as radiation safety (i.e., activation and/or contamination) is concerned.
2. The term 'BNC experiment' shall refer to a boron neutron capture experiment involving the neutron irradiation of biological cells enriched with boron.
3. 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.
4. The term 'functional check of the beam monitors' shall consist of verifying that system output is consistent (± 19%) with previously measured values upon normalization to a common reactor neutronic power level.
5. The term 'characterization' refers to the process of obtaining the dose-versus-depth profile in phantoms. The dose-versus depth profile from the surface of the phantom to a depth at least equivalent to the total thickness of the target volume to be irradiated 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.
6. The term 'calibration of the beam monitors' refers to the process whereby the beam monitors are calibrated against instruments that measure dose including a tissue equivalent

chamber and a graphite or magnesium wall ionization chamber (or the equivalent to any of these three) that have in turn been calibrated by a secondary calibration laboratory.

7. The term 'design modification' as applied to the BNC 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 BNC facility.

8. The term 'radiation fluence' means the total fluence of neutrons and gamma radiation that is emitted in the BNC 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.

Applicability:

This specification applies solely to the generation of the BNC facility beam for BNC experiments. It does not apply to any other use of the BNC facility and/or its beam. Surveillances listed in this specification are required only if BNC experiments are 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 BNC experiments during the interval in question.

Objective:

To acquire testing and operational experience in use of a facility developed specifically for Boron Neutron Capture Technology.

<u>Specifications</u>:

1. It shall be possible to initiate a scram of the reactor from a control panel located in the BNC facility area. In the event that the medical facility scram is inoperable, it shall be acceptable to use one of the control room scrams via communication with the reactor operator as a temporary means of satisfying this provision. Use of this temporary provision is limited to seven consecutive working days.
2. Access to the BNC facility shall be controlled by means of the access gate located at its entrance.
3. The following features and/or interlocks shall be operable:
   (a) An interlock shall prevent moving the bridge from the retracted position unless the BNC facility's access gate is closed.
   (b) The reactor shall scram and the bridge shall move to the retracted position automatically upon opening the treatment room's access gate.
   (c) The bridge shall be designed to move to the retracted position automatically upon failure of facility electric power or low voltage on the backup batteries that power the bridge motor.
   (d) Bridge movement that controls beam delivery shall be designed for manual movement to the retracted position.
   (e) It shall be possible to move the bridge to the retracted position from within the BNC facility.
   (f) A medical BNC facility lockdown near the access gate shall inhibit blade withdrawal when the key is not inserted and turned to the locked position.
4. Bridge shall be equipped with a position readout that indicates the status of the bridge. A bridge position readout shall be visible at the BNC facility's local control panel. In the event of a bridge position readout malfunction, it shall be acceptable to use an alternate means of verifying position such as a video camera in the pool room providing a signal to a

monitor at the BNC facility's local control panel. Use of this alternate means of bridge position verification is limited to seven consecutive working days.

5. The BNC facility shall be equipped with a read out display of the reactor log-power and the linear power on the BNC facility control console just outside of the shielding.

6. The BNC 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 BNC experimentation.

   (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 BNC room has been searched and secured, such as is done immediately prior to initiation of BNC experimentation. If this is done, the monitor and/or its alarm shall be interlocked so that they become functional upon opening of the BNC facility access gate.

   (e) In the event that this monitor is inoperable, personnel entering the BNC 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 WSU 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.

7. An intercom or other means of two-way communication shall be operable both between the BNC facility control panel and the reactor control room, and also between the BNC facility control panel and the interior of the BNC facility shielding.

8. It shall be possible for personnel monitoring a BNC experiment to open the BNC facility access gate manually.

9. It shall be possible to observe the BNC experiment by means of two independent closed-circuit TV cameras. Both cameras providing visualization shall be operable at the outset of any BNC experiment. Should either fail during the irradiation, the experiment may be continued at the discretion of the experimenter. Adequate lighting to permit such viewing shall be assured by the provision of emergency lighting and backup power for one TV camera and monitor.

10. The following interlocks or channels shall be tested at least monthly and prior to a BNC experiment if the interlock or channel has been repaired or deenergized:

	Interlock or Channel	Surveillance
a)	The reactor scrams and the bridge retracts upon BNC facility scram	Scram test
b)	Bridge will not move from the retracted position unless access gate is closed	Operational test
c)	Upon opening the BNC room's access gate the reactor scrams and the bridge moves to the retracted position	Operational test
d)	Upon opening only the bridge retraction switch on the access gate of the bridge retracts	Operational test
e)	The bridge moves toward the retracted position on loss of electrical power and low voltage on the bridge motor batteries	Operational test

f)	Manual movement of bridge	Operational test
g)	Bridge can be moved manually from within the facility	Operational test
h)	Bridge position indicator and status lights	Operational test
i)	Radiation monitor alarm	Operational test
j	Radiation monitor and/or alarm enabled upon opening of shield door	Operational test
k)	Intercoms	Operational test
l)	BNC facility TV cameras, monitors and its power backup	Operational test
m)	BNC facility emergency lighting	Operational test
n)	Medical BNC facility lockdown blade inhibit	Operational test

In addition to the above, the BNC facility scram shall be tested prior to reactor startup if the reactor has been shut down for more than sixteen hours.

11. Manual operation of the BNC facility's access gate in which the door is opened fully shall be verified semi-annually.

12. Use of the BNC facility beam shall be subject to the following:

    a) A calibration check of the beam and a functional check of the beam monitors shall be made weekly for any week that the beam will be used for BNC experiments. These checks shall be made prior to any BNC experiment for a given week. In addition, a calibration check shall be performed prior to any BNC experiment in the event that any component of a given beam design has been replaced. Finally, a calibration and a functional check shall be performed prior to any BNC experiment in the event of a design modification.

    b) A characterization of the beam shall be performed every six months for any six-month interval that the beam will be used for BNC experiments. This six-month

characterization shall be made prior to any BNC experiment for a given six-month interval. A characterization shall also be performed prior to any BNC experiment in the event of a design modification. As part of the characterization process, the proper response of the beam monitors shall be verified.

c) A calibration of the beam monitors shall be performed at least once every two years for any two-year interval that the beam will be used for BNC experimentation. The two-year calibration shall be made prior to any BNC experimentation during any given two-year interval.

d) A scram from full power initiated when the reactor is positioned against the BNC facility filter shall be performed every six months or in the event of a design modification. The BNC room radiation monitor reading shall not exceed 50 mR/hr, 30 seconds after the initiation of the scram and bridge retraction.

13. Maintenance, repair, and modification of the BNC facility shall be performed under the supervision of a senior reactor operator who is licensed by the U.S. Nuclear Regulatory Commission to operate the WSU Research Reactor. All modifications will be reviewed pursuant to the requirements of 10 CFR 50.59.

14. Personnel who are not licensed to operate the WSU Research Reactor but who are responsible for either the BNC or the beam's design including construction and/or modification may operate the controls for the BNC 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 BNC facility's local control panel that specify the procedure to be followed:

(i) to ensure that only the appropriate target is in the irradiation facility before turning the primary beam of radiation on to begin an irradiation;

(ii) if the operator is unable to turn the primary beam of radiation off with controls outside the BNC 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 bridge movement affects reactivity, personnel who are not licensed on the WSU Research Reactor but who have been trained under this provision may initiate bridge movement provided that verbal permission is requested and received from the reactor console operator immediately prior to such action. Emergency scrams causing a bridge retraction 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 WSU 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.

<u>Basis</u>

The requirement that it be possible to initiate a scram from a control panel located in the BNC facility area assures the experimenter of the capability to terminate the irradiation immediately should the need arise. The provision that access to the BNC facility be limited to a single gate ensures that there will be no inadvertent entries. The various interlocks for the bridge movement system that controls beam delivery ensure that exposure levels in the BNC facility will be minimal prior to entry by personnel. The bridge position indicator and status 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 BNC facility prior to entry. The purpose of this monitor's audible alarm is to alert personnel to the presence of elevated radiation levels. This monitor and/or its alarm may be disabled once the BNC facility has been searched and secured so that it will not distract attending personnel. The monitor and/or its alarm are interlocked with the access gate so that they are made functional upon opening that gate, and hence prior to any possible

entry to the BNC facility. One intercom provides a means for the prompt exchange of information between the experimenter(s) and the reactor operator(s).

The provision for manual operation of the BNC facility's access gate ensures access to the experimental area in the event of a loss of electrical power. The presence of the closed-circuit TV cameras provide the experimenter(s) with the opportunity to monitor the target area visually as well as through the use of various instruments. The emergency lighting and the backup power for a TV camera and monitor will permit visual surveillance of the target area in the event of a power failure.

The surveillance requirements for beam calibration checks and characterizations provide a mechanism for ensuring that the BNC facility and its beam will perform as originally designed. Similarly, the surveillance requirements on the beam monitors ensure that these instruments are calibrated by a means traceable to the National Institute of Standards and Technology. The chambers specified (tissue-equivalent, and graphite or magnesium-wall) were chosen because they measure dose as opposed to fluence.

The specifications on maintenance and repair of the BNC facility ensures that all such activities are performed under the supervision of personnel cognizant of quality assurance and other requirements such as radiation safety. The provision on the training and proficiency of non-licensed personnel ensures that all such personnel will receive instruction equivalent to that given to licensed reactor operators as regards use of the BNC facility beam. (Note: Licensed reactor operators may, of course, operate the BNC facility beam.) Also, this provision provides for the posting of instructions to be followed in the event of an abnormality.

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.