January 3, 1996

Dr. Gerald Tripard, Director
Nuclear Radiation Center
Washington State University
Pullman, Washington 99164

SUBJECT: RESPONSE TO WSU COMMENTS ON NRC DRAFT DOCUMENTS

Dear Dr. Tripard:

By letter dated August 14, 1995, W. E. Wilson provided comments on Chapter 16 of the draft "Format and Content for Applications for the Licensing of Non-Power Reactors" and "Standard Review Plan and Acceptance Criteria for Applications for the Licensing of Non-Power Reactors." Thank you for taking the time and effort to review our draft documents. The attachment to this letter is our analysis of your comments and changes made to the drafts as a result of your comments.

If you have any questions concerning our effort on these documents, please contact me at 301-415-1127.

Sincerely,

Original signed by:

Alexander Adams Jr., Senior Project Manager
Non-Power Reactors and Decommissioning
Project Directorate
Division of Reactor Program Manager
Office of Nuclear Reactor Regulation

Docket No. 50-27

Attachment: As stated

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

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cc:

State Planning Division
Office of Financial Management
Room 105, House Office Building
Olympia, Washington 98504

NRC response to WSU comments - Chapter 16, Other License Considerations

Comment - Format and content section 16.2, page 16-6, and review plan section 16.2.2, page 16-5, Medical Use of Non-Power Reactors. The documents state that the facility should be designed with two independent, redundant shutters each which have the capability to cut off the beam. You commented that the standard should not specifically call for "shutters" but rather "two independent redundant systems or mechanisms which have the capability to cut off the beam within 30 seconds".

NRC response - We agree with your comment. The capability to cut off the beam should not be limited to just shutters. The applicant should be able to propose and justify alternate means of cutting off the beam that reduces radiation levels in the medical therapy treatment room to acceptable levels. The fifth bullet on page 16-6 of the format and content will be changed to read:

> The medical therapy treatment facility should be designed with two independent, redundant systems which have the capability to cut off the beam within a short period of time. These systems may be shutters each of which have the capability to cut off the beam. Controls for the systems should be located both outside and inside (beam cut off only) the medical therapy treatment room. If shutters are used, they should be designed with redundant sources of motion (e.g., electrical and pneumatic), or each shutter should have a different method of motion. The systems should be designed so that one of them can be manually operated. The systems should be designed such that one system will cut off the beam if the ability to operate the other system is lost. For example, for redundant shutters, the system should be designed so that electrical failure or low air pressure causes the shutters to close if they have dual sources of motion or that the operable shutter will close if the source of motion is lost to the other shutter. The systems should be interlocked with the medical therapy treatment room entrance so that the beam cannot be turned on unless the medical therapy treatment room is configured to prevent entry. If the beam is on and the medical therapy treatment room is entered, the systems should be interlocked so that this action will cause the beam to be cut off automatically. There should be positive indication of the actuation of the systems at the medical therapy treatment facility control area.

The last bullet on page 16-6 of the format and content will be changed to read:

> The medical therapy treatment room should have a radiation monitoring system inside the room. The primary purpose of the radiation monitoring system is to indicate if the systems used to cut off the beam have worked properly by monitoring radiation levels in the medical therapy treatment room. This system should have visual and audible alarms in the medical therapy treatment facility control area and inside the medical therapy treatment room. These alarms can be bypassed during treatment to prevent continuous alarming. The system should have a backup power supply.

The last bullet on page 16-7 of the format and content will be changed to read:

> If the usual method of indicating the status of the systems used to cut off the beam fails, a temporary alternative method of indicating status may be used for a limited time to allow for repairs of the primary status indication. This alternative method must be justified by the applicant if requested for use.

The fourth bullet on page 16-8 of the format and content will be changed to read:

> The scrams, beam cut off systems interlocks, status indication of beam cut off systems, radiation monitors, communications equipment, and any other systems important to the safety of the medical therapy treatment process should be subject to periodic surveillance requirements if used for therapy. Any systems undergoing maintenance should be successfully tested for operability before patients are treated.

The fifth bullet in section 12.2.2 on page 16-5 of the review plan will be changed to read:

> The medical therapy treatment facility design should have two independent, redundant systems which have the capability to cut off the neutron beam within a short period of time. Beam controls and method of motion should be as described in the format and content guidance. Interlocks between the systems and the medical therapy treatment room door or entrance should be based on the design guidance in the format and content guidance.

The seventh bullet on page 16-6 of the review plan will be changed to read:

> The licensee may propose a temporary alternative to the medical therapy treatment facility control area reactor scram by using the communications link with the control room to verbally ask the operator to scram the reactor if the primary scram method is out of service. A temporary alternative may also be used if the primary method to indicate the status of the systems used to cut off the beam is out of service. The radiation monitor in the medical therapy treatment room may be out of service for a limited time if an alternative method of monitoring radiation in the medical therapy treatment room is proposed. In these cases, the temporary alternative is acceptable if limited to a short period of time (e.g., no more than 10 working days).

The second bullet of section 16.2.4 on page 16-8 of the review plan will be changed to read:

> The design of the medical therapy treatment facility controls and systems used to cut off the neutron beam has been reviewed; there is reasonable assurance that the neutron beam can be controlled by the licensee. Interlocks exist to prevent accidental exposure to the neutron beam. The radiation monitor in the medical therapy treatment room indicates the beam status.

Comment - format and content section 16.2, page 16-6 and review plan section 16.2.2, page 16-5. The document states that the treatment room should have a shielded door or some other method to prevent entry during treatment. You commented that a more inclusive wording would be "shielded door, labyrinth with unshielded door, or other method...that will cut off the beam if the treatment room is entered."

NRC response - We agree with your suggestion for more inclusive wording for this section. The sixth bullet on page 16-6 of the format and content will be changed to read:

> The medical therapy treatment room should have a shielded door, labyrinth with unshielded door, or some other method to prevent entry during treatment. If the door is opened or the room is entered during treatment, the systems used to cut off the beam should automatically operate. If the medical therapy treatment room has a door that is motor operated, that door must also be able to be opened manually.

The fourth bullet of section 16.2.2 on page 16-5 of the review plan will be changed to read:

> The medical therapy treatment facility design should prevent entry during treatment. The entry area should have a shielded door, labyrinth with unshielded door, or some other method to prevent entry during treatment. The door or entrance should be interlocked with the systems used to cut off the beam if someone enters.

Comment - Format and content section 16.2, page 16-6. The seventh bullet on page 16-6 states that if the treatment room does not have a method for directly viewing the patient (such as a lead glass window), the treatment facility should be designed with redundant methods (e.g., multiple television cameras) for viewing the patient. You commented that a single video system with a requirement that the treatment be terminated if the viewing system completely fails is sufficient. The most likely failure is not the closed circuit TV camera, but rather the monitor. Thus simply specifying two cameras is not likely to improve reliability. Two completely independent video systems would be required.

NRC response - This design feature is modeled after regulation 10 CFR 35.615(e) for teletherapy which requires continuous observation of the patient or human subject. This regulation exists to be able to continuously evaluate the condition of the patient. We believe that this design feature should not be relaxed. We agree with your comment concerning the reliability of video systems. It was our intent that two independent systems be present. We will change this section to read:

> If the medical therapy treatment room does not have a method for directly viewing the patient (such as a lead glass window), the medical therapy treatment facility should be designed with redundant methods (e.g., multiple television cameras and monitors) for viewing the patient. A method of emergency lighting in case of power failure should be provided.

Comment - Format and content section 16.2, page 16-7 and 16-9. The document discusses the responsibilities of the reactor licensee and the medical use licensee. You commented that the standard should more clearly specify that "the Medical Licensee shall provide the NPR with a detailed written protocol for each human patient treatment and it shall be the facility's responsibility to deliver the dose specified in the treatment protocol. The Medical Licensee shall be responsible for all aspects of the treatment except the actual operation of the NPR as well as for the patient's safety."

NRC response - We believe that the document as written addresses the responsibilities of the reactor licensee and medical use licensee. For example, the first and second bullet under administrative requirements on page 16-7 and fourth bullet on page 16-9 address responsibilities and the conduct of the treatment. The reactor licensee is responsible for more than just operation of the reactor. For example, the reactor licensee is responsible for ensuring the proper operation of the treatment facility, radiation safety, and for adhering to the quality management program. The second bullet under administrative requirements on page 16-7 of the format and content will be changed to include reference to the treatment plan as follows:

> The responsibilities of the non-power reactor licensee and the physician authorized user should be stated. It should be clearly stated that medical treatment is the responsibility of the physician in charge of the therapy and the medical physicist of the medical use licensee. The medical use licensee is responsible for the treatment plan. The non-power reactor licensee is responsible for delivery of the radiation fluence requested in the written directive and for providing current and accurate beam parameters to the medical use licensee.

Comment - format and content section 16.2, page 16-8. The fifth bullet on page 16-8 states that a requirement for characterizing the beam at regular intervals should be stated. You commented that a one time complete characterization of the beam with spot checks should be sufficient unless a significant modification to the system is made that affects the beam, etc.

NRC response - We believe that there has not been sufficient history of operation of neutron beams for human irradiation to support your suggestion and you have provided no basis for your suggestion. Please note that the statement in the guidance is a "should" statement. We do not consider this to be a requirement. We have accepted a characterization surveillance interval of six months. However, the review plan did not clearly state what intervals the staff has accepted. Applicants may propose any characterization interval they believe can be justified. The NRC staff will then evaluate the proposal and justification for acceptability. We will change section 16.2.2, page 16-7, first bullet, of the review plan to read as follows:

> As discussed in the format and content guidance, calibration checks of the beam, functional checks of the beam monitors, and characterization of the beam should be performed at regular intervals. The staff has accepted an interval for calibration checks of the beam and functional checks of the beam monitors of weekly and an interval for characterization of six months. If no patient is being treated, these checks need not be done. Also, if the beam is modified or maintenance is done, the licensee should ensure that the beam characteristics have not changed.

Comment - Format and content section 16.2, page 16-9. The document discusses the training of personnel to operate the controls of the facility. You commented that the only training modifications that should be specified is that NRC licensed reactor operators and senior reactor operators be trained and retrained in all aspects of the operation and maintenance of the treatment facility and associated procedures, including all aspects of the NPR's operation that could affect the magnitude of the treatment beam.

NRC response - Reactor operators are included in the training requirements discussed in the third bullet on page 16-9 of the format and content document. But there is no requirement for only licensed operators to operate the medical therapy treatment facility controls. From a training perspective, this is similar to a researcher operating the controls of an experimental facility where adequate training is required. Your point about licensed operators being specifically trained is well taken and the bullet will be changed to read:

> There should be requirements for qualification and training of personnel to operate the controls for the medical therapy treatment facility. The applicant should discuss minimum instructions that must be available at the medical therapy treatment facility control area. The applicant should discuss the training for making changes in the medical therapy treatment facility operation that could affect the reactivity of the reactor. NRC licensed reactor operators and senior reactor operators should be trained and requalified in the operation and maintenance of the medical therapy treatment facility and associated procedures, as appropriate, including aspects of the reactor's operation that could affect the treatment beam. The applicant should also discuss requirements for retaining training records.

Comment - Format and content section 16.2, page 16-9. The document discusses that the licensee should have written procedures for the conduct of human irradiations. You commented that the technical specifications of most facilities specify a number of operating procedures for the NPR. A NPR that is involved with BNCT should have the technical specifications modified to include a requirement for a detailed operating procedure for BNCT treatment of patients.

NRC response - We agree with your point. A requirement for procedures for the conduct of medical therapy should be required similar to the technical specification requirement to have procedures for reactor startup and shutdown. The section on procedures on page 16-9 of the format and content document will be changed to read:

> The licensee should have written procedures required by the technical specifications in place for the conduct of medical therapy treatments before starting human irradiations.