



October 8, 2002

United States Nuclear Regulator Commission  
Region III  
801 Warendville Road  
Lisle, Illinois 60532-4351  
Attention: Gary Shear

Dear Mr. Shear:

During our conversation yesterday, you requested that Saint Joseph Mercy Health System ("SJMHS") provide you with an interim action plan for when routine safety procedures were not effectively managing potential exposure to family members of patient's undergoing inpatient therapy. As we discussed and both recognized, this is a true challenge to balance the safety standards, while honoring the wishes of the patient and family. The following is the proposed SJMHS plan to respond to those instances we discussed.

Proposed Plan:

Items 1 and 2 below will apply to all inpatients receiving radio-pharmaceutical therapy as addressed in 10 CFR 35.75. Items 3 through 7 will also be implemented in the event there are concerns regarding patient or family adherence to radiation safety standards.

1. Staff Education: Education to staff will be specific as to the course of therapy being provided to a patient. Education will include the potential safety concerns of staff and family members. Staff will be reminded about the appropriate radiation badge process. Staff will also be reminded to communicate with the family, the RSO, the Nurse Manager, and the primary care physician if safety precautions are not being followed.
2. Obtain a signed acknowledgement form from family members outlining safety standards, risks and the fact that they have received safety instructions regarding the exposure to the patient undergoing therapy.
3. Notify the NRC: We anticipate contacting the NRC in the event we face an unusual circumstance with a family and adherence to radiation safety standards.
4. Obtain an Ethics consult from the organization's ethics committee. This review will include discussion with the patient, the family, the treating physician, the Radiation Safety Officer and other primary care givers as appropriate. The Ethics consult will address issues in balancing patient and family rights and preferences and meeting radiation safety standards. They would also discuss informed consent and the benefits of the treatment compared to the risks and how to best minimize the risks.

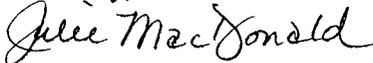
Discussions may also include various approaches with the family. The Ethics consult may also result in a Family Care Conference being convened.

5. Convene a Family Care Conference. This may be a result of the Ethics consult or may be an independent action. This will entail a conference with the patient, the family members, primary care physician, care providers, the Radiation Safety Officer and any other appropriate staff personnel. The purpose of the conference will be to review the proposed course of therapy and the implications of that therapy to both the patient and the family. In addition, a plan for the care of the patient, which addresses the family wishes for visitation and participation in patient care will be initiated.
6. Finally, the strategies listed below will also be considered as appropriate to minimize family exposure if deemed necessary where compliance by the family to usual radiation safety standards is in question.
  - a. Badge immediate family members or those persons who will have significant contact with the patient.
  - b. Consider use of lead aprons to immediate family members or those persons who will have significant contact with the patient.
  - c. If hospitalization is prolonged, we would also develop a log where the family members would sign in and out of the patient room. This log will account for time family members spend with the patient undergoing therapy.
  - d. Make arrangements as necessary for a "back-up" authorized user to be on premises for further evaluation, assessment and discussion with family members as needed.
7. Strengthen upward reporting within the management structure.

Additionally, SJMHS plans to conduct root cause analysis to determine if any additional process and/or system changes may be required.

Please contact me if you should have any questions regarding the specifics of the proposed future plan of action.

Sincerely,



Julie MacDonald  
Senior Vice President/Chief Operating Officer

JM/mz  
VIA OVERNIGHT MAIL