

September 19, 2005



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Steven A. Reynolds  
Director, Division of Nuclear Materials Safety  
United States Nuclear Regulatory Commission ("NRC")  
Region III  
2443 Warrenville Road, Suite 210  
Lisle, Illinois 60532-4352

**SUBJECT: Predecisional Conference Summary**

Dear Mr. Reynolds:

Thank you for providing the NRC's September 11, 2005 summary of the July 27, 2005 predecisional enforcement conference between NRC Region III and Saint Joseph Regional Medical Center ("SJPMC"). Although your September 11 letter states that no response is required, we believe a brief response is appropriate to avoid a misunderstanding of our position on reporting of medical events.

Your letter summarized SJPMC's position with regard to patients 3-5 as follows, "...the medical events were not reportable because these events were caused by patient intervention. Specifically, you indicated that the patients contributed directly to the exposures because the patients sat up in bed during treatment, causing the sources to migrate out of the intended position."

This very brief summary could be read to suggest that SJPMC's position was to blame the patients. That is not true. We accepted responsibility for what occurred and, as your summary noted, we have prepared and have begun implementing a comprehensive corrective action plan to prevent events like this from happening again. We believe confusion about the nature of the NRC's medical event reporting rule may have caused our position to be misunderstood.

When the NRC adopted the current version of 10 C.F.R. § 35.3045 in 2002, it deleted a phrase from the proposed rule that would have hinged reporting on the licensee's judgment whether an action (intervention) by the patient "could not have been reasonably prevented by the licensee." It did so because this language would have required the NRC to intrude into medical judgments when it reviewed licensees' compliance with the regulation. The proposed regulation would have been difficult to implement and enforce, and there could have been unfortunate delays in reporting if physicians and medical staff spent time debating whether a patient's actions could have been prevented.

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Thus, in the final rule, an exposure event involving patient action (intervention) may not be reportable even if reasonable action by the licensee would have prevented it from occurring, and an event involving patient action may be reportable even if there was absolutely nothing the licensee could have done. When a licensee determines that a report is not required under 10 C.F.R. § 35.3045 because an action (intervention) by the patient was the immediate cause of the exposure, this has nothing whatsoever to do with who should be blamed for what happened, and nothing necessarily to do with assessing the root cause of the exposure.

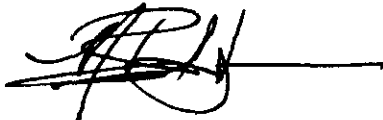
Accordingly, when SJRMC said that no report was required in the case of patients 3-5 because of patient intervention, this was not blaming the patients for anything, and it would be contrary to the regulation, and very unfair both to us and to the patients, to even suggest this. At the conference, we identified a violation of 10 C.F.R. § 35.41(a) as the principal contributor to the exposures, and we (not the patients) are responsible for compliance with all of Part 35.

Your letter also summarized our position on patients 1 and 2 to be that reports were not required because neither had any physical symptoms. A more accurate statement of our position would be that reports were not required simply because there was no evidence of any unintended exposures.

As we stated at the conference, our goal is outstanding patient care, not merely compliance. We hope that this letter clarifies our position on reporting, and we appreciate the NRC's time and attention to this matter.

We request that a copy of this letter be available electronically in the NRC Public Document Room or from the Publicly Available Records (PAR) component of NRC's document system (ADAMS).

Sincerely,

A handwritten signature in black ink, appearing to be 'N. Hellyer', with a horizontal line extending to the right.

Nancy R. Hellyer  
Chief Executive Officer

cc: Gary Perecko  
Chris Karam  
Rich Korman

  
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