

March 8, 2010

Ms. Joyce Lilya
3536 Ingraham Street
San Diego, CA 92109

Dear Ms. Lilya:

I am responding to your February 5, 2010, letter to the Chairman and Commissioners of the U.S. Nuclear Regulatory Commission (NRC), regarding the follow-up that has occurred since the medical event involving your mother's radiotherapy treatment. First, please accept my condolences on the loss of your mother. I am sorry that you believe that the NRC has not been responsive to your concerns. I can assure you that NRC takes its mission to protect public health and safety against the potential hazards associated with the use of radioactive materials very seriously.

Your letter emphasizes your view that your mother was never told of the medical event by the licensee, and expresses concern that the State did not adequately follow up on that issue. Your mother's medical treatments occurred in the State of Ohio, which is an Agreement State. As an Agreement State, Ohio has regulatory jurisdiction over the activities involved in your mother's treatment, through an Agreement that the State maintains with NRC pursuant to the Atomic Energy Act. This is the reason that NRC's earlier response to some of your concerns was to refer to the State of Ohio for review and appropriate response.

NRC does maintain an oversight role of the Agreement State radioactive materials programs to ensure that they are adequate to protect public health and safety and that they are compatible with NRC's program. The NRC requires its licensees to notify those patients who are the subject of a medical event. There is an exception if, based on medical judgment of the referring physician, telling the individual would be harmful. Also, the notification does not need to be written unless requested. These regulations are found in Title 10 of the Code of Federal Regulations, Part 35, specifically in 10 CFR 35.3045(e). The compatible regulations to 10 CFR 35.3045(e) for the Ohio Department of Health appear in Ohio Administrative Code section 3701:1-58-101 (E), "Report and Notification of a Medical Event." It reads the same as the NRC regulation. Copies of these regulations are enclosed.

NRC's and the Agreement States' regulatory jurisdictions are very specific with respect to the practice of medicine. NRC and Agreement State programs do not have jurisdiction over what the doctor decides is an appropriate treatment plan. NRC and the Agreement States do have jurisdiction to determine if that plan is carried out according to his or her direction, which is a requirement in both NRC and Agreement State regulations. When a licensee violates the established regulations, NRC or an Agreement State can take enforcement action against the licensee.

The action taken by the regulator can vary from a written Notice of Violation to a monetary penalty to a suspension or revocation of the license to possess and use radioactive materials. The specific action taken can depend on a number of factors, including the severity of the violations, the licensee's previous enforcement history, the licensee's self-identification of the factors that caused the violations, and the licensee's corrective actions to try to prevent recurrence.

While not based solely on the medical event involving your mother, the State of Ohio did take a significant enforcement action against the licensee during the period in which your mother's treatment occurred. On October 1, 2007, an administrative penalty of \$4,000 was imposed for "a potentially significant lack of attention toward licensed responsibilities." The purpose of the enforcement program is to prevent reoccurrence of violations. The State of Ohio took a significant enforcement action based on multiple instances of non-compliant performance and the performance of the licensee then improved.

In light of several medical events that have been reported to NRC recently, NRC is looking to strengthen certain aspects of its regulations for the use of radioactive materials in medicine found in 10 CFR Part 35. All of NRC's proposed regulations undergo a public comment period. NRC receives many valuable comments from interested stakeholders and members of the public in the rulemaking process. While the current Part 35 rulemaking in progress does not specifically address your concern we invite you to participate in the rulemaking process by visiting <http://www.nrc.gov/about-nrc/regulatory/rulemaking/public-involvement.html>.

Sincerely,

/RA/ Cynthia Carpenter for

Charles L. Miller, Director
Office of Federal and State Materials
and Environmental Management Programs

Enclosure:
As Stated

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Sincerely,

/RA/ Cynthia Carpenter for

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Enclosure:
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