

September 20, 2004

Henry D. Royal, M.D.
President
Society of Nuclear Medicine
1850 Samuel Morse Drive
Reston, Virginia 20190-5316

Dear Dr. Royal:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am providing a final response to your letter on the St. Joseph Hospital dose reconstruction. In his letter of January 12, 2004, on this same subject, NRC Chairman Nils J. Diaz had indicated that the NRC staff would review the reconstruction prepared by Drs. Carol Marcus and Jeffrey Siegel. Chairman Diaz had also indicated that the Advisory Committee on the Medical Use of Isotopes (ACMUI) would also be asked to review the reconstruction, as well as NRC's dose assessments, and to perform its own calculations as necessary. These reviews have been completed, and I am writing to inform you of our conclusions.

This specific dose reconstruction demonstrates the problems encountered when there is very little data directly available from the event to conduct an accurate dose reconstruction. When viewed independently, all three analyses (Drs. Marcus and Siegel, ACMUI, and the staff) make reasonable assumptions and reach different conclusions. The staff's analysis was based on data obtained by interviewing individuals directly involved in the event; however, the data was acquired after considerable time had elapsed since the event occurred. The other two analyses also have uncertainties, in that there were assumptions made about individual behavior and the geometry of the room that did not conform to the reported facts associated with this event. Although the assumptions may or may not be valid, they are opinions, and as such, are subject to challenge. However, in all three analyses, the calculated exposure received by the individual in this case is well above the regulatory limit.

Based on careful review of the dose reconstruction by Drs. Marcus and Siegel, input from the ACMUI, as well as the NRC staff's extensive calculations, the Commission has concluded that the original dose estimate of 15 cSv (15 rem) obtained by NRC's Region III staff is not overly conservative and is within a reasonably plausible scenario. We have come to this conclusion because the staff's review showed that Region III staff used an appropriate method to calculate the dose, obtained necessary data by direct and detailed interviews with the exposed member of the public and the hospital staff on duty at the time of the exposures, and confirmed that the information provided separately by the exposed person and by the hospital staff was consistent.

It has not proven possible to resolve the differences between NRC's and the licensee's dose estimates. Both estimates used identical methods of dose assessment based on the daily

dose rate surveys made by the licensee at the patient's bedside. The difference between the two is due to differences in estimated exposure durations for the family member. This difference, in turn, arose from differences in the recollection of the details of the event by the family member during separate interviews with the NRC and the licensee. The details differed in some respects in the different interviews, and were not entirely consistent. This is not surprising, considering the difficult circumstances for the family member during which the exposures occurred and that the interviews took place as much as 3 months after the incident.

The dose reconstructions performed by Drs. Marcus and Siegel and the ACMUI review relied on a calculated dose rate to the family member considering the 285 millicurie source term, instead of using the survey data more directly. NRC has concluded, based on its own detailed calculations, that this approach carries a larger uncertainty than that based on the radiation surveys. The reason is that there is little numerical data available in this case on which to base an accurate dose rate calculation, and assumptions therefore were necessary to substitute for the missing data. These assumptions were based on what was considered reasonable behavior on the part of the family member, as opposed to information collected from the people involved. Available evidence strongly indicates that the assumptions made do not represent the pattern of exposure that actually occurred. Furthermore, NRC staff calculations show that the radiation fields around the patient were such that relatively small changes in such assumptions could have a large impact on the assessed dose rate. The ACMUI review, in particular, highlighted the variability associated with these dose calculations.

As a result of your letter and subsequent analysis, the NRC is considering some changes in procedures and documentation for future events. For example, the present case suggests that licensees need to be reminded that they have the prime responsibility for promptly recognizing that an event occurred, understanding the types of information that will likely be needed to perform accurate dose reconstructions, and promptly gathering this information. The NRC staff is considering developing generic information and communications in this area. The staff is also considering developing internal guidance and training for NRC inspectors to more fully document findings, dose estimates, and discussions of alternate points of view in inspection reports. Finally, the staff is considering developing procedures that could be used to permit visitors of medical patients to be exposed to doses above the public dose limit under exceptional circumstances if certain conditions are met.

The Commission agrees with you that effective dose equivalent is a more suitable quantity for assessing risk than deep dose equivalent. However, we also recognize that there are currently no acceptable industry-wide medical practice guidelines for calculating effective dose equivalent doses from point measurements or for situations such as this specific case where the radiation field is neither uniform over the patient's body nor uniformly incident on the patient's body surface. We highly encourage the medical industry, perhaps in concert with the Health Physics Society, to develop peer reviewed guidelines for these important dose calculations.

I would like to thank you for pointing out an area of our procedures and documentation that could be improved in addressing situations such as this one. Details of the analysis performed by the staff of the various reconstructions may be found in the staff's report to the Commission, available on NRC's Agency-wide Documents Access and Management System(ADAMS), accession number ML042510591.

Sincerely,

/RA/

Jeffrey S. Merrifield
Acting Chairman

cc: Simin Dadparvar, M.D.
President, American College of Nuclear Physicians