

September 23, 2003

Carol S. Marcus, Ph.D., M.D.
President, ACNP-CA
1877 Comstock Avenue
Los Angeles, California 90025-5014

Dear Dr. Marcus:

I am responding on behalf of the U.S. Nuclear Regulatory Commission (NRC) to your letter of July 2, 2003, to Commissioner McGaffigan. In that letter, you requested that the NRC appoint an expert dosimetry panel to review NRC's internal and external dosimetry calculations affecting medical, pharmacy, and academic licensees.

Although we appreciate your suggestion to establish an independent dosimetry panel to review our calculations, we believe the staff receives sufficient support from its existing medical and scientific consultants; contractors; and our current advisory panel, the Advisory Committee on the Medical Uses of Isotopes (ACMUI), in performing and reviewing its dose reconstructions. However, because of recent interest in this issue, the Commission will place this issue on the agenda for the next public meeting with the ACMUI so there can be further public discussion on this topic.

The staff will continue to augment its dose reconstruction capabilities with specific individuals, dosimetry groups, and laboratories when their unique expertise is needed. The staff also will continue to evaluate the state-of-the-art in dose reconstruction in order to keep its determinations as realistic as possible.

I have enclosed a copy of a letter the Commission recently sent to the Society of Nuclear Medicine and the American College of Nuclear Physicians on a similar topic. The NRC staff is available to meet with you to discuss its dose calculation approaches in detail. If you have further questions on the matter, please contact Charles L. Miller, of the NRC staff at (301) 415-7197.

Sincerely,

/RA/

Nils J. Diaz

Enclosure: As stated

September 9, 2003

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

Dear Dr. Royal:

I am responding to your letter of July 8, 2003, to Commissioner McGaffigan in which you expressed concerns about dose reconstructions that the U.S. Nuclear Regulatory Commission (NRC) performed. Your letter discussed a specific dose reconstruction performed by NRC staff, and you requested that the details of this and other dose reconstructions be made publicly available so that they can be peer reviewed to ensure that they are not overly conservative.

It is my understanding that during your meetings with Commissioners McGaffigan and Merrifield on July 29, 2003, a specific dose reconstruction case was discussed. This case involved the therapeutic administration of about 300 mCi of I-131 to a terminally ill patient and the subsequent exposure of the patient's daughter while sitting next to the hospital bed. In this particular case, the hospital had performed daily dose rate measurements at the bedside. The NRC estimated the stay times next to the bed based on interviews with the daughter and the hospital staff. The dose to the daughter was then calculated using these stay times and the measured exposure rate for each day. Since the NRC staff was able to use measured dose rates and did not have to perform a complex dose reconstruction analysis, the Commission does not feel that the staff's results were overly conservative. Based on information presented by the staff on several other cases, we do not have any other indications that the staff's analyses are overly conservative. The NRC staff is available to meet with you to discuss its dose calculation approaches in detail. In addition, the Commission will place this issue on the agenda for the next public meeting with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) so there can be further public discussion on this topic.

As for making all dose reconstruction information publicly available, the NRC inspection reports that contain the details of these analyses are publicly available in NRC's AgencyWide Documents Access and Management System (ADAMS). These reports should include sufficient information concerning the dose evaluations for the public to see the particular methodologies NRC used in specific dose reconstructions. The inspection report for the case mentioned above can be located at accession number ML023440102. If you have trouble accessing this or other documents, please notify the staff, and they will assist you in obtaining copies of publicly available documents.

In your letter, you also suggest that the NRC consult an independent committee composed of experts from the Society of Nuclear Medicine and American College of Nuclear Physicians (SNM/ACNP) and other dosimetry experts to conduct peer reviews of NRC's calculations. While we appreciate your offer to have an independent SNM/ACNP Committee review our calculations, we believe the staff gets sufficient support from its existing medical and scientific consultants, contractors, and the ACMUI in performing and reviewing its dose reconstructions. The staff will continue to augment its dose reconstruction capabilities with specific individuals, dosimetry groups, and laboratories when their unique expertise is needed.

The staff will also continue to evaluate the state-of-the-art in dose reconstruction in order to keep its determinations as realistic as possible.

If you wish to meet with the staff or have any questions, please contact Charles L. Miller, of NRC's Office of Nuclear Materials Safety and Safeguards. Mr. Miller can be reached by telephone at (301) 415-7197

Sincerely,

/RA/

Nils J. Diaz

cc: Dr. Dadparvar
Mr. Uffelman

Identical letter sent to:

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

Simin Dadparvar, M.D., President
American College of Nuclear Physicians
1850 Samuel Morse Drive
Reston, Virginia 20190-5316