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FINAL REPLY:

Henry D. Royal
Society of Nuclear Medicine

Simin Dadparvar
American College of Nuclear Physicians

TO:

Comm. McGaffigan

FOR SIGNATURE OF : ** PRI **

CRC NO: 03-0436

Chairman Diaz

DESC:

ROUTING:

Dose Reconstruction Methodology

Travers
Paperiello
Kane
Norry
Dean
Burns/Cyr
Thadani, RES

DATE: 07/09/03

ASSIGNED TO: CONTACT:

NMSS

Virgilio

SPECIAL INSTRUCTIONS OR REMARKS:

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**OFFICE OF THE SECRETARY
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| AUTHOR: | Henry Royal | | |
| AFFILIATION: | VA | | |
| ADDRESSEE: | Edward McGaffigan | | |
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American College of Nuclear Physicians/Society of Nuclear Medicine
GOVERNMENT RELATIONS OFFICE

July 8, 2003

Commissioner Edward McGaffigan, Jr.
Nuclear Regulatory Commission
One White Flint North Building
11555 Rockville Pike
Rockville, MD 20852

Dear Commissioner McGaffigan:

On behalf of the Society of Nuclear Medicine and the American College of Nuclear Physicians (SNM/ACNP), international scientific and professional organizations with 16,000 members dedicated to promoting and enhancing the science, technology and practical application of nuclear medicine to clinical practice, we are writing to express our concerns about some of the dose reconstructions that have been performed by the NRC in the past. Most recently, our concerns have been raised by an NRC calculation related to the dose received by a family member of a patient who was treated with I-131. The patient died and the hospital was subsequently cited for not taking additional measures to lower the dose to the grieving family member. This incident raises many issues regarding the appropriateness of the NRC's actions. One of the issues is the accuracy of the dose reconstruction.

The culture of the NRC seems to be to perform "conservative" dose reconstructions that are based on a series of worst-case assumptions. The resultant calculation is often much higher than a more realistic estimate of the dose. Unfortunately, the details of the NRC's dose reconstruction are not revealed in enough detail so that the NRC's methodology can be peer reviewed.

SNM and ACNP urge that the NRC review its dose reconstruction methodology. SNM and ACNP believe that the details of the dose reconstruction should be publicly available in enough detail so that the methodology can be peer reviewed. The goal of the dose reconstruction should be to estimate an accurate dose, not the worst-case dose.

Finally, an independent committee composed of SNM/ACNP and other dosimetry experts should review the NRC calculations using realistic calculation methodologies as described in the new SNM/ACNP therapy guidance document. The SNM/ACNP *Guide for Diagnostic and Therapeutic Nuclear Medicine*, now "in press", addresses this issue in some depth.

We look forward to working with you and the other Commissioners to review this matter. The NRC and the regulated community will be better served if a more realistic and credible dose calculation method can be put in place. If you have any questions, please feel free to contact us

Commissioner McGaffigan

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at our national office or through Bill Uffelman at 703-708-9773 or by email at wuffelman@snm.org.

Thank you for your attention to this important matter.

Sincerely,

Henry D. Royal, M.D.

Henry D. Royal, M.D.

President

Society of Nuclear Medicine

Simin Dadparvar, M.D.

Simin Dadparvar, M.D.

President

American College of Nuclear Physicians



1850 Samuel Morse Drive
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Date: July 8, 2003

To: Commissioner Edward McGaffigan, Jr.

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of Pages (including cover sheet): 3

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Comments:

Letter regarding dose
reconstruction methodology
attached.

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For more information: Call 703-708-9000 ext. 1229

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