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SANTA BARBARA · SANTA CRUZ

January 10, 1995

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Carl J. Paperiello, Ph.D., Director
Division of Industrial and Medical
Nuclear Safety
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 200555-0001

Dear Dr. Paperiello:

Thank you for your letter of 23 Dec. 94, which was prepared in answer to my letters of 30 Nov. 94 and 12 Dec. 94 to Chairman Selin. Unfortunately, your letter is entirely unsatisfactory.

First, you have Nuclear Medicine confused with Radiation Oncology. These are two completely different medical specialties, with different residency training programs, different specialty board certifications, and different representative professional specialty societies. Radiation oncology deals with radiation from sealed sources or machines to treat cancer. Radiation absorbed doses are often carefully chosen to optimize therapeutic success without causing irreparable damage in normal surrounding tissues. Radiation absorbed doses used in Radiation Oncology are about 10,000 times higher than those used in Nuclear Medicine. Radiation Oncology generally requires precision because tissues are being irradiated to tolerance.

In Nuclear Medicine we use unsealed sources of radioactively labeled pharmaceuticals, which travel in the body and concentrate in different organs, tissues, and pathophysiologic and anatomic sites depending upon the patient's condition. Ninety-nine point five per cent of Nuclear Medicine is diagnostic, and the average effective dose equivalent is 440 mrem, somewhere between yearly background radiation in Washington, D.C., and that in Denver, CO. Precision is irrelevant, the absorbed doses are exceedingly low, and radiopharmaceuticals are administered in units of activity, such as mCi, not absorbed dose, such as mrads. In Nuclear Medicine therapy, we use purposely high administered activities to result in therapeutic radiation absorbed doses, but the absorbed doses achieved can only be estimated, and there is no precision present or needed. As NRC is not capable of performing internal dosimetry, and is forced to contract all of it out to consultants, perhaps you are unfamiliar with the imprecision of

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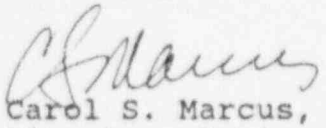
internal dosimetry. In the words of Roger J. Cloutier, the first Director of the Radiation Internal Dose Information Center (RIDIC) at Oak Ridge (your principal contractor), "I only use one significant digit because you can't use any fewer". We do not irradiate to tissue tolerance, and as I said in my letter, we can vary activity ordered on the same patient by 600% depending on the physician.

Your argument in your letter is therefore irrelevant. It has nothing to do with the specialty of Nuclear Medicine. If you think Radiation Oncology requires more precision, just ask the radiation oncologist what precision he requires; it will differ from one patient to another, and will differ significantly with teletherapy vs. brachytherapy. When I write "20 mCi ± 30%", it means that I will accept any activity from 14 to 36 mCi. Stating that "...the supervised individual is made responsible for determining the actual dose to be delivered" is inane; the actual dose is somewhere between 14-36 mCi. I don't care where it ends up. I am the authorized user physician, I am ordering that which I feel is appropriate, and your peculiar stubbornness on this issue is ignorant, irrational, and scientifically and medically without foundation. I cannot respect your opinion, and believe that if you do not even know what Nuclear Medicine <u>is</u>, you certainly are not entitled to any opinions about it.

Your gratuitous suggestion that the way to resolve the conflict between the way I and other qualified physicians write a legal prescription and NRC's nonsensical requirement for a "written directive" is for us to stop being appropriate and start writing silly prescriptions that suit the staff in your non-medical "Medical" Section is the typical perversion of the more dysfunctional members of your Agency.

For these reasons, I ask that you return the answering of my letters to Chairman Selin, who, if he cannot find someone more qualified to answer them, ought to answer them himself or get out of the business altogether. The most sensible thing at this point would be to retract the non-Quality. non-Management, non-Program, perpetrated by NRC with lies and fraud, and enforced by a federal "goon squad" held in contempt by the entire nation's knowledgeable, qualified, Nuclear Medicine physicians, including members of NRC's own Medical Advisory Committee.

Sincerely,



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and
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cc: Chairman Ivan Selin, Ph.D.
Commissioner E. Gail de Planque, Ph.D.
Hugh Thompson, Deputy EDO, NMSS

Enclosure

CSM:sfd