



January 24, 1995

The Honorable Ivan Selin, Ph.D.
Chairman
US Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

UCLA SCHOOL OF MEDICINE
HARBOR · UCLA MEDICAL CENTER
DEPARTMENT OF RADIOLOGY
1000 CARSON STREET
TORRANCE, CALIFORNIA 90509

Dear Chairman Selin:

The purpose of this letter is to inquire about the reason for the puzzling delay concerning the "Patient Discharge Rule". This is NRC's rule which is supposed to state that the most exposed contact of a patient treated with radionuclide therapy should remain at the 500 mrem maximum, and that the methodology published by the National Council for Radiation Protection and Measurements (NCRP) in 1970 (NCRP no. 37) should be employed for estimating such doses. This would end needless and expensive hospitalizations.

As a representative of the Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP), I met with you on the subject of poor performance by NRC on this Proposed Rule published in the Federal Register on 15 June 94 (Criteria for the Release of Patients Administered Radioactive Material, RIN 3150-AE41, 59FR 30724-30732, and associated analysis and regulatory guidance). Our meeting was held in your office the third week of Sept. 1994, and dealt with the points made in my 18-page letter to NRC pointing out its serious scientific, mathematical, and medical mistakes. You agreed with my points, stated that NRC "had not done its homework", and vowed that it would be repaired. Given the fact that I did all the physics, math, pharmacokinetics, and pathophysiology for NRC, and contributed model calculations, model language and the pertinent references, one would assume that it would require no more than about an hour of NRC time to complete the rule. After all, it was NRC that asked me to write a petition on the subject in the first place, in December of 1990.

The reason for pushing for progress on this rulemaking is very simple. NRC is frivolously wasting medical dollars for no good reason at all.

Let us see what NRC's delays are costing those who pay for health care in this country. According to NRC's estimates in the regulatory analysis of this rule, we treat about 50,000 patients a year for hyperthyroidism. In my experience, about 20% require total administered activities of NaI-131 greater than 30 mCi, your present outpatient limit. As my experience is skewed by working in a public hospital whose patients often present with advanced disease, let us say that only 10% nationally require greater than 30 mCi, or 5000 patients/year. In addition, about

9502060175 950124
PDR COMMS NRCC
CORRESPONDENCE PDR

JF03
1/0

January 24, 1995
The Honorable Ivan Selin, Ph.D.
Page -2-

10,000 patients a year are treated with NaI-131 for thyroid cancer, virtually all of whom require more than 30 mCi per therapy.

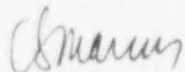
Let us say that the average inpatient hospital cost for the hyperthyroid patient is \$3000, and that the average cost for a thyroid cancer patient is \$2000. That is $(3000)(5000) + (2000)(10,000) = 15,000,000 + 20,000,000 = \35 million per year, of unnecessary expenses.

For 25 years, NRC has failed to understand NCRP no. 37, and these costs, in 1995 dollars, amount to about \$675 million (assuming a mean population of 200 million). For 4 years NRC has delayed my petition, at a patient cost of \$140 million and a User Fee of perhaps \$0.5-1 million. For 6 months, all NRC had to do was copy my comment letter but instead cost patients \$17.5 million. During the 4 months after our meeting, NRC has cost America's patients about \$12 million. While many physicians "get around" NRC's "30 mCi" rule, mainly for hyperthyroid patients, by breaking up administered activity into 30 mCi chunks or less, no radiation dose is saved by the public, inpatient costs are avoided, but the patient may be ill for several extra months. It is not ethically acceptable that NRC should impose several extra months of illness on patients who need to avoid costs that result from a scientifically unrespectable and foolish NRC regulation in the first place.

I recommend that you rectify this situation immediately. If your staff and management still find it too difficult to accomplish, then perhaps you could either copy my recommendations or those of an intelligent Agreement State, such as California.

Thank you for your attention and consideration.

Sincerely,



Carol S. Marcus, Ph.D., M.D.
Director, Nuclear Med. Outpt. Clinic
and
Professor of Radiological Sciences
UCLA,
Vice-President, Society of Nuclear Medicine
and
President, American College of Nuclear Physicians,
California Chapter

Phone: (310) 222-2845
FAX: (310) 533-7159

cc: Commissioner E. Gail de Planque
Hugh Thompson, Deputy EDO
David Nichols, ACNP/SNM Conjoint Office