February 15, 1990

NOTE FOR: Hugh Thompson

FROM: Peter Crane

SUBJECT: NIH COMMENTS ON EPA'S RECONSIDERATION OF ITS RADIONUCLIDE EMISSION RULE

The attached letter, dated February 9, 1990, was given to me yesterday by a young woman in NIH's Radiation Safety department as a souvenir of the cooperative effort of NRC and NIH to prevent duplicative regulation of medical facilities. (I'm back in NIH, briefly I trust, this time having brought along a laptop.) It was a chance conversation she and I had during my previous stay here, last July, that led to the realization that our two agencies had a common interest in opposing a rule that is not only unnecessary, but actually pernicious.

I think it is a first-rate letter that deserves to be disseminated. It makes the point, very effectively I think, that the central risk issue involved is not the risk to some hypothetical members of the public with a minuscule chance of developing a thyroid problem as a result of emissions from a hospital. Rather, the central risk issue relates to some thousands of real people with a present thyroid problem requiring treatment with radioiodine in the here and now. For the hypothetical people in the former class, the risk is on the order of 1 in 1 million; for the real people in the latter class, the risk is 1 in 1. If those of us in the latter class -- people like Barbara Bush, people like me -- ever have our treatment withheld or greatly burdened out of bureaucratic or Congressional solicitude for those in the former class, it will mean that something has gone terribly wrong somewhere.

I think this letter is also relevant to the potassium iodide DPO that is now in front of you, in this sense: regardless of whether one comes down in favor of stockpiling KI or against it, it should not be, even in part, because of a perception that thyroid problems, if and when they occur, are inconsequential. They aren't. You don't have to take my word for that any more; you can now take NIH's.

Unfortunately, the last word that some members of the public had from NRC on this issue was the public briefing of November 22, 1983. At that briefing, the consequences of a thyroid problem, if radiation were to cause such a problem, were represented as extremely trivial, it is fair to say. The staff told the Commissioners and the public that

"survival was not the issue," that the issue was one of "averting an illness" that might mean "a few days off." I believe that the NRC owes it to the public to correct the record, and that you owe it to the Commissioners to tell them so.

Of the three staff persons who briefed the Commission that day, two have left the agency. The third is, for my money, one of the best and most principled people we have. So who of us bats 1.000? The issue isn't personalities and never was. The issue is being accurate as an agency in what we tell the public. Correction is overdue.

Attachment: Letter, Dr. Joseph E. Rall, NIH to EPA, February 9, 1990

cc: Commissioners
OGC
NMSS
NRR
RES
GPA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
Building
Room
(301) 496-

February 9, 1990

Central Docket Section (A-130)
Environmental Protection Agency
Attn: Docket No. A-79-11
Washington, DC 20460

Dear Sir or Ms:

In accordance with the opportunity to submit comments on the proposed amendment to 40 CFR Part 61, issued March 7, 1989, the National Institutes of Health (NIH) provided comments to the Environmental Protection Agency on May 11, 1989. Those comments were based on a brief review of the available documentation, due to the severely short time constraints imposed by the court order under which EPA was issuing the standards. In addition to NIH's opposition to the standards based on the fact that existing regulations of the Nuclear Regulatory Commission (NRC) and the Agreement States provide an ample margin of safety for the medical and research uses of radioactive materials, we were particularly concerned with the potential effect that the regulation would have on the use of radioactive iodine 131 in the therapy of hyperthyroidism and thyroid cancer. We based this concern on a parametric analysis of the COMPLY code, using individual nuclides and release to receptor scenarios to determine which nuclides contributed substantively to the controlling effective dose equivalent (ede). Our analyses revealed that the radioactive iodines, particularly I-125 and I-131, were the controlling nuclides in the calculation. In addition, it seemed that the risk-based standard setting methodology used by EPA only considered the inherently *negative* factors in the use of the radioactivity, i.e. effect of dose on incidentally exposed populations to airborne releases. No consideration was given of the life-saving and life-prolonging factor of use of the radioactivity in therapy.

I-131 is the most effective treatment for hyperthyroidism, which occurs in about 1.5 percent of the population. Alternative therapies are antithyroid drugs which have toxicity and require long term continuation, and surgical thyroidectomy, which is more costly and more dangerous to the patient in terms of morbidity and mortality. The effectiveness of I-131 in the treatment of thyroid cancer is an additional factor. In the United States there are approximately 10,000 new cases of thyroid cancer per year. After initial surgical removal, ablation with I-131 is used to complete the thyroidectomy in at least half of these patients (i.e. ~5000) in doses ranging from 30 to 150 mCi. Most of these patients then receive one or more test doses of I-131 (2 to 10 mCi) to detect the occurrence of metastases. A conservative estimate of the number of patients who develop metastatic thyroid cancer who could benefit from I-131 therapy is 2000 new cases per year. These patients receive from one to ten treatment doses of 150 to 300 mCi over a period of up to 20 years or more. This treatment is curative in some cases and prolongs disease-free survival in many cases. Alternative treatments for metastatic thyroid cancer are external irradiation, which is less effective than I-131 and can be used only when metastases are localized;

and chemotherapy, which is only partially effective and considerably more toxic than I-131 therapy.

The National Institutes of Health *again requests that the EPA consider an exemption of medical treatment and research facilities from the provisions of 40 CFR Part 61* related to radioactive air emissions through a finding that existing regulatory and voluntary controls provide an ample margin of safety. The NIH believes that imposition of the new EPA NESHAPS on NRC medical and medical research licensees is not only unwarranted but could have a negative effect on the treatment and survival of some patients. It is our position that the current NRC regulatory program insures an adequate margin of safety and that additional regulations constitute a wasteful use of scarce medical resources. To superimpose complicated, resource consuming requirements to prove compliance with unnecessary regulations which could discourage the use of radiopharmaceuticals available to physicians is not in the best interest of the public or the practice of medicine.

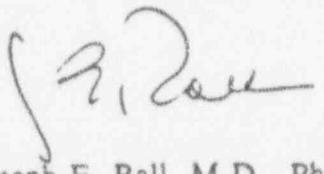
In our original comments NIH expressed the opinion that the implementation of the rule for NRC medical and medical research licensees could have an impact on patients and could result in an increase in mortality for both hyperthroidism and thyroid carcinoma. The NIH was not alone in expressing this opinion; similar concerns were expressed by the Society of Nuclear Medicine and the American College of Nuclear Physicians. While granting a period of reconsideration based on this contention, EPA has *not* indicated in the notice of December 15, 1989 that they have considered or investigated these genuine concerns. We again request that EPA address these concerns as part of the public record and provide any supporting technical basis for the contention that there will be no negative impact on medical care from the implementation of the rule. The relatively low annual maximum possession limit for automatic compliance (i.e. no reporting) for I-131 (6.7 Ci.) may dissuade medical treatment facilities from using that isotope and to resort to use of other, less effective, but otherwise recognized treatment modalities. A small but definable increase in patient deaths could result, completely overshadowing any benefit from the rule. The EPA admits in the Federal Register Notice (54 FR 51654) "In this source category, almost all of the incidence comes from people whose risk level is less than 1×10^{-6}. This means that small reductions in the emissions of a few licensees will have little, if any, effect on the number of health effects, both fatal and non-fatal, in the population." In fact according to EPA's analysis of model facilities, in the hospital sub-category the risk level never exceeded 1×10^{-6} for any of the U.S. Population. Thus, if even a single hyperthyroid or thyroid cancer patient is affected by the implementation of this standard, the benefit/risk balance is negative. It is reasonable for EPA to make a determination similar to that made for the High Level Nuclear Waste Disposal Facilities, namely "Safe With an Ample Margin of Safety" based on the fact that the risk presented by this source sub-category ($< 10^{-6}$) is significantly lower than the 1×10^{-4} benchmark.

EPA has attempted to demonstrate the ease with which a facility which is not exempted from the reporting requirement can show compliance. We agree that the methodology is relatively simple *if, and only if* every facility has access to the required computer, the required data for input to the program, release points may be aggregated, and reasonable assumptions can be made about receptor locations and locations of milk and other food supplies. Our concern is that, while *current intentions* are to ease the burden on the licensee, future implementation will be based on

the letter of the law. Those who will be required to report face the *extensive* requirements of 61.104. EPA has not addressed the cost of the recommended program (Alternative I) despite the fact that medical facilities could be required to spend appreciable sums to prove compliance, report annually and with every facility change, or to needlessly refine and construct complex emissions control systems.

We trust that you will carefully consider these comments in your reconsideration of the rule. If you require clarification or additional information please contact the Radiation Safety Branch at 301-496-5774.

Sincerely,



Joseph E. Rall, M.D., Ph.D.
Deputy Director for Intramural Research
Office of the Director