UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555
October 16, 1989

NOTE TO: Peter Crane

FROM: Hugh L. Thompson, Jr.

SUBJECT: DPO ON STOCKPILING POTASSIUM IODIDE

Attached is provided for your information.

If you have any concern, please let me know.

Hugh L. Thompson, Jr.

Attachment:
Memo dtd 10/13/89
Beckjord to Thompson

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

DEC 14 1989

MEMORANDUM FOR: Hugh L. Thompson, Jr., Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support

FROM: Themis P. Speis
Frank J. Congel
Alan K. Roecklein
Leonard Soffer

SUBJECT: REVIEW OF DIFFERING PROFESSIONAL OPINION (DPO) ON STOCKPILING POTASSIUM IODIDE

The review of the Differing Professional Opinion (DPO) (Enclosure 1) on stockpiling of potassium iodide (KI) has been completed. Under the direction of T. Speis, we met as a review panel with Mr. Crane on July 24 and November 21, 1989. At the first meeting there were broad discussions with Mr. Crane of his concerns. T. Speis' note of August 11, 1989 to you (Enclosure 2) summarized this meeting and also appended Mr. Crane's notes of the meeting. A major point of this DPO, which is directed solely to the merits of stockpiling KI, appears to be that previous staff analyses neither explicitly noted nor adequately treated the fact that a fraction of the thyroid nodules produced as a result of an accidental release of iodine could result in cancers, with a small fraction of these predicted to result in fatalities.

As a result of the first meeting, it was agreed that the panel would try to obtain the most recent information on the dose level needed to ablate the thyroid gland, the cost of thyroid nodule treatment and the cost of KI tablets. This information is summarized in a note from A. Roecklein to T. Speis, dated November 9, 1989 (Enclosure 3). Revised data on the incidence of thyroid cancer was also obtained (Enclosure 4).

The panel also agreed to utilize this information to prepare a simplified cost-benefit analysis directed at examining the merits of stockpiling KI. The panel utilized the insights of NUREG-1150 with regard to the magnitude of severe accident releases, and also specifically added the effects of hypothyroidism (an insufficiency of thyroid hormone production for carrying out normal physiologic function) as a fourth health effect not included in previous staff analyses in addition to considering benign thyroid nodules, cancerous nodules and fatalities. The panel met a second time with Mr. Crane on November 21, 1989 to inform him of the information

9403080330

3PP

obtained and to discuss preliminary results of the cost-benefit analysis.

Although the cost-benefit analysis (Enclosure 5) is a best estimate analysis, it also provides additional calculations to show the sensitivity of the results to the assumptions made. On the basis of this analysis, the panel concludes that stockpiling of potassium iodide clearly is not cost-beneficial, and we recommend that present federal guidance should remain unchanged. While our present emergency planning regulations were never justified on any rigorous cost/benefit analysis, but rather on the basis of prudence, it is also important to note the panel's strong conviction that potassium iodide has a very limited efficacy as a public protective measure, in the event of a reactor accident compared to other available measures. This is due not only to the fact that it is useful for only one organ, one nuclide of interest and one exposure pathway, but also because its efficacy is crucially dependent upon its being available either before or within a few hours after exposure.

The panel also had the benefit of recent information obtained from Soviet sources on thyroid effects of the Chernobyl accident. The high thyroid exposure estimates provided by Soviet authorities, particularly for children, were stated to be primarily a result of ingestion of locally produced milk and dairy products which were contaminated by iodine deposition on grass and pasture areas, rather than from inhalation of iodine. The existence of a diversified nation-wide food distribution system in the U. S. which could readily provide alternative foodstuffs for those which might be contaminated represents a significant difference in this regard. Follow-up studies in this, as well as related areas, are planned as part of the U. S. - U. S. S. R. Joint Coordinating Committee on Nuclear Reactor Safety (JCCCNRS).

In view of the fact that federal policy, as stated in the Federal Register (FR Vol. 50, No. 142, page 30258) leaves the decision to use KI and/or other protective measures to the states and, if

appropriate, local authorities on a site specific basis, the panel recommends that the information developed as a result of pursuing this DPO be transmitted to the states and other interested federal agencies for their information.

Themis P. Speis

Frank J. Congel

Alan K. Roecklein

Leonard Soffer

Enclosures:

1. Memorandum, P. Crane to H. Thompson dated June 16, 1989, NRC Position on Potassium Iodide: Differing Professional Opinion

2. Note, T. Speis to H. Thompson dated August 11, 1989, NRC Position on KI-DPO-Mr. Peter Crane

3. Memorandum, A. Roecklein to T. Speis, dated November 9, 1989

4. Note, S. Yaniv to T. Speis dated December 8, 1989, Risks Associated with Thyroid Irradiation

5. Simplified Cost-Benefit Analysis Regarding Stockpiling of KI

cc: P. Crane
F. Congel
A. Roecklein
L. Soffer

File
JPK

June 16, 1989

MEMORANDUM FOR: Hugh L. Thompson, Jr.
Deputy Executive Director
for Operations

FROM: Peter G. Crane
Counsel for Special Projects

SUBJECT: NRC POSITION ON POTASSIUM IODIDE: DIFFERING PROFESSIONAL OPINION

I. Introduction

The NRC staff has recently obtained Commission approval of two staff documents, NUREG-1355 ("The Status of Recommendations of the President's Commission on the Accident at Three Mile Island") and NUREG-1251 ("Final Report on Chernobyl Implications"). Both documents address, among many other issues, the desirability of stockpiling potassium iodide for thyroid protection after nuclear accidents, and assert that a requirement to stockpile the drug "should not be required" because "it would not be worthwhile." Both documents rely on a 1980 cost-benefit analysis, NUREG-CR-1433, prepared jointly by NRC and DOE's Sandia National Laboratory, and on a 1985 federal policy statement which reflected the influence of NUREG-CR-1433 and cited it.

At least as it was presented to Commission by the NRC staff, NUREG-CR-1433 takes the position that when it comes to thyroid abnormalities resulting from a nuclear accident, society should put its resources into cure rather than prevention. What you have just read is not a typographical error. In urging the Commission to adopt and endorse NUREG-CR-1433 in 1983, the staff argued that it is more cost-effective for society to treat radiation-caused thyroid abnormalities after a nuclear accident than to seek to prevent such abnormalities by stockpiling potassium iodide for administration to the public during a nuclear accident. The staff made this argument very explicitly in a November 22, 1983 briefing. Excerpts from that transcript appear as Appendix A to this memorandum.

I do not pretend to find NUREG-CR-1433 easy to understand; I am not convinced that it is as clear-cut in its cost-benefit conclusions as the staff represented it in the November 1983 briefing. For purposes of this Differing Professional Opinion, however, I am proceeding on the assumption that NUREG-CR-1433 is as it was described to the Commission in November 1983. However, even if it is not as flawed as the staff briefing might suggest, I believe that its analysis does not provide an adequate basis for reasoned decisionmaking on health and safety issues.

My reasons are as follows. Based on personal knowledge in this area, I believe that the information provided to the Commission in 1983 by the staff was erroneous in major respects. In a nutshell, both the risk of fatality from radiation-caused thyroid cancer and the adverse consequences for individuals of non-fatal thyroid abnormalities are vastly greater than the Commission was led to believe. Given that a stockpile of potassium iodide sufficient for the entire U.S. population could be purchased for less than the Government paid for the office building we work in, I think it is inappropriate for the NRC staff to be advising states and localities that the stockpiling of potassium iodide is not cost-effective.

I feel obligated to bring these facts to your attention so that appropriate corrective action can be taken. As NRC Manual Chapter 4125 states: "It is not only the right but the duty of all NRC employees to make known their best professional judgments on any matter relating to the mission of the agency." Differing professional opinions, according to the definition in Chapter 4125-041, "are not limited to the originator's area of expertise." In this case, the subject matter has nothing to do with law, which is my official area of expertise. I have discussed the matter with the General Counsel, who suggested that because it involves a technical matter under your jurisdiction, I direct my concerns to you.

I should add that I did not wait for the Commission to act on the papers before making my concerns known. As will be discussed below, I was the author in 1984 of a memorandum, signed by the then General Counsel, which pointed out a crucial flaw in the cost-benefit analysis. (SECY-84-161.) Although the then Executive Director for Operations acknowledged that flaw, in an April 30, 1984 intra-agency memorandum to the Commission, the staff never changed NUREG-CR-1433 accordingly. In March of this year, when I became aware that in two papers pending before the Commission, the staff was yet again preparing to endorse NUREG-CR-1433 publicly, I expressed my concerns to, among others, relevant staff members involved in the preparation of the papers, and, in a memorandum, to my immediate supervisor.

II. Background

At the risk of covering familiar ground, let me offer some factual background. The thyroid gland has two characteristics that make it of special interest to NRC. First, it is highly radiosensitive, especially in infancy and childhood. For some reason, girls are more sensitive than boys. Second, it is, as the doctors say, "avid" for iodine in all its forms. Thus releases of radioiodines after a major nuclear accident raise a danger that the

thyroids of exposed persons will soak up the radioiodine and later develop radiation-caused abnormalities. Fortunately, such abnormalities are comparatively rarely fatal.

The same avidity for iodine that puts thyroids at risk after a nuclear accident makes it possible to protect them effectively, if protective measures are taken in time. The thyroid has a limited capacity to hold iodine; once it is saturated, no more can be absorbed. Thus if there is a known risk of exposure to released radioiodine, it is a simple and inexpensive matter to administer iodine in a harmless form -- such as a pill of potassium iodide -- and thereby preclude subsequent uptake of harmful iodines. Laboratory workers using radioisotopes of iodine routinely take potassium iodide as a preventive measure. The NRC and FEMA recommend (in NUREG-0655/FEMA-REP-1) that licensees and State and local authorities keep stocks of potassium iodide on hand for use in the event of a nuclear accident -- but only for use by plant workers and institutionalized persons. With regard to the general public, the NRC's position is as indicated above.

The Kemeny Commission recommended in November 1979 that potassium iodide be stockpiled on a regional basis. As late as September 1980, in SECY-80-275A, the NRC staff itself was proposing that FEMA be asked to conduct "a study of the feasibility of establishing a single national stockpile and developing a distribution plan and system including estimates of times to transport and distribute the KI to the general public within various regions of the country." SECY-80-275A estimated the cost of purchasing stockpiles of potassium iodide at $.10 per person per year. (I have elsewhere seen even lower estimates.)

III. The Staff's Position Changes -- SECY-83-362

On August 30, 1983, in SECY-83-362 ("Emergency Planning - Predistribution/Stockpiling of Potassium Iodide for the General Public"), the Executive Director for Operations, Mr. Dircks, advised the Commission that "a cost/benefit uncertainty analysis performed by the staff conclusively shows that potassium iodide offers extremely small benefit in relation to its costs and is <u>not</u> cost effective as a preplanned emergency protective measure for the general public." The staff proposed that the NRC take this position in working with other federal agencies of the Federal Radiological Preparedness Coordinating Committee on the development of a coordinated federal policy statement on the stockpiling or predistribution of potassium iodide.

SECY-83-362 had several attachments. They included the following:

1) A report, "Radiation Protection: An Analysis of Thyroid Blocking," IAEA-CN-39/102, presented to an International Atomic Energy Agency conference in October 1980, by David C. Aldrich of Sandia National Laboratories and Roger M. Blond of the NRC staff. In the background section, that report explained:

> "The risk to the thyroid of exposed individuals posed by potential accidents is especially great for several reasons:
>
> -- Radioactive isotopes of iodine are produced in abundance by the fission process.
>
> -- Iodine and iodine compounds are normally quite volatile. Therefore, a sizeable fraction of core radioiodine inventories could be available for release to the atmosphere.
>
> -- Inhaled or ingested radioiodines are quickly absorbed into the bloodstream and concentrate preferentially in the thyroid.
>
> -- Iodines are eliminated from the thyroid with a relatively long biological half-life.
>
> As a result, the radiation dose to the thyroid is likely to far exceed the dose to the rest of the body, and thyroid damage is likely to affect more individuals than any other accident-induced health effect."

The report went on to discuss the pros and cons of using potassium iodide for thyroid blocking. It explained that radiation-caused thyroid nodules typically appear 10 to 40 years after exposure and may be benign or cancerous. It observed: "Most thyroid cancers are well differentiated, slow growing, and relatively amenable to therapy." The report noted that WASH-1400 (the 1975 Reactor Safety Study) assumed that 40% of accident-caused nodules would be cancerous, and that of these cancers, 10% would be fatal.

The report to the IAEA observed that in the event of an accident in the Core Melt Atmospheric category, "the thyroid dose levels of concern are likely to be exceeded at very large distances from the reactor (and correspondingly over very large areas if this type of accident were to occur." The report recognized that substantial uncertainties were involved in the underlying assumptions. Nevertheless based on the three factors it deemed relevant -- cost, degree of reduction of accident impacts by the use of potassium iodide, and accident probabilities -- it reached the following conclusion:

> "To some extent, the large uncertainties in the above

assumptions hinder our ability to provide definitive guidance. Nevertheless, for the assumptions made, the calculated cost-benefit rations are high; and even including uncertainties, KI appears only marginally cost-effective, at best."

2. "Examination of the Use of Potassium Iodide (KI) as an Emergency Protective Measure for Nuclear Reactor Accidents," NUREG-CR-1433, prepared by Sandia Laboratories and, like the IAEA report, written by David C. Aldrich and Roger M. Blond of the NRC staff.

This report, longer and more detailed than the IAEA report, reached the same result. Its "Summary, Conclusions and Recommendations" section includes verbatim the paragraph just quoted from the IAEA report.

3. "ACRS Subcommittee Report on the Use of Potassium Iodide (KI) as a Thyroid Blocking Agent," May 17, 1983.

The ACRS subcommittee report made three comments on the NRC staff's proposed approach to the use of potassium iodide:

a. If the staff was correct in believing that the greatest risk of accident-caused fatalities came from whole body exposures rather than thyroid exposures, then the desirability of KI was questionable, and this issue should therefore be reevaluated.

b. Cost-benefit analyses to decide on the usefulness of potassium iodide "do not appear to be compatible with (or comparable to) approaches used in evaluating other aspects of nuclear emergency planning. For example, if the same evaluations were made, would there be justification for the conduct of emergency drills or the installation of warning sirens?"

c. The NRC should work with FEMA to develop guidance for state and local agencies on whether to use KI; should leave the decision to judgment of state and local authorities; and should not make stockpiling or predistribution of KI a licensing requirement.

The ACRS subcommittee report attached comments by Dr. Eugene L. Saenger of the University of Cincinnati Medical Center, writing on behalf of the National Council on Radiation Protection. He observed, among other things, that based on the information available to him, only 1.5 percent of the U.S. population lived within 10 miles of a nuclear reactor. Thus, he suggested, the NRC staff was overestimating the amount of potassium iodide that might need to be purchased, and this was incorrectly affecting the cost-benefit balance. He also commented: "In a period when

there are enormous investments in nuclear power plants many of which are not completed for various reasons and great concern by citizens concerning safety, it does not seem useful to engage in debates concerning the protection of the thyroid gland between agencies of the Government."

4. "Recommendations on the Use of Potassium Iodide as a Thyroid-Blocking Agent in Radiation Accidents: An FDA Update," by Dr. Bernard Schleien and four co-authors.

This report noted that in 1978, the Food and Drug Administration had issued a Federal Register notice stating "that potassium iodide is safe and effective for use as a thyroid-blocking agent in a radiation emergency in which radioiodines are accidently released into the environment." In this report, the authors reviewed the extensive debate on the subject, including the argument that there might be harmful side effects from using potassium iodide, and stated FDA's conclusion:

> "The paucity of human data relevant to the induction of radiation effects from iodine-131, particularly in children, has convinced the FDA that it is prudent to employ risk estimates from external irradiation studies in reaching the conclusions upon which its recommendations are based. From this evidence, the FDA concluded that the risks of radio-iodine induced thyroid nodules or cancer at a projected radiation dose of 25 rem or greater to the thyroid gland from radioiodines released into the environment outweigh the risks from the short-term use of relatively low doses of potassium iodide for thyroid blocking in a radiation emergency. The FDA recommends that potassium iodide in doses of 130 mg per day for adults and children 1 year and above, and 65 mg per day for children below 1 year of age, be considered in those persons likely to receive a projected radiation dose of 25 rem or greater to the thyroid gland from radioiodines released to the environment."

The FDA noted that the American Thyroid Association had earlier commented, before certain animal studies were available, that at a threshold of 50 rads, potassium iodide should be given "to provide an added measure of protection for children and pregnant women." The FDA commented that "given that the most sensitive segments of the population should be protected the opinion of the American Thyroid Association and the conclusions of the FDA are not very far apart."

IV. The Staff Briefs the Commission on Potassium Iodide

On November 22, 1983, the Executive Director for Operations, accompanied by the co-author of NUREG-CR-1433

and another staff member, briefed the Commission on the document. Pertinent excerpts from the discussion appear in Appendix A to this memorandum. I hope I have done a fair job of representing the discussion, and capturing its flavor; I would have attached the entire transcript, but it is 82 pages long. I'll be glad to make you a copy if you would like it, however.

For simplicity's sake, let me try to summarize some of the major points of the staff's presentation (not necessarily in the same order as the staff) and offer my comments on each point. If the arguments you see made by the staff appear in places inconsistent with the IAEA report summarized earlier, I can only urge you to read the transcript and assure yourself that I am not mischaracterizing the discussion.

1. "The surviving question is not the question, and that's the piece that really should also be emphasized." Rather, the question is whether you "avert an illness."

Comment: The IAEA report and NUREG-CR-1433 itself assume, based on the Reactor Safety Study, that 40% of accident-caused nodules will be malignant, and that 10% of those malignancies will be fatal. Thus for 1 in 25 accident-caused nodules, survival <u>is</u> the issue.

2. If a person does develop a thyroid nodule as the result of an accident, $20,000 represents "the upper end of the scale" in terms of the cost of medical treatment and the loss of productivity: "There's a few days' loss from -- it's a relatively simple operation that's involved in removing the thyroid or removing the nodules --"

Comment: I once quoted that sentence to a doctor at NIH who is himself a thyroid cancer patient. He looked at me in incredulity and exclaimed, "They ought to have one!" In reality, radiation-caused thyroid abnormalities -- and recall that 40% of these nodules will be cancerous -- mean a lifetime of being followed up medically and of taking medication every day. In preparation for scanning, which may take place as often as every six months, the patient is taken off normal medication, so that the pituitary will produce thyroid stimulator hormone and any thyroid cells in the body will take up radioiodine when it is administered in a diagnostic dose. The withdrawal of the normal medication produces exhaustion, weakness, and extreme sensitivity to cold. It means going on sick leave. Radioiodine treatments for inpatients mean being placed in complete isolation for two to four days, with paper covering the floor to protect the hospital from the patient's radioactive footprints. Even at lower, outpatient doses, it means becoming a radioactive source and having to stay away from loved ones and even pets. (You may recall that when the First Lady

recently had a radioiodine treatment as an outpatient, she was told not to handle her dog's puppies for a few days.) For persons of childbearing years, it means, to be prudent, postponing conception for six months to two years. And though statistics on thyroid cancer are good, patients and their families are human and they worry.

From the economic standpoint, radiation-caused thyroid problems can quickly run up costs considerably above $20,000 in medical bills and time lost from work. From an environmental standpoint, diagnostic and therapeutic doses of radioiodine, eliminated through the kidneys, wind up in sewage systems. An NRC staff member who used to work for a state health department once told me that they always knew when someone was being treated locally for thyroid cancer because of the spike of radioactivity at the sewage treatment plant.

3. There are so few nodules likely to result from a nuclear accident that the actual cost of preventing a nodule is on the order of $10,000,000.

Comment: I am frankly not conversant with the latest estimates either on the source term or on accident probabilities, but if we assume $.10 per person per year cost for KI, you can protect the entire population of the United States for something like $25,000,000. For it to cost $10,000,000 to prevent a thyroid nodule must mean either extraordinarily low accident probabilities or extraordinarily minuscule releases if there is an accident. If that is the case, why -- as the ACRS asked in 1983 -- have emergency planning at all? I think that these statistics ought to be checked carefully by persons with expertise in this area.

4. Recommending in favor of potassium iodide stockpiling would mean "sponsoring an industry (the manufacture of potassium iodide) that may have a very low cost payoff in societal needs."

Comment: The NRC should make its decisions based on what the public health and safety requires, not on who will or will not make money as a result.

5. Potassium iodide may seem to be an inexpensive way to protect the public, but in reality it is like an inexpensive accident insurance policy for which, when you read the fine print, "there has to [be] a stampeding elephant that kills you."

Comment: The American Cancer Society estimates that there will be 11,300 new cases of thyroid cancer in 1989, and 1025 fatalities.

Toward the end of the briefing, Chairman Palladino alluded to the fact that the staff had earlier favored the use of potassium iodide. The Executive Director for Operations acknowledged that, commenting that in the rush to respond to the Three Mile Island accident, certain positions had been taken "quickly because it [the NRC] was under a good deal of pressure to move quickly." To go back and question those positions, he said, "takes a much more rational and sometimes courageous attitude."

The transcript shows Chairman Palladino expressing considerable reservations about the staff's cost-benefit analysis. At the direction of Chairman Palladino and the Commissioners, the staff agreed to prepare a letter to the Federal Emergency Management Agency that would "support the policy statement" on potassium iodide then being circulated in draft among the agencies of the interagency working group, while also offering the staff's view that use of the drug was not worthwhile.

V. Subsequent Developments

I will review subsequent developments only very summarily. At some point after the briefing, I had a discussion with one of the staff briefers in which he acknowledged, after checking, that the figure of $20,000 for costs associated with a thyroid nodule referred not to all nodules (including the 4% which will prove fatal), but only to those which will not prove fatal. Subsequently, arrangements were made -- I no longer remember by whom -- for me to meet with staff members involved with the potassium iodide issue, to address my questions. At that briefing, two more arguments against the use of potassium iodide were offered: that in the event of an accident, it would be necessary to follow exposed persons anyway [i.e., so there would be no cost savings to the Government in assuring that they were healthy rather than diseased], and that potassium iodide, while a good idea from a technical standpoint, might be used as an issue to hold up operating licenses. These views may well have reflected no more than the personal opinions of the individuals who offered them.

On January 20, 1984, the staff sent the Commission SECY-83-362A, "Use of Potassium Iodide for Thyroid Blocking." It included a draft letter to FEMA that urged that the interagency working group be "reconvened" to "develop a new policy statement" reflecting the staff's cost-benefit evaluation of potassium iodide. The Office of the General Counsel answered this on April 17, 1984 with a memorandum, written by me, which urged a more neutral approach, and which expressed "serious doubts about the validty of the staff's cost-benefit analysis," citing the staff's acknowledgment that the $20,000 figure represented the benefit associated with averting "only those nodules

which will not prove fatal." The Executive Director for Operations responded on April 30, 1984 with a memorandum, "Supplementary Information on Potassium Iodide for Thyroid Blocking," which took issue with the OGC paper. It asserted that fatal nodules had been "implicitly considered," and it said:

> "The analysis is sufficiently transparent that one could add explicit consideration of the latent cancer fatality component. For example, even taking the upper value of $1,000,000 per latent cancer fatality and a higher mortality rate of ten percent latent cancer fatalities per thyroid nodule would inject a cost component of $100,000 to the $20,000 used in the staff analysis, a five fold increase. This would still not change the staff conclusion that KI is not cost beneficial, since the lowest value at which KI use would be cost beneficial was determined in SECT-83-362 to be about $300,000 per thyroid nodule averted. In summary, the staff conclusion does not rest on whether $20,000 per thyroid nodule averted is an absolutely accurate value, but rather that it is significantly lower than the value at which use of KI does become cost beneficial."

In the end, resolution of the dispute between the staff and the Office of the General Counsel was deferred because of the imminence of a new draft of the policy statement.

On July 24, 1985, the Federal Government published its polciy statement on the use of potassium iodide. 50 Federal Register 30258. It provides:

> "While valid arguments may be made for the use of KI, the preponderance of information indicates that a nationwide requirement for the predistribution or stockpiling for use by the general public would not be worthwhile. This is based on the ability to evacuate the general population and the cost effectiveness of a nationwide program which has been analyzed by the NRC and DOE National Laboratories (NUREG/CR-1433). While the use of KI can clearly provide additional protection in certain circumstances, the assessment of the effectiveness of KI and other protective actions and their implementation problems indicates that the decision to use KI (and/or other protective actions) should be made by the states and, if appropriate, local authorities on a site specific basis."

In April 1986, the catastrophic accident at Chernobyl led to the first use of potassium iodide on a mass scale. According to one set of figures I have seen, 5,000,000 Russians and 6,000,000 Poles received potassium iodide. The NRC staff's report on the implications of Chernobyl,

NUREG-1241, reports that the Poles credit use of the drug with having "reduced the potential thyroid dose to children by factors of 6 to 10." The Soviets, according to the same report, said that at one relocation center, use of potassium iodide kept thyroid exposures within permissible limits for 97% of evacuees. The Soviets also reported "no serious adverse reactions from the use of KI," according to the staff.

The Chernobyl experience did not alter the NRC staff's view of the issue. It explained that, under the 1985 federal policy statement, the effectiveness of KI was acknowledged for emergency workers or institutionalized individuals, who may be exposed to the release for an extended period. For the general public, however, "these conditions generally are not applicable, because evacuation is generally feasible and, when carried out, is more effective in dose reduction than administration of KI, since it can reduce the dose for all body organs and not merely the thyroid gland." The staff report did not discuss the possible desirability of having the capacity, in the event of an accident, both to evacuate the affected public and to administer potassium iodide to evacuees.

The staff therefore concluded:

> "The apparently successful use of potassium iodide by the Soviets does not alter the validity of U.S. Government policy that predistributing or stockpiling potassium iodide for use by the general public should not be required. Rather, this decision should be made by individual States and by local authorities."

VI. Statement of Personal Interest

I feel that I ought to state, for the purpose of letting the reader know what biases I may bring to the issue, my own personal interest in it. In 1973, I had a partial thyroidectomy, for a malignancy resulting from x-ray treatment of enlarged tonsils and adenoids when I was two. In more recent years, I have had several radioiodine treatments at NIH, designed to ablate (burn out) any thyroid tissue in my neck. Since there is no way to know for sure whether such tissue is benign or not, the doctors proceed conservatively. In my case, statistics are very much on my side, and I have only to look around at the medical troubles that life has brought to some of my co-workers or their family members to realize how lightly, at least so far, I have gotten off.

But I'd be lying if I said that years of scans, treatments, periodic removal from medication with resulting exhaustion, or the accompanying anxieties, have been completely inconsequential in their effect on the quality of

life for my wife and me, at least from time to time. That certainly affects the intensity with which I feel that NUREG-CR-1433 is off base in recommending that society put its resources into treatment rather than prevention of thyroid abnormalities. I feel very strongly -- there is no point in pretending otherwise -- that if a dime's worth of medication sitting on the shelf of an evacuation center could someday prevent another family from having a similar experience, it would be a dime well spent.

I do not believe, however, that this strength of feeling on a personal level has interfered with my professional objectivity in evaluating the factual flaws in the staff's position. 1/ As noted above, the staff itself admitted in 1984 that the $20,000 cost-benefit figure for averting a thyroid nodule excluded those nodules which will prove fatal, and was thus inaccurate by a factor of five. That admission alone, in my view, is sufficient to warrant the withdrawal of NUREG-CR-1433. I might add that anyone who knows me or my work on behalf of this agency over the past 14+ years knows that I am not phobic either about nuclear power or radiation. 2/

VI. Conclusion.

Potassium iodide is not a panacea against radiation. It protects just a single gland -- albeit a highly radiosensitive gland. The NRC staff is correct in saying, in its discussion of the implications of Chernobyl, that evacuation is generally preferable to potassium iodide as a protective measure in a radiological emergency. <u>But there is no reason to have to choose between the two.</u> The real issue is whether in an emergency one wants to have the capability both to evacuate the public <u>and</u> administer potassium iodide to evacuees and others. If there are no stockpiles of potassium iodide in evacuation centers, emergency operations facilities, and the like, that option will not be available. As a society, we could have the potassium iodide option, and the additional protection it might afford, for a sum that is a drop in the bucket compared to the cost of other emergency preparedness measures we require. If an accident occurred today in Britain, a stockpile of thyroid-protecting drugs would be on hand, because Britain requires it. (The British use iodine in the iodate rather than the iodide form, but the principle is the same.) In this country, such drugs might well not be on hand, because the Federal Government, relying on the NRC's cost-benefit analysis, has been advising states and localities that to require the stockpiling of potassium iodide "would not be worthwhile."

There is not a person in the NRC who is not fully committed to seeing that our country never experiences another TMI or, what is worse, a Chernobyl. We all agree on

that; it is the goal toward which all of us are working. We all hope that the emergency requiring special protective measures never comes. But the premise from which we start is that a serious accident might happen, and that adequate protective measures have to be in place just in case. If there is ever such an accident in this country, no one should have grounds to say that the Russians and the Poles took better care of their children after Chernobyl than we took of ours, or that Americans failed to get adequate protection because the NRC had disseminated erroneous information. I believe that the NRC should promptly withdraw NUREG-CR-1433; advise states, localities, other federal agencies, and the public of the flaws and omissions in its analysis; and take affirmative steps to ensure that potassium iodide is stockpiled for possible emergencies.

cc: Chairman Zech
Commissioner Roberts
Commissioner Carr
Commissioner Rogers
Commissioner Curtiss
William C. Parler
Martin G. Malsch
The Director, NMSS

1/ For what it is worth, I did not become interested in the potassium iodide issue because I was a patient at NIH, but just the other way around. At the time I went to the November 1983 briefing, I believed my own thyroid problems to be far in the past. Because the statements I heard at the briefing seemed inconsistent with what I remembered from my own days as a thyroid patient, I called NIH seeking up-to-date information. The NIH doctors were most helpful in providing such information. They also told me, to my surprise, that my own medical history suggested that followup evaluation was appropriate. As a result, I became a patient there, and now know considerably more about the consequences of radiation-caused thyroid abnormalities than I did when I first wrote memos on the subject in 1984.

2/ It is perhaps ironic that in 1980 I was (I believe) alone in the General Counsel's office in asserting that irrational fear of radiation was not an environmental impact cognizable under the National Environmental Policy Act. (I believed then, as I believe now, that regulatory decisions affecting public health and safety should be made on the basis of sound technical information, honestly and professionally evaluated, without the intrusion of extraneous considerations.) As a result, when the Commission's 2-2 split on the issue had the effect of

excluding psychological impacts from the TMI restart proceeding, and the D.C. Circuit ruled against us in PANE v. NRC (a case I argued), I was made Acting General Counsel for a day to visit the Solicitor General and urge him to seek certiorari, along lines most favorable to the NRC. The Solicitor General took the case to the Supreme Court, where we won unanimously.

APPENDIX A

Excerpts from the NRC Staff Briefing to the Commission on NUREG-CR-1433

Mr. Blond (co-author of NUREG-CR-1433): At the bottom of this figure [a slide was on the screen] you see a dashed line at about the $20,000 figure, and that represents what we feel the cost-benefit breakpoint would be. If the cost of averting one nodule is on the order of $20,000, that's the cost that will be represented by the medical treatment and the loss of productivity of an individual if he had a thyroid nodule. And it's on the upper end of the values which we have seen. There's a few days' loss from -- it's a relatively simple operation that's involved in removing the thyroid or removing the nodules --

. . .

The whole point of the analysis focuses to this [$20,000] figure in some sense. When we look at this we feel we've done the analysis ... with a bias in favor of potassium iodide if anything. ... And our analysis still comes down and shows that ... this is not a viable measure to be taken, it is not something that we should consider in terms of our policy.

As far as we're concerned, the message couldn't be any clearer. Unfortunately, when we perform similar analyses or

I think when we've seen other analyses, we never get quite this clear a message that we're getting here, and that's the important point that from our perspective has to be driven home. We have taken every factor that we can think of into account; it's not just single arguments that we throw at each other; we have factored in all the uncertainties that we can think about, and this is where we come down to it, and the message is clear.

Chairman Palladino: But it sounds crass. It doesn't satisfy me as an individual.

Commissioner Asselstine: I must say I share that view.

Chairman Palladino: Something just does not sit with me right.

Mr. Blond: Let's move on to the next slide --

(Laughter.)

. . .

Mr. Dircks (Executive Director for Operations): Let me just add a point. This is not just a question of your mandating potassium iodide or outlining potassium iodide. I think the question is we have to go back to that policy

statement [interagency policy statement on potassium iodide, then being developed] -- and I guess you're coming to that point. Do you stand neutral and not bring these factors to the attention of the other federal agencies and to the state and local governments, or do you endorse it, or do you just stand aside and say it's not my business?

I think the fact is that because these other agencies do look to the Nuclear Regulatory Commission, we have data here that probably would be useful to factor into the decision, not only the federal agencies but the state and local agencies, the question is do we make this analysis available, do we make these conclusions available, or do we not.

Chairman Palladino: Yes. I'm not ready to even address that because I don't understand in the cost analysis -- for example, you say it costs -- what were your dollars? $10 million per nodule averted, and you said boy, that's pretty high. But then you tell me it's a low cost operation.

So now to me, for example, as an individual, what would it cost me for my pill? Twenty cents. So now, that sounds like a very low cost, and if I got the probability or possibility of averting a nodule -- . I don't understand my 20 cents versus $10 million.

Mr. Blond: You have to consider now what is the likelihood of your exceeding that 25 rem requirement that is the recommendation for you to take that pill.

. . .

Chairman Palladino: You're saying that there's so few nodules you're going to get out of an accident --

. . .

Commissioner Bernthal: It's 20 cents per person to cover you, but so few nodules -- the probability of anybody getting a nodule is so small that it turns out to be $10 million.

Chairman Palladino: Yes, but that's from one perspective. As an individual I say boy, that's among the lowest-cost protection ...

Mr. Dircks: ... You may be sponsoring an industry [manufacturers of potassium iodide] that may have a very low cost payoff in societal needs. I mean, --

Mr. Blond: What we're indicating is from our perspective, the government should not sponsor that because we do not see the benefit in terms of its cost.

. . .

Chairman Palladino: I guess I was taking a more personal view of cost-benefit. 20 cents or some nominal amount of money every year or every five years to replace them seems like small change compared to the risk, from my perception.

Commissioner Bernthal. For the individual. But that's not the statistical argument; that's the sort of gut argument that an individual might make to himself.

Mr. Bernero (NRC staff): Mr. Chairman, there's a large industry in the United States selling cost-ineffective insurance policies to people but you will subscribe to a newspaper and you get $25,000 worth of accident insurance with enough clauses in it to certify that there has to [be] a stampeding elephant that kills you.

. . .

Chairman Palladino: ... [Y]ou said something that bothers me a little bit. You said that we were paying a low cost for something that wasn't worthwhile. You related it to a worthless insurance policy.

But as an individual, I may say the potential benefit is that I might survive a nuclear accident at that plant, which I live near.

Commissioner Asselstine: Or that you may not have to go through an operation --

Mr. Blond: Except that -- the surviving question is not the question, and that's the piece that really should also be emphasized.

Chairman Palladino: All right, survive in the terms of I avert --

Mr. Bernero: An illness. I will avert an illness which I might incur. But my father's argument in buying his insurance policies was the very same. He might leave my mother $10,000 from an accident insurance policy.

There was a residual chance that he would be killed by that stampeding elephant. It was not a well thought-out choice.

Chairman Palladino: Let's not carry analogies too far because then I start thinking of the analogy and don't think of the subject I'm supposed to be thinking about.

I agree, I'm paying low cost for averting a very improbable circumstance. I won't argue that. But it is a low cost.

Mr. Bernero: Yes.

Mr. Dircks: But that's again, an individual decision.

Chairman Palladino: I agree, and both sides of the picture must be examined because when you say they're high cost, I tend to think the risk of low cost -- and incidentally, I'm not pushing either side. I have intuitive feelings on this potential thing, but I'd like to understand your position.

[Later, the discussion turns to the question of what position the NRC should take in the interagency group developing a coordinated federal policy statement on the use of potassium iodide.]

Mr. Blond: What it really comes down to is the issue is, as Mr. Dircks indicated, from our perspective, we have two options. We can take a neutral position and indicate

that we, -- the state and locals should make their decision. Here is a body of information along with other bodies of information which might be taken into consideration. And from our point of view, that's a neutral position the Commission could take.

Or we could, if you so desire, take a stronger position and say from our perspective, we do not feel that federal or state or local governments should sponsor such programs, that it is not in the benefit of the public for the government establishments to sponsor such programs as potassium iodide.

On an individual basis [i.e., individuals purchasing their own potassium iodide over the counter for possible emergency use] that's another question, and I don't think we need take a position. If somebody wants to wear that amulet and have that available to them, that's their business, and that's where we'd stand on it.

Chairman Palladino: What does the staff recommend? I re-read the recommendation; I still would like to know what they recommend. I can read it. "Staff will proceed to recommend to the Federal Radiological Preparedness Coordinating Committee that federal policy in this area should be against requiring the planned stockpile or predistribution of KI [potassium iodide] for the general public."

Mr. Bernero: Or the staff offers the alternative, in the most recent memorandum, of taking a more neutral policy. Basically, the current draft policy statement is neutral itself, but that neutral policy statement would be accompanied by clear advice of the NRC providing its technical advice to competent local and state authorities that this material is not worthwhile for predistribution, general public use.

[Chairman Palladino tries several more times to get a clear picture of what the staff is asking the Commission to approve.]

* * *

Chairman Palladino: Bill [Dircks], could I ask you, suppose we went along with your proposal in your letter or the proposal in your report. How would we implement it; by writing a letter to --

Mr. Dircks: I think we would write a letter to FEMA outlining the basic conclusions reached in this analysis, transmitting the analysis along with it, and meeting with them to present this data.

Chairman Palladino: All right. I gather also that you would not interfere with the states going ahead and doing what they want.

Mr. Dircks: State and local, that's right.

Chairman Palladino: So you would support the policy statement but you would make available a statement that the protective measure is not cost-effective or not worthwhile.

Mr. Dircks: Yes.

. . .

Commissioner Asselstine: I have a question that I just thought of. Why did the other agencies [e.g. FDA] believe that it's a good idea to predistribute potassium iodide, and why did the state of Tennessee decide that they wanted to do that?

Chairman Palladino: Incidentally, we were among the other agencies that --

[Chairman Palladino is apparently referring to the fact that in 1980, after the Three Mile Island accident, the NRC

staff proposed that creation of a national stockpile of potassium iodide be studied. SECY-80-257A.]

Commissioner Asselstine: Originally that's right but I gather that view still prevails --

Mr. Bernero: I think you're touching on -- one of the great difficulties in a matter such as this, being on the side of potassium iodide is somewhat like being on the side of the angels.

(Laughter.)

The FDA has found it is not harmful for its potential benefit, and there is a large body of opinion, at least subconsciously, that we must recognize that coming out in favor of potassium iodide predistribution has the force of reminding people of nuclear reactor accidents and how dangerous nuclear reactors are, whereas coming out in favor of -- or rather against potassium iodide implies that the accident risks are low and you don't need such special precautions.

I think when you look at the thing, this colors people's decisions, that you don't want to get into that kind of argument. You just want to look at the thing and say is it worth doing, it it a worthwhile thing. And if you take the single element of a threat to an organ and you simplify the decision as much as possible, it appears to be, on a personal

basis, an excellent thing to do. An inexpensive tablet that -- like my father's insurance policy -- it's only a quarter a week, it's only 20 cents a tablet, and it's self-evidently good. It protects the thyroid under those circumstances. And I think approaching the decision from that point of view leads you to favor potassium iodide. It is quite inexpensive.

Mr. Dircks: But I think, going back to your other question about why the analysis that went into the -- say the rush of regulations after TMI in the emergency planning area, I think looking back on that experience, there wasn't that much analysis and weighing of alternatives and looking at options.

I think the agency moved quickly because it was under a good deal of pressure to move quickly, and there were very few people in the agency who were against going all out in the area of emergency planning. And I think we're seeing some of the effects of that rushed regulation right now, as we try to go back and question why we did certain things in that timeframe, and what should we be doing differently now. It takes a much more rational and sometimes courageous attitude to go back and question the network of emergency planning regulations, as well as some of the other regulations.

July 25, 1989

MEMORANDUM FOR: Themis Speis
Len Soffer
Frank Congel
Alan Roecklein

FROM: Peter Crane

SUBJECT: MEETING OF JULY 24, 1989

I appreciated the opportunity to meet with you and discuss the issues involved in my differing professional opinion on the stockpiling of potassium iodide. For the sake of clarity, I thought it might be useful for me to summarize my views in the aftermath of that meeting.

1. The assumptions as to the likelihood of an accident such as to cause a thyroid nodule need reexamination. As described by the staff in 1983, the figure of $10,000,000 cost per thyroid nodule prevented seems to say that accidents would result in no more than two and a half thyroid nodules per year. (The preliminary calculation circulated by Len Soffer at the meeting already indicates that this figure is low.)

2. The Commission, in its briefing of November 22, 1983, was not given to understand that approximately four percent of the nodules resulting from an accident will prove fatal. Such fatalities may be delayed in their onset, and thyroid cancer is generally slow in its progress, but they are fatalities nonetheless. (The slowness of an illness is not always a recommendation. I'm told that one of my kindergarten classmates, given X-ray treatment for tonsils or adenoids at about the same time I was, has had four operations for metastatic thyroid cancer that has spread to his head.) The Commission and the public should be aware of what the stakes are, not misled with facetious comparisons to events which do not take place in the United States, such as elephant stampedes.

3. Even non-fatal cancers are well worth preventing, if prevention is practicable. Thyroid cancer involves a lot more unpleasantness than the "few days' loss" that the staff described to the Commission in the November 1983 briefing. I'm not asking that the staff elaborate on the hardship to children of worrying about a parent who disappears to the hospital periodically, but if the staff does a fair job of representing what thyroid cancer involves for the patient -- the periodic scans, the exhaustion that results from the withdrawal of thyroid hormone, the amount of time lost from work, the need to be placed in isolation for treatment as an inpatient, the amount of radiation received from therapeutic

3pp.

and diagnostic doses, the need to avoid one's family when there are still levels of radioiodine in the body -- then the reader can use his or her own imagination and values to take account of these non-monetary impacts on the family.

4. In its assessment of dollar costs of radiation-caused nodules (including the 40% of nodules which will prove malignant), the staff's figure of $20,000 is extremely and unreasonably low, when one figures in the time lost from work for periodic scans, the cost of scans, and the cost of treatment, not to mention the environmental cost of radioiodine dumped into sewage systems. (As discussed further in item 9 below, the staff acknowledged in 1984 that the $20,000 figure for "a nodule" was low by a factor of 5.) Because I am a patient at NIH and do not pay for my medical treatment, I cannot offer an estimate of the full costs involved, but the American Thyroid Association or such experts as Dr. Jacob Robbins of NIH might be able to offer an estimate.

5. I believe that the staff's estimates of the likelihood that thyroids will be ablated in an accident (and thus rendered at no risk from nodules or cancer) are wishful thinking in the extreme. First of all, it takes a lot of iodine to ablate a thyroid, as I know from personal experience of receiving ablating doses. Secondly, even those persons whose thyroids were theoretically ablated by the iodine received in an accident would need medical followup on a regular basis.

6. I see innumerable problems with predistribution of potassium iodide. This differing professional opinion is directed solely to the merits of stockpiling.

7. Even if the outcome of the staff's analysis is that the use of potassium iodide is not justifiable on a cost-benefit basis, the Commission and the public should be aware that by the same test, much if not all of what the NRC requires in the area of emergency planning would not be justifiable. Rather, such measures are required because the Commission made a policy decision that it was prudent and responsible to have emergency planning measures in place. Both the ACRS and OPE raised the objection, when the potassium iodide issue came up five years ago, that other emergency planning requirements would also fail the cost-benefit test, but that objection was never answered, to my knowledge. When the NRC says that a particular emergency planning measure, such as potassium iodide, is not cost-effective, it is implicitly suggesting that those emergency planning measures which are required do meet the test of cost-effectiveness. The Commission, the public, and the states -- which must decide for themselves whether to stockpile potassium iodide -- should be aware that this is not the case.

8. I understand from Dr. Robbins of NIH that the international thyroid community is eagerly awaiting the results of studies on adverse side effects of the the millions of doses of potassium iodide administered in Poland after Chernobyl. These studies might well affect the judgment of whether potassium iodide is desirable.

9. I believe that when the costs and benefits of potassium iodide are recalculated along the lines indicated above, the disparity between costs and benefits will be much smaller than the staff represented to the Commission at the 1983 briefing. (In effect, the Commission was being told that the benefit was virtually zero.) But even if costs are still found to exceed benefits in some measure, that does not mean that it would not be desirable to stockpile potassium iodide, simply as a matter of prudence. For example, earlier this summer the NRC issued a notice to all employees warning them to buy sun block and use it to prevent skin cancer. As far as I know, this was not based on any cost-benefit analysis of the cost of sun block compared to the risks of skin cancer, or the number of days lost if one develops skin cancer. Rather, this was based on a common-sense judgment that if it is easy and cheap to prevent a certain kind of cancer, it makes sense to do so. I think the NRC owes the public the same kind of common-sense approach with regard to radiation from nuclear accidents that it provides to its employees with regard to radiation from the sun.

10. Even if the NRC's bottom line remains the same -- that potassium iodide is not desirable -- the scientific and policy basis for that judgment should be valid. As I have described in my differing professional opinion of June 16, the staff acknowledged five years ago that the $20,000 figure was in error by a factor of 5, but did not change the underlying document because changing it would not have altered the ultimate conclusion that potassium iodide was not worthwhile. I disagree with that approach. I believe that it is essential not only that the bottom line be correct, but that the pathway to that bottom line be correct. We have no way of knowing the extent to which states and other federal agencies relied on elements in that pathway rather than simply on the bottom line. To the extent that the NRC has disseminated incorrect information in the past, either in public documents or in public briefings, I think we have an obligation to correct the record, and to do so loudly and clearly.

cc: Hugh Thompson

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

AUG 1 1 1989

NOTE TO: Hugh Thompson

FROM: Themis Speis

SUBJECT: NRC POSITION ON KI - DPO - MR. PETER CRANE

As indicated in the enclosed meeting notes, the DPO panel will be compiling some additional information regarding this issue and will revisit the staff's earlier cost-benefit analysis. With Mr. Crane's agreement, the group will meet again informally in September to discuss results of this effort and to consider how to proceed further.

Themis Speis

Enclosure:
Meeting Notes

cc: w/enclosure
P. Crane
F. Congel
L. Soffer
A. Roecklein

9403080333

5pp.

MEETING NOTES

Differing Professional Opinion Re. Stockpiling KI
Informal Meeting Notes: July 24, 1989

Attending: Themis P. Speis
Peter G. Crane
Frank J. Congel
Leonard Soffer
Alan K. Roecklein

Purpose: To clarify points at issue in the DPO submitted to the EDO by Mr. Peter Crane regarding the NRC position on stockpiling of Potassium Iodide.

Summary: Mr. Crane's concerns were as follows:

1. NUREG/CR-1433, "Examination of the Use of Potassium Iodide (KI) as an Emergency Protective Measure for Nuclear Reactor Accidents," does not seem to represent good science in that

- the 20K cost of treating a thyroid nodule including lost time at work, etc., is to low.
- a dose of 3,000 Rad to ablate the thyroid may be low. If up to 7,000 Rad is required, then many more thyroids are at risk from cancer than indicated In any case, medical follow-up is needed.
- does not evaluate impact of non-fatal cancer.

There was agreement that the 20K cost for treatment of a thyroid nodule may be too low and that costs associated with non-fatal cancer should not be ignored. It was noted that more recent accident analyses suggest probability of large releases is lower and that the expected fraction of total iodine release has decreased from approximately 70% to 15% (NUREG-1150), factors which would deflate the benefit side of the analysis.

It was agreed that an effort would be made to develop a more realistic value for the cost of treatment and that the threshold dose for thyroid ablation would be investigated.

2. Mr. Crane believes that the staff presentation to the Commission on the issue of stockpiling KI was greatly at variance with the Commission Paper SECY-83-362.

- the staff presentation implied no fatalities from thyroid cancer, when by the staff's own estimates, 4% of radiation caused nodules will be fatal.
- the staff transcript said it is not cost effective to spend 20K to prevent a thyroid nodule without making clear that this refers to a harmless nodule, not to all nodules.
- the transcript "glosses-over" the impact of thyroid disease.

3. Mr. Crane noted that NIH is expecting extensive data on adverse effects (if any) from using KI on adults and children in Poland after the Chernobyl accident. There may be new evidence, and this information should be factored into any new analysis. The Chernobyl accident may have more to contribute to this issue than the staff indicated.

It was suggested that the Chernobyl post accident data analysis should be followed closely and noted that an NRC contingent including Dr. Shlomo Yaniv and Dr. Frank Congel would be traveling to the Soviet Union in Sept. to begin implementation of the joint USA/USSR agreement on the evaluation of the health effects of the Chernobyl accident. The KI experience will be included.

4. Mr. Crane said he does not believe that predistribution will work and that his DPO is directed to the issue of whether stockpiling of KI should be added to the option of sheltering and evacuation.

Mr. Soffer noted that revised numbers in a cost benefit analysis for predistribution would probably still not support it, but that the stockpiling option would be worth investigating with the use of updated information in the regulatory analysis.

5. Mr. Crane said he would like agency experts to take a new look at the science behind the cost benefit analysis. He noted that though an April 30, 1984 memorandum from the EDO to the Commissioners acknowledged that the 20K figure was low by a factor of 5, the cost-benefit analysis was never corrected accordingly. NRC guidance to states and localities should use accurate numbers for cost of incidence of thyroid nodules versus cost of stockpiling. The Commission meeting transcript and NUREG/CR-1433 should be openly repudiated to the extent that they are erroneous even if correcting the data does not alter the staff's view that stockpiling of KI is not cost-effective. If a new analysis warrants it, states and localities should be advised to rethink their decisions regarding KI, but in any case, states and localities should have accurate information on which to base their decisions.

Mr. Speis questioned whether a revised cost-benefit analysis and new look at the questions raised by Mr. Crane might resolve the DPO issue informally, since even if Mr. Crane agrees with a 'revised' cost-benefit analysis, there still remains the question in his mind of why use cost-benefit at all (see Item 6 below). Mr. Crane said that in any event, it is NRC's responsibility to share any new or revised analysis with the decision makers at the state and local level.

6. Mr. Crane asked why a cost-benefit analysis was done for the issue of predistribution of KI while several other emergency response items were decided without such an analysis. He noted that to say that KI is not cost-effective implies that those emergency planning measures which <u>are</u> required can meet the test of cost-effectiveness, which may not be the case. He noted that in 1983-84, both OPE and the ACRS had questioned the use of cost-benefit analysis for this issue, if other emergency measures were not subject to the same analysis.

It was noted that the benefits versus risks of predistribution and stockpiling were carefully analyzed at the time and both options were considered inadvisable. A cost-benefit analysis was done on this option as a way of formalizing the decision. Some of the factors considered in

the analysis were: KI addresses only one organ, for only one radionuclide and only one pathway; the shelter and evacuation options were preferred since they address the entire potential radiological impact; adverse health effects from use of KI may outweigh the effects being prevented.

Mr. Speis closed the meeting with an offer to revisit the cost-benefit calculation and to consider some options for resolving Mr. Crane's concerns. The group will meet again in early September.

NOTE: At Mr. Crane's request, a summary of his comments prepared after the July 24 meeting is appended to these notes.

July 25, 1989

MEMORANDUM FOR: Themis Speis
Len Soffer
Frank Congel
Alan Roecklein

FROM: Peter Crane

SUBJECT: MEETING OF JULY 24, 1989

I appreciated the opportunity to meet with you and discuss the issues involved in my differing professional opinion on the stockpiling of potassium iodide. For the sake of clarity, I thought it might be useful for me to summarize my views in the aftermath of that meeting.

1. The assumptions as to the likelihood of an accident such as to cause a thyroid nodule need reexamination. As described by the staff in 1983, the figure of $10,000,000 cost per thyroid nodule prevented seems to say that accidents would result in no more than two and a half thyroid nodules per year. (The preliminary calculation circulated by Len Soffer at the meeting already indicates that this figure is low.)

2. The Commission, in its briefing of November 22, 1983, was not given to understand that approximately four percent of the nodules resulting from an accident will prove fatal. Such fatalities may be delayed in their onset, and thyroid cancer is generally slow in its progress, but they are fatalities nonetheless. (The slowness of an illness is not always a recommendation. I'm told that one of my kindergarten classmates, given X-ray treatment for tonsils or adenoids at about the same time I was, has had four operations for metastatic thyroid cancer that has spread to his head.) The Commission and the public should be aware of what the stakes are, not misled with facetious comparisons to events which do not take place in the United States, such as elephant stampedes.

3. Even non-fatal cancers are well worth preventing, if prevention is practicable. Thyroid cancer involves a lot more unpleasantness than the "few days' loss" that the staff described to the Commission in the November 1983 briefing. I'm not asking that the staff elaborate on the hardship to children of worrying about a parent who disappears to the hospital periodically, but if the staff does a fair job of representing what thyroid cancer involves for the patient -- the periodic scans, the exhaustion that results from the withdrawal of thyroid hormone, the amount of time lost from work, the need to be placed in isolation for treatment as an inpatient, the amount of radiation received from therapeutic

3pp.

and diagnostic doses, the need to avoid one's family when there are still levels of radioiodine in the body -- then the reader can use his or her own imagination and values to take account of these non-monetary impacts on the family.

4. In its assessment of dollar costs of radiation-caused nodules (including the 40% of nodules which will prove malignant), the staff's figure of $20,000 is extremely and unreasonably low, when one figures in the time lost from work for periodic scans, the cost of scans, and the cost of treatment, not to mention the environmental cost of radioiodine dumped into sewage systems. (As discussed further in item 9 below, the staff acknowledged in 1984 that the $20,000 figure for "a nodule" was low by a factor of 5.) Because I am a patient at NIH and do not pay for my medical treatment, I cannot offer an estimate of the full costs involved, but the American Thyroid Association or such experts as Dr. Jacob Robbins of NIH might be able to offer an estimate.

5. I believe that the staff's estimates of the likelihood that thyroids will be ablated in an accident (and thus rendered at no risk from nodules or cancer) are wishful thinking in the extreme. First of all, it takes a lot of iodine to ablate a thyroid, as I know from personal experience of receiving ablating doses. Secondly, even those persons whose thyroids were theoretically ablated by the iodine received in an accident would need medical followup on a regular basis.

6. I see innumerable problems with predistribution of potassium iodide. This differing professional opinion is directed solely to the merits of stockpiling.

7. Even if the outcome of the staff's analysis is that the use of potassium iodide is not justifiable on a cost-benefit basis, the Commission and the public should be aware that by the same test, much if not all of what the NRC requires in the area of emergency planning would not be justifiable. Rather, such measures are required because the Commission made a policy decision that it was prudent and responsible to have emergency planning measures in place. Both the ACRS and OPE raised the objection, when the potassium iodide issue came up five years ago, that other emergency planning requirements would also fail the cost-benefit test, but that objection was never answered, to my knowledge. When the NRC says that a particular emergency planning measure, such as potassium iodide, is not cost-effective, it is implicitly suggesting that those emergency planning measures which are required do meet the test of cost-effectiveness. The Commission, the public, and the states -- which must decide for themselves whether to stockpile potassium iodide -- should be aware that this is not the case.

8. I understand from Dr. Robbins of NIH that the international thyroid community is eagerly awaiting the results of studies on adverse side effects of the the millions of doses of potassium iodide administered in Poland after Chernobyl. These studies might well affect the judgment of whether potassium iodide is desirable.

9. I believe that when the costs and benefits of potassium iodide are recalculated along the lines indicated above, the disparity between costs and benefits will be much smaller than the staff represented to the Commission at the 1983 briefing. (In effect, the Commission was being told that the benefit was virtually zero.) But even if costs are still found to exceed benefits in some measure, that does not mean that it would not be desirable to stockpile potassium iodide, simply as a matter of prudence. For example, earlier this summer the NRC issued a notice to all employees warning them to buy sun block and use it to prevent skin cancer. As far as I know, this was not based on any cost-benefit analysis of the cost of sun block compared to the risks of skin cancer, or the number of days lost if one develops skin cancer. Rather, this was based on a common-sense judgment that if it is easy and cheap to prevent a certain kind of cancer, it makes sense to do so. I think the NRC owes the public the same kind of common-sense approach with regard to radiation from nuclear accidents that it provides to its employees with regard to radiation from the sun.

10. Even if the NRC's bottom line remains the same -- that potassium iodide is not desirable -- the scientific and policy basis for that judgment should be valid. As I have described in my differing professional opinion of June 16, the staff acknowledged five years ago that the $20,000 figure was in error by a factor of 5, but did not change the underlying document because changing it would not have altered the ultimate conclusion that potassium iodide was not worthwhile. I disagree with that approach. I believe that it is essential not only that the bottom line be correct, but that the pathway to that bottom line be correct. We have no way of knowing the extent to which states and other federal agencies relied on elements in that pathway rather than simply on the bottom line. To the extent that the NRC has disseminated incorrect information in the past, either in public documents or in public briefings, I think we have an obligation to correct the record, and to do so loudly and clearly.

: Hugh Thompson

File JPK

June 16, 1989

MEMORANDUM FOR: Hugh L. Thompson, Jr.
Deputy Executive Director
for Operations

FROM: Peter G. Crane
Counsel for Special Projects

SUBJECT: NRC POSITION ON POTASSIUM IODIDE: DIFFERING PROFESSIONAL OPINION

I. Introduction

The NRC staff has recently obtained Commission approval of two staff documents, NUREG-1355 ("The Status of Recommendations of the President's Commission on the Accident at Three Mile Island") and NUREG-1251 ("Final Report on Chernobyl Implications"). Both documents address, among many other issues, the desirability of stockpiling potassium iodide for thyroid protection after nuclear accidents, and assert that a requirement to stockpile the drug "should not be required" because "it would not be worthwhile." Both documents rely on a 1980 cost-benefit analysis, NUREG-CR-1433, prepared jointly by NRC and DOE's Sandia National Laboratory, and on a 1985 federal policy statement which reflected the influence of NUREG-CR-1433 and cited it.

At least as it was presented to Commission by the NRC staff, NUREG-CR-1433 takes the position that when it comes to thyroid abnormalities resulting from a nuclear accident, society should put its resources into cure rather than prevention. What you have just read is not a typographical error. In urging the Commission to adopt and endorse NUREG-CR-1433 in 1983, the staff argued that it is more cost-effective for society to treat radiation-caused thyroid abnormalities after a nuclear accident than to seek to prevent such abnormalities by stockpiling potassium iodide for administration to the public during a nuclear accident. The staff made this argument very explicitly in a November 22, 1983 briefing. Excerpts from that transcript appear as Appendix A to this memorandum.

I do not pretend to find NUREG-CR-1433 easy to understand; I am not convinced that it is as clear-cut in its cost-benefit conclusions as the staff represented it in the November 1983 briefing. For purposes of this Differing Professional Opinion, however, I am proceeding on the assumption that NUREG-CR-1433 is as it was described to the Commission in November 1983. However, even if it is not as flawed as the staff briefing might suggest, I believe that its analysis does not provide an adequate basis for reasoned decisionmaking on health and safety issues.

26 pp.

My reasons are as follows. Based on personal knowledge in this area, I believe that the information provided to the Commission in 1983 by the staff was erroneous in major respects. In a nutshell, both the risk of fatality from radiation-caused thyroid cancer and the adverse consequences for individuals of non-fatal thyroid abnormalities are vastly greater than the Commission was led to believe. Given that a stockpile of potassium iodide sufficient for the entire U.S. population could be purchased for less than the Government paid for the office building we work in, I think it is inappropriate for the NRC staff to be advising states and localities that the stockpiling of potassium iodide is not cost-effective.

I feel obligated to bring these facts to your attention so that appropriate corrective action can be taken. As NRC Manual Chapter 4125 states: "It is not only the right but the duty of all NRC employees to make known their best professional judgments on any matter relating to the mission of the agency." Differing professional opinions, according to the definition in Chapter 4125-041, "are not limited to the originator's area of expertise." In this case, the subject matter has nothing to do with law, which is my official area of expertise. I have discussed the matter with the General Counsel, who suggested that because it involves a technical matter under your jurisdiction, I direct my concerns to you.

I should add that I did not wait for the Commission to act on the papers before making my concerns known. As will be discussed below, I was the author in 1984 of a memorandum, signed by the then General Counsel, which pointed out a crucial flaw in the cost-benefit analysis. (SECY-84-161.) Although the then Executive Director for Operations acknowledged that flaw, in an April 30, 1984 intra-agency memorandum to the Commission, the staff never changed NUREG-CR-1433 accordingly. In March of this year, when I became aware that in two papers pending before the Commission, the staff was yet again preparing to endorse NUREG-CR-1433 publicly, I expressed my concerns to, among others, relevant staff members involved in the preparation of the papers, and, in a memorandum, to my immediate supervisor.

II. Background

At the risk of covering familiar ground, let me offer some factual background. The thyroid gland has two characteristics that make it of special interest to NRC. First, it is highly radiosensitive, especially in infancy and childhood. For some reason, girls are more sensitive than boys. Second, it is, as the doctors say, "avid" for iodine in all its forms. Thus releases of radioiodines after a major nuclear accident raise a danger that the

thyroids of exposed persons will soak up the radioiodine and later develop radiation-caused abnormalities. Fortunately, such abnormalities are comparatively rarely fatal.

The same avidity for iodine that puts thyroids at risk after a nuclear accident makes it possible to protect them effectively, if protective measures are taken in time. The thyroid has a limited capacity to hold iodine; once it is saturated, no more can be absorbed. Thus if there is a known risk of exposure to released radioiodine, it is a simple and inexpensive matter to administer iodine in a harmless form -- such as a pill of potassium iodide -- and thereby preclude subsequent uptake of harmful iodines. Laboratory workers using radioisotopes of iodine routinely take potassium iodide as a preventive measure. The NRC and FEMA recommend (in NUREG-0655/FEMA-REP-1) that licensees and State and local authorities keep stocks of potassium iodide on hand for use in the event of a nuclear accident -- but only for use by plant workers and institutionalized persons. With regard to the general public, the NRC's position is as indicated above.

The Kemeny Commission recommended in November 1979 that potassium iodide be stockpiled on a regional basis. As late as September 1980, in SECY-80-275A, the NRC staff itself was proposing that FEMA be asked to conduct "a study of the feasibility of establishing a single national stockpile and developing a distribution plan and system including estimates of times to transport and distribute the KI to the general public within various regions of the country." SECY-80-275A estimated the cost of purchasing stockpiles of potassium iodide at $.10 per person per year. (I have elsewhere seen even lower estimates.)

III. The Staff's Position Changes -- SECY-83-362

On August 30, 1983, in SECY-83-362 ("Emergency Planning - Predistribution/Stockpiling of Potassium Iodide for the General Public"), the Executive Director for Operations, Mr. Dircks, advised the Commission that "a cost/benefit uncertainty analysis performed by the staff conclusively shows that potassium iodide offers extremely small benefit in relation to its costs and is <u>not</u> cost effective as a preplanned emergency protective measure for the general public." The staff proposed that the NRC take this position in working with other federal agencies of the Federal Radiological Preparedness Coordinating Committee on the development of a coordinated federal policy statement on the stockpiling or predistribution of potassium iodide.

SECY-83-362 had several attachments. They included the following:

1) A report, "Radiation Protection: An Analysis of Thyroid Blocking," IAEA-CN-39/102, presented to an International Atomic Energy Agency conference in October 1980, by David C. Aldrich of Sandia National Laboratories and Roger M. Blond of the NRC staff. In the backxground section, that report explained:

> "The risk to the thyroid of exposed individuals posed by potential accidents is especially great for several reasons:
>
> -- Radioactive isotopes of iodine are produced in abundance by the fission process.
>
> -- Iodine and iodine compounds are normally quite volatile. Therefore, a sizeable fraction of core radioiodine inventories could be available for release to the atmosphere.
>
> -- Inhaled or ingested radioiodines are quickly absorbed into the bloodstream and concentrate preferentially in the thyroid.
>
> -- Iodines are eliminated from the thyroid with a relatively long biological half-life.
>
> As a result, the radiation dose to the thyroid is likely to far exceed the dose to the rest of the body, and thyroid damage is likely to affect more individuals than any other accident-induced health effect."

The report went on to discuss the pros and cons of using potassium iodide for thyroid blocking. It explained that radiation-caused thyroid nodules typically appear 10 to 40 years after exposure and may be benign or cancerous. It observed: "Most thyroid cancers are well differentiated, slow growing, and relatively amenable to therapy." The report noted that WASH-1400 (the 1975 Reactor Safety Study) assumed that 40% of accident-caused nodules would be cancerous, and that of these cancers, 10% would be fatal.

The report to the IAEA observed that in the event of an accident in the Core Melt Atmospheric category, "the thyroid dose levels of concern are likely to be exceeded at very large distances from the reactor (and correspondingly over very large areas if this type of accident were to occur." The report recognized that substantial uncertainties were involved in the underlying assumptions. Nevertheless based on the three factors it deemed relevant -- cost, degree of reduction of accident impacts by the use of potassium iodide, and accident probabilities -- it reached the following conclusion:

> "To some extent, the large uncertainties in the above

assumptions hinder our ability to provide definitive guidance. Nevertheless, for the assumptions made, the calculated cost-benefit ratios are high; and even including uncertainties, KI appears only marginally cost-effective, at best."

2. "Examination of the Use of Potassium Iodide (KI) as an Emergency Protective Measure for Nuclear Reactor Accidents," NUREG-CR-1433, prepared by Sandia Laboratories and, like the IAEA report, written by David C. Aldrich and Roger M. Blond of the NRC staff.

This report, longer and more detailed than the IAEA report, reached the same result. Its "Summary, Conclusions and Recommendations" section includes verbatim the paragraph just quoted from the IAEA report.

3. "ACRS Subcommittee Report on the Use of Potassium Iodide (KI) as a Thyroid Blocking Agent," May 17, 1983.

The ACRS subcommittee report made three comments on the NRC staff's proposed approach to the use of potassium iodide:

a. If the staff was correct in believing that the greatest risk of accident-caused fatalities came from whole body exposures rather than thyroid exposures, then the desirability of KI was questionable, and this issue should therefore be reevaluated.

b. Cost-benefit analyses to decide on the usefulness of potassium iodide "do not appear to be compatible with (or comparable to) approaches used in evaluating other aspects of nuclear emergency planning. For example, if the same evaluations were made, would there be justification for the conduct of emergency drills or the installation of warning sirens?"

c. The NRC should work with FEMA to develop guidance for state and local agencies on whether to use KI; should leave the decision to judgment of state and local authorities; and should not make stockpiling or predistribution of KI a licensing requirement.

The ACRS subcommittee report attached comments by Dr. Eugene L. Saenger of the University of Cincinnati Medical Center, writing on behalf of the National Council on Radiation Protection. He observed, among other things, that based on the information available to him, only 1.5 percent of the U.S. population lived within 10 miles of a nuclear reactor. Thus, he suggested, the NRC staff was overestimating the amount of potassium iodide that might need to be purchased, and this was incorrectly affecting the cost-benefit balance. He also commented: "In a period when

there are enormous investments in nuclear power plants many of which are not completed for various reasons and great concern by citizens concerning safety, it does not seem useful to engage in debates concerning the protection of the thyroid gland between agencies of the Government."

4. "Recommendations on the Use of Potassium Iodide as a Thyroid-Blocking Agent in Radiation Accidents: An FDA Update," by Dr. Bernard Schleien and four co-authors.

This report noted that in 1978, the Food and Drug Administration had issued a Federal Register notice stating "that potassium iodide is safe and effective for use as a thyroid-blocking agent in a radiation emergency in which radioiodines are accidently released into the environment." In this report, the authors reviewed the extensive debate on the subject, including the argument that there might be harmful side effects from using potassium iodide, and stated FDA's conclusion:

> "The paucity of human data relevant to the induction of radiation effects from iodine-131, particularly in children, has convinced the FDA that it is prudent to employ risk estimates from external irradiation studies in reaching the conclusions upon which its recommendations are based. From this evidence, the FDA concluded that the risks of radio-iodine induced thyroid nodules or cancer at a projected radiation dose of 25 rem or greater to the thyroid gland from radioiodines released into the environment outweigh the risks from the short-term use of relatively low doses of potassium iodide for thyroid blocking in a radiation emergency. The FDA recommends that potassium iodide in doses of 130 mg per day for adults and children 1 year and above, and 65 mg per day for children below 1 year of age, be considered in those persons likely to receive a projected radiation dose of 25 rem or greater to the thyroid gland from radioiodines released to the environment."

The FDA noted that the American Thyroid Association had earlier commented, before certain animal studies were available, that at a threshold of 50 rads, potassium iodide should be given "to provide an added measure of protection for children and pregnant women." The FDA commented that "given that the most sensitive segments of the population should be protected the opinion of the American Thyroid Association and the conclusions of the FDA are not very far apart."

IV. The Staff Briefs the Commission on Potassium Iodide

On November 22, 1983, the Executive Director for Operations, accompanied by the co-author of NUREG-CR-1433

and another staff member, briefed the Commission on the document. Pertinent excerpts from the discussion appear in Appendix A to this memorandum. I hope I have done a fair job of representing the discussion, and capturing its flavor; I would have attached the entire transcript, but it is 82 pages long. I'll be glad to make you a copy if you would like it, however.

For simplicity's sake, let me try to summarize some of the major points of the staff's presentation (not necessarily in the same order as the staff) and offer my comments on each point. If the arguments you see made by the staff appear in places inconsistent with the IAEA report summarized earlier, I can only urge you to read the transcript and assure yourself that I am not mischaracterizing the discussion.

1. "The surviving question is not the question, and that's the piece that really should also be emphasized." Rather, the question is whether you "avert an illness."

Comment: The IAEA report and NUREG-CR-1433 itself assume, based on the Reactor Safety Study, that 40% of accident-caused nodules will be malignant, and that 10% of those malignancies will be fatal. Thus for 1 in 25 accident-caused nodules, survival *is* the issue.

2. If a person does develop a thyroid nodule as the result of an accident, $20,000 represents "the upper end of the scale" in terms of the cost of medical treatment and the loss of productivity: "There's a few days' loss from -- it's a relatively simple operation that's involved in removing the thyroid or removing the nodules --"

Comment: I once quoted that sentence to a doctor at NIH who is himself a thyroid cancer patient. He looked at me in incredulity and exclaimed, "They ought to have one!" In reality, radiation-caused thyroid abnormalities -- and recall that 40% of these nodules will be cancerous -- mean a lifetime of being followed up medically and of taking medication every day. In preparation for scanning, which may take place as often as every six months, the patient is taken off normal medication, so that the pituitary will produce thyroid stimulator hormone and any thyroid cells in the body will take up radioiodine when it is administered in a diagnostic dose. The withdrawal of the normal medication produces exhaustion, weakness, and extreme sensitivity to cold. It means going on sick leave. Radioiodine treatments for inpatients mean being placed in complete isolation for two to four days, with paper covering the floor to protect the hospital from the patient's radioactive footprints. Even at lower outpatient doses, it means becoming a radioactive source and having to stay away from loved ones and even pets. (You may recall that when the First Lady

recently had a radioiodine treatment as an outpatient, she was told not to handle her dog's puppies for a few days.) For persons of childbearing years, it means, to be prudent, postponing conception for six months to two years. And though statistics on thyroid cancer are good, patients and their families are human and they worry.

From the economic standpoint, radiation-caused thyroid problems can quickly run up costs considerably above $20,000 in medical bills and time lost from work. From an environmental standpoint, diagnostic and therapeutic doses of radioiodine, eliminated through the kidneys, wind up in sewage systems. An NRC staff member who used to work for a state health department once told me that they always knew when someone was being treated locally for thyroid cancer because of the spike of radioactivity at the sewage treatment plant.

3. There are so few nodules likely to result from a nuclear accident that the actual cost of preventing a nodule is on the order of $10,000,000.

Comment: I am frankly not conversant with the latest estimates either on the source term or on accident probabilities, but if we assume $.10 per person per year cost for KI, you can protect the entire population of the United States for something like $25,000,000. For it to cost $10,000,000 to prevent a thyroid nodule must mean either extraordinarily low accident probabilities or extraordinarily minuscule releases if there is an accident. If that is the case, why -- as the ACRS asked in 1983 -- have emergency planning at all? I think that these statistics ought to be checked carefully by persons with expertise in this area.

4. Recommending in favor of potassium iodide stockpiling would mean "sponsoring an industry (the manufacture of potassium iodide) that may have a very low cost payoff in societal needs."

Comment: The NRC should make its decisions based on what the public health and safety requires, not on who will or will not make money as a result.

5. Potassium iodide may seem to be an inexpensive way to protect the public, but in reality it is like an inexpensive accident insurance policy for which, when you read the fine print, "there has to [be] a stampeding elephant that kills you."

Comment: The American Cancer Society estimates that there will be 11,300 new cases of thyroid cancer in 1989, and 1025 fatalities.

Toward the end of the briefing, Chairman Palladino alluded to the fact that the staff had earlier favored the use of potassium iodide. The Executive Director for Operations acknowledged that, commenting that in the rush to respond to the Three Mile Island accident, certain positions had been taken "quickly because it [the NRC] was under a good deal of pressure to move quickly." To go back and question those positions, he said, "takes a much more rational and sometimes courageous attitude."

The transcript shows Chairman Palladino expressing considerable reservations about the staff's cost-benefit analysis. At the direction of Chairman Palladino and the Commissioners, the staff agreed to prepare a letter to the Federal Emergency Management Agency that would "support the policy statement" on potassium iodide then being circulated in draft among the agencies of the interagency working group, while also offering the staff's view that use of the drug was not worthwhile.

V. Subsequent Developments

I will review subsequent developments only very summarily. At some point after the briefing, I had a discussion with one of the staff briefers in which he acknowledged, after checking, that the figure of $20,000 for costs associated with a thyroid nodule referred not to all nodules (including the 4% which will prove fatal), but only to those which will not prove fatal. Subsequently, arrangements were made -- I no longer remember by whom -- for me to meet with staff members involved with the potassium iodide issue, to address my questions. At that briefing, two more arguments against the use of potassium iodide were offered: that in the event of an accident, it would be necessary to follow exposed persons anyway [i.e., so there would be no cost savings to the Government in assuring that they were healthy rather than diseased], and that potassium iodide, while a good idea from a technical standpoint, might be used as an issue to hold up operating licenses. These views may well have reflected no more than the personal opinions of the individuals who offered them.

On January 20, 1984, the staff sent the Commission SECY-83-362A, "Use of Potassium Iodide for Thyroid Blocking." It included a draft letter to FEMA that urged that the interagency working group be "reconvened" to "develop a new policy statement" reflecting the staff's cost-benefit evaluation of potassium iodide. The Office of the General Counsel answered this on April 17, 1984 with a memorandum, written by me, which urged a more neutral approach, and which expressed "serious doubts about the validty of the staff's cost-benefit analysis," citing the staff's acknowledgment that the $20,000 figure represented the benefit associated with averting "only those nodules

which will not prove fatal." The Executive Director for Operations responded on April 30, 1984 with a memorandum, "Supplementary Information on Potassium Iodide for Thyroid Blocking," which took issue with the OGC paper. It asserted that fatal nodules had been "implicitly considered," and it said:

> "The analysis is sufficiently transparent that one could add explicit consideration of the latent cancer fatality component. For example, even taking the upper value of $1,000,000 per latent cancer fatality and a higher mortality rate of ten percent latent cancer fatalities per thyroid nodule would inject a cost component of $100,000 to the $20,000 used in the staff analysis, a five fold increase. This would still not change the staff conclusion that KI is not cost beneficial, since the lowest value at which KI use would be cost beneficial was determined in SECT-83-362 to be about $300,000 per thyroid nodule averted. In summary, the staff conclusion does not rest on whether $20,000 per thyroid nodule averted is an absolutely accurate value, but rather that it is significantly lower than the value at which use of KI does become cost beneficial."

In the end, resolution of the dispute between the staff and the Office of the General Counsel was deferred because of the imminence of a new draft of the policy statement.

On July 24, 1985, the Federal Government published its polciy statement on the use of potassium iodide. 50 Federal Register 30258. It provides:

> "While valid arguments may be made for the use of KI, the preponderance of information indicates that a nationwide requirement for the predistribution or stockpiling for use by the general public would not be worthwhile. This is based on the ability to evacuate the general population and the cost effectiveness of a nationwide program which has been analyzed by the NRC and DOE National Laboratories (NUREG/CR-1433). While the use of KI can clearly provide additional protection in certain circumstances, the assessment of the effectiveness of KI and other protective actions and their implementation problems indicates that the decision to use KI (and/or other protective actions) should be made by the states and, if appropriate, local authorities on a site specific basis."

In April 1986, the catastrophic accident at Chernobyl led to the first use of potassium iodide on a mass scale. According to one set of figures I have seen, 5,000,000 Russians and 6,000,000 Poles received potassium iodide. The NRC staff's report on the implications of Chernobyl,

NUREG-1241, reports that the Poles credit use of the drug with having "reduced the potential thyroid dose to children by factors of 6 to 10." The Soviets, according to the same report, said that at one relocation center, use of potassium iodide kept thyroid exposures within permissible limits for 97% of evacuees. The Soviets also reported "no serious adverse reactions from the use of KI," according to the staff.

The Chernobyl experience did not alter the NRC staff's view of the issue. It explained that, under the 1985 federal policy statement, the effectiveness of KI was acknowledged for emergency workers or institutionalized individuals, who may be exposed to the release for an extended period. For the general public, however, "these conditions generally are not applicable, because evacuation is generally feasible and, when carried out, is more effective in dose reduction than administration of KI, since it can reduce the dose for all body organs and not merely the thyroid gland." The staff report did not discuss the possible desirability of having the capacity, in the event of an accident, both to evacuate the affected public and to administer potassium iodide to evacuees.

The staff therefore concluded:

> "The apparently successful use of potassium iodide by the Soviets does not alter the validity of U.S. Government policy that predistributing or stockpiling potassium iodide for use by the general public should not be required. Rather, this decision should be made by individual States and by local authorities."

VI. Statement of Personal Interest

I feel that I ought to state, for the purpose of letting the reader know what biases I may bring to the issue, my own personal interest in it. In 1973, I had a partial thyroidectomy, for a malignancy resulting from x-ray treatment of enlarged tonsils and adenoids when I was two. In more recent years, I have had several radioiodine treatments at NIH, designed to ablate (burn out) any thyroid tissue in my neck. Since there is no way to know for sure whether such tissue is benign or not, the doctors proceed conservatively. In my case, statistics are very much on my side, and I have only to look around at the medical troubles that life has brought to some of my co-workers or their family members to realize how lightly, at least so far, I have gotten off.

But I'd be lying if I said that years of scans, treatments, periodic removal from medication with resulting exhaustion, or the accompanying anxieties, have been completely inconsequential in their effect on the quality of

life for my wife and me, at least from time to time. That certainly affects the intensity with which I feel that NUREG-CR-1433 is off base in recommending that society put its resources into treatment rather than prevention of thyroid abnormalities. I feel very strongly -- there is no point in pretending otherwise -- that if a dime's worth of medication sitting on the shelf of an evacuation center could someday prevent another family from having a similar experience, it would be a dime well spent.

I do not believe, however, that this strength of feeling on a personal level has interfered with my professional objectivity in evaluating the factual flaws in the staff's position. 1/ As noted above, the staff itself admitted in 1984 that the $20,000 cost-benefit figure for averting a thyroid nodule excluded those nodules which will prove fatal, and was thus inaccurate by a factor of five. That admission alone, in my view, is sufficient to warrant the withdrawal of NUREG-CR-1433. I might add that anyone who knows me or my work on behalf of this agency over the past 14+ years knows that I am not phobic either about nuclear power or radiation. 2/

VI. Conclusion.

Potassium iodide is not a panacea against radiation. It protects just a single gland -- albeit a highly radiosensitive gland. The NRC staff is correct in saying, in its discussion of the implications of Chernobyl, that evacuation is generally preferable to potassium iodide as a protective measure in a radiological emergency. <u>But there is no reason to have to choose between the two.</u> The real issue is whether in an emergency one wants to have the capability both to evacuate the public <u>and</u> administer potassium iodide to evacuees and others. If there are no stockpiles of potassium iodide in evacuation centers, emergency operations facilities, and the like, that option will not be available. As a society, we could have the potassium iodide option, and the additional protection it might afford, for a sum that is a drop in the bucket compared to the cost of other emergency preparedness measures we require. If an accident occurred today in Britain, a stockpile of thyroid-protecting drugs would be on hand, because Britain requires it. (The British use iodine in the iodate rather than the iodide form, but the principle is the same.) In this country, such drugs might well not be on hand, because the Federal Government, relying on the NRC's cost-benefit analysis, has been advising states and localities that to require the stockpiling of potassium iodide "would not be worthwhile."

There is not a person in the NRC who is not fully committed to seeing that our country never experiences another TMI or, what is worse, a Chernobyl. We all agree on

that; it is the goal toward which all of us are working. We all hope that the emergency requiring special protective measures never comes. But the premise from which we start is that a serious accident might happen, and that adequate protective measures have to be in place just in case. If there is ever such an accident in this country, no one should have grounds to say that the Russians and the Poles took better care of their children after Chernobyl than we took of ours, or that Americans failed to get adequate protection because the NRC had disseminated erroneous information. I believe that the NRC should promptly withdraw NUREG-CR-1433; advise states, localities, other federal agencies, and the public of the flaws and omissions in its analysis; and take affirmative steps to ensure that potassium iodide is stockpiled for possible emergencies.

cc: Chairman Zech
Commissioner Roberts
Commissioner Carr
Commissioner Rogers
Commissioner Curtiss
William C. Parler
Martin G. Malsch
The Director, NMSS

1/ For what it is worth, I did not become interested in the potassium iodide issue because I was a patient at NIH, but just the other way around. At the time I went to the November 1983 briefing, I believed my own thyroid problems to be far in the past. Because the statements I heard at the briefing seemed inconsistent with what I remembered from my own days as a thyroid patient, I called NIH seeking up-to-date information. The NIH doctors were most helpful in providing such information. They also told me, to my surprise, that my own medical history suggested that followup evaluation was appropriate. As a result, I became a patient there, and now know considerably more about the consequences of radiation-caused thyroid abnormalities than I did when I first wrote memos on the subject in 1984.

2/ It is perhaps ironic that in 1980 I was (I believe) alone in the General Counsel's office in asserting that irrational fear of radiation was not an environmental impact cognizable under the National Environmental Policy Act. (I believed then, as I believe now, that regulatory decisions affecting public health and safety should be made on the basis of sound technical information, honestly and professionally evaluated, without the intrusion of extraneous considerations.) As a result, when the Commission's 2-2 split on the issue had the effect of

excluding psychological impacts from the TMI restart proceeding, and the D.C. Circuit ruled against us in PANE v. NRC (a case I argued), I was made Acting General Counsel for a day to visit the Solicitor General and urge him to seek certiorari, along lines most favorable to the NRC. The Solicitor General took the case to the Supreme Court, where we won unanimously.

APPENDIX A

Excerpts from the NRC Staff Briefing to the Commission on NUREG-CR-1433

Mr. Blond (co-author of NUREG-CR-1433): At the bottom of this figure [a slide was on the screen] you see a dashed line at about the $20,000 figure, and that represents what we feel the cost-benefit breakpoint would be. If the cost of averting one nodule is on the order of $20,000, that's the cost that will be represented by the medical treatment and the loss of productivity of an individual if he had a thyroid nodule. And it's on the upper end of the values which we have seen. There's a few days' loss from -- it's a relatively simple operation that's involved in removing the thyroid or removing the nodules --

. . .

The whole point of the analysis focuses to this [$20,000] figure in some sense. When we look at this we feel we've done the analysis ... with a bias in favor of potassium iodide if anything. ... And our analysis still comes down and shows that ... this is not a viable measure to be taken, it is not something that we should consider in terms of our policy.

As far as we're concerned, the message couldn't be any clearer. Unfortunately, when we perform similar analyses or

I think when we've seen other analyses, we never get quite this clear a message that we're getting here, and that's the important point that from our perspective has to be driven home. We have taken every factor that we can think of into account; it's not just single arguments that we throw at each other; we have factored in all the uncertainties that we can think about, and this is where we come down to it, and the message is clear.

Chairman Palladino: But it sounds crass. It doesn't satisfy me as an individual.

Commissioner Asselstine: I must say I share that view.

Chairman Palladino: Something just does not sit with me right.

Mr. Blond: Let's move on to the next slide --

(Laughter.)

. . . .

Mr. Dircks (Executive Director for Operations): Let me just add a point. This is not just a question of your mandating potassium iodide or outlining potassium iodide. I think the question is we have to go back to that policy

statement [interagency policy statement on potassium iodide, then being developed] -- and I guess you're coming to that point. Do you stand neutral and not bring these factors to the attention of the other federal agencies and to the state and local governments, or do you endorse it, or do you just stand aside and say it's not my business?

I think the fact is that because these other agencies do look to the Nuclear Regulatory Commission, we have data here that probably would be useful to factor into the decision, not only the federal agencies but the state and local agencies, the question is do we make this analysis available, do we make these conclusions available, or do we not.

Chairman Palladino: Yes. I'm not ready to even address that because I don't understand in the cost analysis -- for example, you say it costs -- what were your dollars? $10 million per nodule averted, and you said boy, that's pretty high. But then you tell me it's a low cost operation.

So now to me, for example, as an individual, what would it cost me for my pill? Twenty cents. So now, that sounds like a very low cost, and if I got the probability or possibility of averting a nodule -- . I don't understand my 20 cents versus $10 million.

Mr. Blond: You have to consider now what is the likelihood of your exceeding that 25 rem requirement that is the recommendation for you to take that pill.

. . .

Chairman Palladino: You're saying that there's so few nodules you're going to get out of an accident --

. . .

Commissioner Bernthal: It's 20 cents per person to cover you, but so few nodules -- the probability of anybody getting a nodule is so small that it turns out to be $10 million.

Chairman Palladino: Yes, but that's from one perspective. As an individual I say boy, that's among the lowest-cost protection ...

Mr. Dircks: ... You may be sponsoring an industry [manufacturers of potassium iodide] that may have a very low cost payoff in societal needs. I mean, --

Mr. Blond: What we're indicating is from our perspective, the government should not sponsor that because we do not see the benefit in terms of its cost.

. . .

Chairman Palladino: I guess I was taking a more personal view of cost-benefit. 20 cents or some nominal amount of money every year or every five years to replace them seems like small change compared to the risk, from my perception.

Commissioner Bernthal. For the individual. But that's not the statistical argument; that's the sort of gut argument that an individual might make to himself.

Mr. Bernero (NRC staff): Mr. Chairman, there's a large industry in the United States selling cost-ineffective insurance policies to people but you will subscribe to a newspaper and you get $25,000 worth of accident insurance with enough clauses in it to certify that there has to [be] a stampeding elephant that kills you.

. . .

Chairman Palladino: ... [Y]ou said something that bothers me a little bit. You said that we were paying a low cost for something that wasn't worthwhile. You related it to a worthless insurance policy.

But as an individual, I may say the potential benefit is that I might survive a nuclear accident at that plant, which I live near.

Commissioner Asselstine: Or that you may not have to go through an operation --

Mr. Blond: Except that -- the surviving question is not the question, and that's the piece that really should also be emphasized.

Chairman Palladino: All right, survive in the terms of I avert --

Mr. Bernero: An illness. I will avert an illness which I might incur. But my father's argument in buying his insurance policies was the very same. He might leave my mother $10,000 from an accident insurance policy.

There was a residual chance that he would be killed by that stampeding elephant. It was not a well thought-out choice.

Chairman Palladino: Let's not carry analogies too far because then I start thinking of the analogy and don't think of the subject I'm supposed to be thinking about.

I agree, I'm paying low cost for averting a very improbable circumstance. I won't argue that. But it is a low cost.

Mr. Bernero: Yes.

Mr. Dircks: But that's again, an individual decision.

Chairman Palladino: I agree, and both sides of the picture must be examined because when you say they're high cost, I tend to think the risk of low cost -- and incidentally, I'm not pushing either side. I have intuitive feelings on this potential thing, but I'd like to understand your position.

[Later, the discussion turns to the question of what position the NRC should take in the interagency group developing a coordinated federal policy statement on the use of potassium iodide.]

Mr. Blond: What it really comes down to is the issue is, as Mr. Dircks indicated, from our perspective, we have two options. We can take a neutral position and indicate

that we, -- the state and locals should make their decision. Here is a body of information along with other bodies of information which might be taken into consideration. And from our point of view, that's a neutral position the Commission could take.

Or we could, if you so desire, take a stronger position and say from our perspective, we do not feel that federal or state or local governments should sponsor such programs, that it is not in the benefit of the public for the government establishments to sponsor such programs as potassium iodide.

On an individual basis [i.e., individuals purchasing their own potassium iodide over the counter for possible emergency use] that's another question, and I don't think we need take a position. If somebody wants to wear that amulet and have that available to them, that's their business, and that's where we'd stand on it.

Chairman Palladino: What does the staff recommend? I re-read the recommendation; I still would like to know what they recommend. I can read it. "Staff will proceed to recommend to the Federal Radiological Preparedness Coordinating Committee that federal policy in this area should be against requiring the planned stockpile or predistribution of KI [potassium iodide] for the general public."

Mr. Bernero: Or the staff offers the alternative, in the most recent memorandum, of taking a more neutral policy. Basically, the current draft policy statement is neutral itself, but that neutral policy statement would be accompanied by clear advice of the NRC providing its technical advice to competent local and state authorities that this material is not worthwhile for predistribution, general public use.

[Chairman Palladino tries several more times to get a clear picture of what the staff is asking the Commission to approve.]

* * *

Chairman Palladino: Bill [Dircks], could I ask you, suppose we went along with your proposal in your letter or the proposal in your report. How would we implement it; by writing a letter to --

Mr. Dircks: I think we would write a letter to FEMA outlining the basic conclusions reached in this analysis, transmitting the analysis along with it, and meeting with them to present this data.

Chairman Palladino: All right. I gather also that you could not interfere with the states going ahead and doing what they want.

Mr. Dircks: State and local, that's right.

Chairman Palladino: So you would support the policy statement but you would make available a statement that the protective measure is not cost-effective or not worthwhile.

Mr. Dircks: Yes.

. . .

Commissioner Asselstine: I have a question that I just thought of. Why did the other agencies [e.g. FDA] believe that it's a good idea to predistribute potassium iodide, and why did the state of Tennessee decide that they wanted to do that?

Chairman Palladino: Incidentally, we were among the other agencies that --

[Chairman Palladino is apparently referring to the fact that in 1980, after the Three Mile Island accident, the NRC

staff proposed that creation of a national stockpile of potassium iodide be studied. SECY-80-257A.]

Commissioner Asselstine: Originally that's right but I gather that view still prevails --

Mr. Bernero: I think you're touching on -- one of the great difficulties in a matter such as this, being on the side of potassium iodide is somewhat like being on the side of the angels.

(Laughter.)

The FDA has found it is not harmful for its potential benefit, and there is a large body of opinion, at least subconsciously, that we must recognize that coming out in favor of potassium iodide predistribution has the force of reminding people of nuclear reactor accidents and how dangerous nuclear reactors are, whereas coming out in favor of -- or rather against potassium iodide implies that the accident risks are low and you don't need such special precautions.

I think when you look at the thing, this colors people's decisions, that you don't want to get into that kind of argument. You just want to look at the thing and say is it worth doing, it it a worthwhile thing. And if you take the single element of a threat to an organ and you simplify the decision as much as possible, it appears to be, on a personal

basis, an excellent thing to do. An inexpensive tablet that -- like my father's insurance policy -- it's only a quarter a week, it's only 20 cents a tablet, and it's self-evidently good. It protects the thyroid under those circumstances. And I think approaching the decision from that point of view leads you to favor potassium iodide. It is quite inexpensive.

Mr. Dircks: But I think, going back to your other question about why the analysis that went into the -- say the rush of regulations after TMI in the emergency planning area, I think looking back on that experience, there wasn't that much analysis and weighing of alternatives and looking at options.

I think the agency moved quickly because it was under a good deal of pressure to move quickly, and there were very few people in the agency who were against going all out in the area of emergency planning. And I think we're seeing some of the effects of that rushed regulation right now, as we try to go back and question why we did certain things in that timeframe, and what should we be doing differently now. It takes a much more rational and sometimes courageous attitude to go back and question the network of emergency planning regulations, as well as some of the other regulations.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

ENCLOSURE 2

AUG 1 1 1989

NOTE TO: Hugh Thompson

FROM: Themis Speis

SUBJECT: NRC POSITION ON KI - DPO - MR. PETER CRANE

As indicated in the enclosed meeting notes, the DPO panel will be compiling some additional information regarding this issue and will revisit the staff's earlier cost-benefit analysis. With Mr. Crane's agreement, the group will meet again informally in September to discuss results of this effort and to consider how to proceed further.

Themis Speis

Enclosure:
Meeting Notes

cc: w/enclosure
P. Crane
F. Congel
J. Soffer
A. Roecklein

MEETING NOTES

Differing Professional Opinion Re. Stockpiling KI
Informal Meeting Notes: July 24, 1989

Attending: Themis P. Speis
Peter G. Crane
Frank J. Congel
Leonard Soffer
Alan K. Roecklein

Purpose: To clarify points at issue in the DPO submitted to the EDO by Mr. Peter Crane regarding the NRC position on stockpiling of Potassium Iodide.

Summary: Mr. Crane's concerns were as follows:

1. NUREG/CR-1433, "Examination of the Use of Potassium Iodide (KI) as an Emergency Protective Measure for Nuclear Reactor Accidents," does not seem to represent good science in that

- the 20K cost of treating a thyroid nodule including lost time at work, etc., is to low.
- a dose of 3,000 Rad to ablate the thyroid may be low. If up to 7,000 Rad is required, then many more thyroids are at risk from cancer than indicated. In any case, medical follow-up is needed.
- does not evaluate impact of non-fatal cancer.

There was agreement that the 20K cost for treatment of a thyroid nodule may be too low and that costs associated with non-fatal cancer should not be ignored. It was noted that more recent accident analyses suggest probability of large releases is lower and that the expected fraction of total iodine release has decreased from approximately 70% [illegible] (NUREG-1150), factors which would deflate the benefit sid[illegible] analysis.

It was agreed that an effort would be made to develop a more realistic value for the cost of treatment and that the threshold dose for thyroid ablation would be investigated.

2. Mr. Crane believes that the staff presentation to the Commission on the issue of stockpiling KI was greatly at variance with the Commission Paper SECY-83-362.

- the staff presentation implied no fatalities from thyroid cancer, when by the staff's own estimates, 4% of radiation caused nodules will be fatal.
- the staff transcript said it is not cost effective to spend 20K to prevent a thyroid nodule without making clear that this refers to a harmless nodule, not to all nodules.
- the transcript "glosses-over" the impact of thyroid disease.

3. Mr. Crane noted that NIH is expecting extensive data on adverse effects (if any) from using KI on adults and children in Poland after the Chernobyl accident. There may be new evidence, and this information should be factored into any new analysis. The Chernobyl accident may have more to contribute to this issue than the staff indicated.

It was suggested that the Chernobyl post accident data analysis should be followed closely and noted that an NRC contingent including Dr. Shlomo Yaniv and Dr. Frank Congel would be traveling to the Soviet Union in Sept. to begin implementation of the joint USA/USSR agreement on the evaluation of the health effects of the Chernobyl accident. The KI experience will be included.

4. Mr. Crane said he does not believe that predistribution will work and that his DPO is directed to the issue of whether stockpiling of KI should be added to the option of sheltering and evacuation.

Mr. Soffer noted that revised numbers in a cost benefit analysis for predistribution would probably still not support it, but that the stockpiling option would be worth investigating with the use of updated information in the regulatory analysis.

5. Mr. Crane said he would like agency experts to take a new look at the science behind the cost benefit analysis. He noted that though an April 30, 1984 memorandum from the EDO to the Commissioners acknowledged that the 20K figure was low by a factor of 5, the cost-benefit analysis was never corrected accordingly. NRC guidance to states and localities should use accurate numbers for cost of incidence of thyroid nodules versus cost of stockpiling. The Commission meeting transcript and NUREG/CR-1433 should be openly repudiated to the extent that they are erroneous even if correcting the data does not alter the staff's view that stockpiling of KI is not cost-effective. If a new analysis warrants it, states and localities should be advised to rethink their decisions regarding KI, but in any case, states and localities should have accurate information on which to base their decisions.

Mr. Speis questioned whether a revised cost-benefit analysis and new look at the questions raised by Mr. Crane might resolve the DPO issue informally, since even if Mr. Crane agrees with a 'revised' cost-benefit analysis, there still remains the question in his mind of why use cost-benefit at all (see Item 6 below). Mr. Crane said that in any event, it is NRC's responsibility to share any new or revised analysis with the decision makers at the state and local level.

6. Mr. Crane asked why a cost-benefit analysis was done for the issue of predistribution of KI while several other emergency response items were decided without such an analysis. He noted that to say that KI is not cost-effective implies that those emergency planning measures which <u>are</u> required can meet the test of cost-effectiveness, which may not be the case. He noted that in 1983-84, both OPE and the ACRS had questioned the use of cost-benefit analysis for this issue, if other emergency measures were not subject to the same analysis.

It was noted that the benefits versus risks of predistribution and stockpiling were carefully analyzed at the time and both options were considered inadvisable. A cost-benefit analysis was done on this option as a way of formalizing the decision. Some of the factors considered in

the analysis were: KI addresses only one organ, for only one radionuclide and only one pathway; the shelter and evacuation options were preferred since they address the entire potential radiological impact; adverse health effects from use of KI may outweigh the effects being prevented.

Mr. Speis closed the meeting with an offer to revisit the cost-benefit calculation and to consider some options for resolving Mr. Crane's concerns. The group will meet again in early September.

NOTE: At Mr. Crane's request, a summary of his comments prepared after the July 24 meeting is appended to these notes.

July 25, 1989

MEMORANDUM FOR: Themis Speis
Len Soffer
Frank Congel
Alan Roecklein

FROM: Peter Crane

SUBJECT: MEETING OF JULY 24, 1989

I appreciated the opportunity to meet with you and discuss the issues involved in my differing professional opinion on the stockpiling of potassium iodide. For the sake of clarity, I thought it might be useful for me to summarize my views in the aftermath of that meeting.

1. The assumptions as to the likelihood of an accident such as to cause a thyroid nodule need reexamination. As described by the staff in 1983, the figure of $10,000,000 cost per thyroid nodule prevented seems to say that accidents would result in no more than two and a half thyroid nodules per year. (The preliminary calculation circulated by Len Soffer at the meeting already indicates that this figure is low.)

2. The Commission, in its briefing of November 22, 1983, was not given to understand that approximately four percent of the nodules resulting from an accident will prove fatal. Such fatalities may be delayed in their onset, and thyroid cancer is generally slow in its progress, but they are fatalities nonetheless. (The slowness of an illness is not always a recommendation. I'm told that one of my kindergarten classmates, given X-ray treatment for tonsils or adenoids at about the same time I was, has had four operations for metastatic thyroid cancer that has spread to his head.) The Commission and the public should be aware of what the stakes are, not misled with facetious comparisons to events which do not take place in the United States, such as elephant stampedes.

3. Even non-fatal cancers are well worth preventing, if prevention is practicable. Thyroid cancer involves a lot more unpleasantness than the "few days' loss" that the staff described to the Commission in the November 1983 briefing. I'm not asking that the staff elaborate on the hardship to children of worrying about a parent who disappears to the hospital periodically, but if the staff does a fair job of representing what thyroid cancer involves for the patient -- the periodic scans, the exhaustion that results from the withdrawal of thyroid hormone, the amount of time lost from work, the need to be placed in isolation for treatment as an inpatient, the amount of radiation received from therapeutic

3pp.

and diagnostic doses, the need to avoid one's family when there are still levels of radioiodine in the body -- then the reader can use his or her own imagination and values to take account of these non-monetary impacts on the family.

4. In its assessment of dollar costs of radiation-caused nodules (including the 40% of nodules which will prove malignant), the staff's figure of $20,000 is extremely and unreasonably low, when one figures in the time lost from work for periodic scans, the cost of scans, and the cost of treatment, not to mention the environmental cost of radioiodine dumped into sewage systems. (As discussed further in item 9 below, the staff acknowledged in 1984 that the $20,000 figure for "a nodule" was low by a factor of 5.) Because I am a patient at NIH and do not pay for my medical treatment, I cannot offer an estimate of the full costs involved, but the American Thyroid Association or such experts as Dr. Jacob Robbins of NIH might be able to offer an estimate.

5. I believe that the staff's estimates of the likelihood that thyroids will be ablated in an accident (and thus rendered at no risk from nodules or cancer) are wishful thinking in the extreme. First of all, it takes a lot of iodine to ablate a thyroid, as I know from personal experience of receiving ablating doses. Secondly, even those persons whose thyroids were theoretically ablated by the iodine received in an accident would need medical followup on a regular basis.

6. I see innumerable problems with predistribution of potassium iodide. This differing professional opinion is directed solely to the merits of stockpiling.

7. Even if the outcome of the staff's analysis is that the use of potassium iodide is not justifiable on a cost-benefit basis, the Commission and the public should be aware that by the same test, much if not all of what the NRC requires in the area of emergency planning would not be justifiable. Rather, such measures are required because the Commission made a policy decision that it was prudent and responsible to have emergency planning measures in place. Both the ACRS and OPE raised the objection, when the potassium iodide issue came up five years ago, that other emergency planning requirements would also fail the cost-benefit test, but that objection was never answered, to my knowledge. When the NRC says that a particular emergency planning measure, such as potassium iodide, is not cost-effective, it is implicitly suggesting that those emergency planning measures which are required do meet the test of cost-effectiveness. The Commission, the public, and the states -- which must decide for themselves whether to stockpile potassium iodide -- should be aware that this is not the case.

8. I understand from Dr. Robbins of NIH that the international thyroid community is eagerly awaiting the results of studies on adverse side effects of the the millions of doses of potassium iodide administered in Poland after Chernobyl. These studies might well affect the judgment of whether potassium iodide is desirable.

9. I believe that when the costs and benefits of potassium iodide are recalculated along the lines indicated above, the disparity between costs and benefits will be much smaller than the staff represented to the Commission at the 1983 briefing. (In effect, the Commission was being told that the benefit was virtually zero.) But even if costs are still found to exceed benefits in some measure, that does not mean that it would not be desirable to stockpile potassium iodide, simply as a matter of prudence. For example, earlier this summer the NRC issued a notice to all employees warning them to buy sun block and use it to prevent skin cancer. As far as I know, this was not based on any cost-benefit analysis of the cost of sun block compared to the risks of skin cancer, or the number of days lost if one develops skin cancer. Rather, this was based on a common-sense judgment that if it is easy and cheap to prevent a certain kind of cancer, it makes sense to do so. I think the NRC owes the public the same kind of common-sense approach with regard to radiation from nuclear accidents that it provides to its employees with regard to radiation from the sun.

10. Even if the NRC's bottom line remains the same -- that potassium iodide is not desirable -- the scientific and policy basis for that judgment should be valid. As I have described in my differing professional opinion of June 16, the staff acknowledged five years ago that the $20,000 figure was in error by a factor of 5, but did not change the underlying document because changing it would not have altered the ultimate conclusion that potassium iodide was not worthwhile. I disagree with that approach. I believe that it is essential not only that the bottom line be correct, but that the pathway to that bottom line be correct. We have no way of knowing the extent to which states and other federal agencies relied on elements in that pathway rather than simply on the bottom line. To the extent that the NRC has disseminated incorrect information in the past, either in public documents or in public briefings, I think we have an obligation to correct the record, and to do so loudly and clearly.

: Hugh Thompson

ENCLOSURE 3

NOV 9 - 1989

NOTE TO: Themis P. Speis, DD:GI/RES

FROM: Alan K. Roecklein, RPHEB/DRA/RES

SUBJECT: INFORMATION REQUESTED RE: KI

During discussions regarding Mr. Peter Crane's DPO on the agencies position on use of potasium iodide you requested that I find information on several questions that were raised. The questions and findings are as follows:

1. What is the current cost of KI tablets?

   On 9/8/89, I spoke with Ms. Patricia Hendrickson of Wallace Laboratories (609-655-6146). Wallace Labs market "Thyrobloc," 130 mg KI tablets. The quoted price for 1 case, containing 100 vials, each with 14 tablets was $75.00. This represents a cost of approximately 5 cents per tablet.

2. What is the current cost of treating a tyroid nodule?

   On 8/28/89, I talked with Dr. David Becker, a member of the Thyroid Health Effects Committee of the American Thyroid Association (212-746-4583). Dr. Becker said that 20-30 thousand dollars was still a reasonable estimate because current diagnostic and treatment techniques have kept costs down. For example, needle biopsy is now used in most hospitals, and nodule surgery is now usually performed on an outpatient basis.

   Dr. Becker volunteered the information that the thyroid Association supported stockpiling of KI, and that the thyroid cancer incidence numbers used earlier by the NRC were now believed to be too high. He referred us to several technical papers on the subject.

2pp

3. What is the dose required to ablate the thyroid?

I spoke with Dr. Shlomo Yaniv who reviewed the findings on this issue as published recently in NUREG/CR-4214, Rev. 1, Part II. It is well known that large doses to the thyroid can ablate it, but the available data are insufficient for development of a dose-effect relationship.

There are only a small number of euthoiroid (normal) people treated with radioiodine (cardiac patients). In one study, it was found that at least 27,000 rads was required to obtain total ablation of the thyroid within one year after exposure. In another study, a mean dose of about 49,000 rads was required to ablate the thyroids of 65 euthoiroid adult cardiac patients.

Alan K. Roecklein
RPHEB/DRA/RES

cc: LSoffer NLS-32
FCongel
PCrane

DEC 8 - 1989

NOTE TO: T. Speis, DD/RES

FROM: S. Yaniv, RPHEB/DRA/RES

SUBJECT: RISKS ASSOCIATED WITH THYROID IRRADIATION

I. Lifetime risk following ^{131}I exposure.

a) Thyroid cancer

The best estimate of lifetime thyroid cancer risk for U.S. population following ^{131}I exposure is 24 cases per 10^6 person.rad. This is the central estimate in NUREG/CR-4214. Rev. 1, 1989, and is based on linear non-threshold dose response model. The mortality from thyroid cancer is believed to be 10 percent

b) Benign thyroid nodules

The estimate of lifetime risk of benign thyroid nodules following exposure to ^{131}I for U.S. population is 54 cases per 10^6 person.rad.

c) Hypothyroidism

Hypothyroidism is most certainly a threshold effect. The best estimate for threshold in case of ^{131}I exposure is 1000 rad. The lifetime risk, above threshold, is estimated as 17 cases per 10^6 person.rad.

11 pp.

II. Lifetime risk following exposure to external radiation or to ^{132}I, ^{133}I, or ^{135}I.

a) Thyroid cancer

The risk of thyroid cancer is three times higher than from I^{131} i.e., 72 cases per 10^6 person.rad.

b) Benign thyroid nodules

The risk of thyroid nodules is five times higher than from ^{131}I i.e., 268 cases per 10^6 person.rad.

c) Hypothyroidism

The risk of hypothyroidism is five times higher than from ^{131}I i.e.,

threshold: 200 rad and
83 cases per 10^6 person.rad above threshold

The above risk values apply to population composed of both genders and all ages. In general, children are more sensitive than adults and females more sensitive than males.

S. Yaniv
RPHEB/DRA/RES

Simplified Cost-Benefit Analysis Regarding Stockpiling of KI

1. Using WASH-1400 (Ref. 1), it is estimated that the probability of a large accidental release is about 10^{-5} per reactor -yr.

2. Assume 100 reactors in U. S.

3. Therefore, the probability of a large release per year somewhere in the U. S. is 10^{-5}/RY x 100 reactors = 10^{-3} per year.

4. From data in the Strip report (NUREG/CR-2723) (Ref. 2) a large release is calculated to result in a whole body dose of about 10^{7} man-rem, for a typical U. S. site.

5. From staff experience with preparation of environmental impact statements (EIS), the thyroid dose is about an order of magnitude greater than the whole body dose, for a large release. Therefore, a large release will result in 10^{8} man-rem to the thyroid for a typical site.

6. The average thyroid dose is then

$$10^{8}\ \frac{\text{man-rem}}{\text{release}} \times 10^{-3}\ \frac{\text{release}}{\text{yr.}} = 10^{5}\ \frac{\text{man-rem}}{\text{yr.}}$$

7. The above estimate is based upon the release fractions of WASH-1400, which estimated releases averaging 50% of the core iodine inventory for core-melt atmospheric releases (equivalent to core-melt with early containment failure). NUREG-1150 (Ref. 3) has estimated that such releases would be lower and would average about 10 to 20% of the core iodine inventory. This is about a factor of three lower. Consequently, using the NUREG-1150 release fractions which are based upon the best available research information to date, the average thyroid dose is estimated to be

$$\frac{1}{3} \times 10^{5} = 3.3\text{x}10^{4}\ \frac{\text{man-rem}}{\text{yr.}}$$

8. WASH-1400 used risk coefficients of 334 thyroid nodules per 10^{6} man-rem, 200 of which were benign thyroid nodules and 134 were thyroid cancers. WASH-1400 also assumed that 10% of the cancers would result in fatalities. The thyroid cancer risk coefficient of WASH-1400 is no longer considered valid. Instead, the values given in NCRP Report No. 80 (Ref. 4), namely, 74 thyroid cancers per 10^{6} man-rem (thyroid) is regarded as the best available data.

9. Then, using risk coefficients of 200 benign thyroid nodules/10^4 man-rem, and 74 thyroid cancers/10^4 man-rem with 10% of the cancers resulting in fatalities, the average number of health effects per year becomes

$$200 \frac{\text{benign nodules}}{10^4 \text{ man-rem}} \times 3.3 \times 10^4 \frac{\text{man-rem}}{\text{yr.}} = 6.6 \frac{\text{benign nodules}}{\text{yr.}}$$

plus

$$74 \frac{\text{thyroid cancers}}{10^4 \text{ man-rem}} \times 3.3 \times 10^4 \frac{\text{man-rem}}{\text{yr.}} = 2.44 \frac{\text{thyroid cancers}}{\text{yr.}}$$

and 10% of the cancers, or 0.25 fatalities per year, are predicted.

10. In addition to these health effects, hypothyroidism must also be considered, as well. From information taken from NUREG/CR-4214 (Ref. 5), the risk coefficient for hypothyroidism is 17 cases per 10^4 man-rem (thyroid), with a threshold dose of 1000 rad (10 Gy) of occurrence.

11. Since hypothyroidism has a relatively high threshold for occurrence, it will occur over a limited area. NUREG-CR/1443 (Ref. 6) presents data showing that the average thyroid dose for a core-melt atmospheric release is equal to or greater than 1000 rem out to about 25 miles from the reactor. Since the analysis in NUREG-CR/1443 made use of WASH-1400 release fractions, the average doses should be reduced by about a factor of three to be in agreement with the results of NUREG-1150. With this correction, thyroid doses equal to or in excess of 1000 rem would be confined, on average, to distances of about 10 miles from the reactor.

12. Using demographic data from NUREG-0348 (Ref. 7), the average population within ten miles of a U. S. reator is 37,000 (1970 census). Adjusting for the 1980 census, this is estimated to be 40,000 persons.

13. The average number of cases of hypothyroidism per year can now be estimated. Given a large release, the average dose in the region from the reactor out to 10 miles is expected to be about 2000 rem to the thyroid (using data from Ref. 6 and adjusting for the reduced release fractions of NUREG-1150, Ref. 3). Although the average population within 10 miles is 40,000 persons, only a small fraction would be exposed to the plume of a release. Generally, estimates are that no more than about 3 sectors, each comprising 22 1/2 degrees, would

be exposed to the plume. Since there are a total of 16 such sectors, the affected population is $\frac{3}{16} \times 40{,}000 = 7500$ persons.

The total population dose is 7500 persons x 2000 rem = 15×10^6 man-rem and the number of cases of hypothyroidism, given a large release, is

$$\frac{17}{10^6 \text{ man-rem}} \times 15 \times 10^6 \text{ man-rem} = 255 \text{ cases}$$

Since the probability of a large release is 10^{-3} per yr., the average number per year is

$$255 \times 10^{-3} = 0.255 \text{ or } 0.26 \frac{\text{cases}}{\text{yr.}} \text{ hypothyroidism}$$

(Actually, this is likely an overestimate. If a timely evacuation is carried out, the number of persons exposed would be much lower. Since this is difficult to estimate with precision, however, the above estimate will be used despite its conservatism.)

14. Taking values of $25,000 for the cost of treatment for benign nodules (Ref. 8); $50,000 for the cost of treatment of thyroid cancers (non-fatal); $50,000 for the cost of treatment for hypothyroidism (Ref. 9) and $1,000,000 for the cost of a cancer fatality, the average costs per year become

6.6 x $25,000 = $165,000 (benign nodules)

2.19 x $50,000 = $109,500 (non-fatal cancers)

0.25 x $1,000,000 = $250,000 (cancer fatalities)

0.26 x $50,000 = $13,000 (hypothyroidism)

Total = $537,500 per year

15. The number of thyroid health effects predicted and the associated costs to society shown above assume that no protective measures are taken to reduce or avoid such exposures. However, a range of protective measures (other than use of KI), including evacuation, sheltering and avoiding the consumption of contaminated food and water are included in emergency plans, would likely be taken, and would significantly reduce radiation exposure not only to the

thyroid gland but to other body organs as well. Consequently, the thyroid costs shown above are significantly overestimated, probably by a factor of from two to ten times. Using a factor of two reduction, the total thyroid costs to society (assuming other protective measures) are estimated to be 1/2 x 537,500 $/yr. = 270,000 $/yr. (approx.)

16. Assume that KI is to be stockpiled at a number of locations throughout the U. S. and is to be distributed to the affected populace after an accident and that the number of locations is sufficient that KI could be distributed to the general public within a few hours after an accident.

17. Representatives of the American Thyroid Association have stated (Ref. 10) that clinically significant thyroid disease appears unlikely to result from individual thyroid exposures of less than 100 rads. To provide an added measure of protection for children and pregnant women, however, the authors of Ref. 10 suggest a radiation dose of 50 rads to the thyroid as a threshold for iodine blockade for this group.

18. Based on thyroid dose vs. distance data presented in Ref. 6 Table 3, (and with correction for NUREG-1150 reductions) doses in excess of about 50 rad for a child would be expected at distances up to about 100 miles from a reactor.

19. If KI is to be distributed to children and pregnant women, it is not likely that it could practically be withheld from the general population, in an emergency. It is assumed, therefore, that KI will be stockpiled in sufficient quantities to be distributed to the general population within 100 miles of a nuclear power reactor.

20. Based on the analysis of Ref. 11, it is estimated that 67 percent of the U. S. population resides within 100 miles of a nuclear power plant. Using 1980 census data, KI must be stockpiled for $0.67 \times 226 \times 10^6 = 151 \times 10^6$ persons.

21. Ref. 12 indicates that in a reactor emergency KI will be taken for a minimum of several days and for a maximum of ten days. Assuming stockpiling for a minimum of three days, with a usage of one KI tablet per day, the number of KI tablets to be stockpiled is $151 \times 10^6 \times 3 = 453 \times 10^6$.

22. The cost of KI is taken as $0.05 per tablet (Ref. 13). (The actual costs are likely higher since this reflects only the cost of KI tablets in bulk. Not only have warehousing,

distribution and inventory control costs have neglected, but the need for rapid distribution at the time of an accident would suggest that KI tablets should be pre-packaged in readily dispensable individual packets containing 3 tablets each. The cost of such packaging has also been neglected.)

23. The cost of stockpiling KI then becomes 151 x 10^6 persons x

$$\frac{3 \text{ tablets}}{\text{person}} \times .05 \frac{\$}{\text{tablet}} = 2.27 \times 10^7 \$$$

Since the tablets should be replaced every 3 years (Ref. 12) the annual cost is one-third of this or 7.5×10^6 $/yr.

24. Timing is critical in the effectiveness of KI as a blocking agent. If KI is given 4 hours after intake of radioiodine, then its effectiveness is sharply reduced (about 10-30% blocking). It is difficult to quantify the time delay associated with stockpiling. If KI is available to evacuees at relocation centers and other places within 3 to 4 hours after accident initiation, and if accident releases occur primarily after several hours warning, then this may be effective. For fast acting scenarios this may not be the case. Overall, it is estimated that stockpiling will result in a time delay sufficient to reduce the blocking effectiveness to 50% of what it would be if each individual had KI in his possession prior to an accident (predistribution). (For a blocking effectiveness of 50% to be achieved, KI must be received by individuals no later than about 2 hours after the release of iodine begins.)

25. The cost/benefit results are summarized below

Cost of KI = 7.5×10^6 $/yr.

Benefit of KI = 1.4×10^5 $/yr. (using a best estimate blocking value of 50%, and assuming other protective measures)

26. Additional calculations displaying the sensitivity of the benefits of KI to the assumptions used are shown on the following page.

Conclusion: Stockpiling of KI is not cost beneficial.

Cost/Benefit Summary for Stockpiling KI

Cost of KI = 7.5×10^4 $/yr.

Benefits	Reduced Blocking (50%)	Unreduced Blocking (100%)
NUREG-1150 release fractions	1.4×10^5 $/yr.* ($2 \times 10^5$ $/yr.)**	2.7×10^5 $/yr. ($4 \times 10^5$ $/yr.)
WASH-1400 release fractions	4.1×10^5 $/yr. ($6 \times 10^5$ $/yr.)	8×10^5 $/yr. ($1.2 \times 10^6$ $/yr.)

* Best estimate value. The benefits would be increased by a factor of two if no other protective actions (evacuation, sheltering, food interdiction) are taken.

** The values in parentheses make use of the thyroid cancer risk estimates of Wash-1400, rather than those given in NCRP Report No. 80. See Note 1 for further details.

Note 1 - Risk of Thyroid Cancer

Wash-1400 used a risk coefficient of 334 thyroid nodules per 10^6 man-rem (to the thyroid). WASH-1400 also assumed that 60% of the nodules produced were benign, 40% were cancerous, and that 10% of the cancerous nodules (4% of the total nodules) would result in fatalities. The WASH-1400 risk coefficient for thyroid cancer is therefore 0.4 x 334 or 134 thyroid cancers per 10^6 man-rem (thyroid).

This value was re-examined in light of recent information that was unavailable to the authors of SECY-83-362. Two sources were used. The first was a Swedish study by Holm, et. al. "Thyroid Cancer after Diagnostic Doses of Iodine-131: A Retrospective Cohort Study", reported in the Journal of the National Cancer Institute, Vol. 80, No. 14, September 21, 1988. The second source was "Introduction of Thyroid Cancer by Ionizing Radiation," National Council on Radiation Protection and Measurements (NCRP), Report No. 80, March 30, 1985. Holm studied 35, 074 patients in Swedish hospitals receiving doses of I-131 and included a 20 year followup. The average thyroid dose per patient was stated to be 50 rads. The collective population dose was 35,074 x 50 or 1.75 x 10^6 person-rad. The total number of thyroid cancers observed in this therefore 29 thyroid cancers/10^6 man-rem, or about a factor of four less than that used in Wash-1400.

NCRP Report No. 80 gives an absolute thyroid cancer risk of about 72 to 74 cases per 10^6 person-rad. This value is stated to be based on population studies of North Americans exposed to external radiotherapy in childhood. This risk estimate is also considered to be applicable for thyroid doses in the range from 6 to 1500 rads. This value is about a factor of two less than that used in WASH-1400.

References

1. U. S. Nuclear Regulatory Commission (USNRC), "Reactor Safety Study - An Assessment of Accident Risks in U. S. Commercial Nuclear Power Plants," WASH-1400 (NUREG/75-014), October 1975.

2. D. R. Strip, "Estimates of the Financial Consequences of Nuclear Power Reactor Accidents", Sandia National Laboratories, NUREG/CR-2723, September 1982.

3. USNRC, "Severe Accident Risks: An Assessment for Five U. S. Nuclear Power Plants", Second Draft for Peer Review, NUREG-1150, June 1989.

4. National Council on Radiation Protection and Measurements (NCRP)," Induction of Thyroid Cancer by Ionizing Radiation", NCRP Report No. 80, March 1985.

5. S. Abrahamson, et. al., "Health Effects Models for Nuclear Power Plant Accident Consequence Analysis", Part II: Scientific Bases for Health Effects Models, Sandia National Laboratories, NUREG/CR-4214, May 1989.

6. D. C. Aldrich, R. M. Blond, "Examination of the Use of Potassium Iodide (KI) as an Emergency Protective Measure for Nuclear Reactor Accidents", Sandia National Laboratories, NUREG/CR-1433, March 1980.

7. USNRC, "Demographic Statistics Pertaining to Nuclear Power Reactor Sites", NUREG-0348, October 1979.

8. Telephone call from A. K. Roecklein to D. Becker, Memorandum from Alan K. Roecklein to Themis Speis, November 9, 1989.

9. Personal communication, M. Fleishman to L. Soffer, November 30, 1989.

10. D. V. Becker, et. al., "The Use of Iodine as a Thyroidal Blocking Agent in the Event of a Reactor Accident", Journal of the American Medical Association, Vol. 252, No. 5, August 1984.

11. L. Soffer, personal analysis, November 29, 1989.

12. D. V. Becker, "Physiological Basis for the Use of Potassium Iodide as a Thyroid Blocking Agent-Logistic Issues in its Distribution", Bulletin of the New York Academy of Medicine, Second series, Vol. 59, No. 10, December 1983.

13. Telephone call from A. K. Roecklein to P. Hendrickson, Memorandum from Alan K. Roecklein to Themis Speis, November 9, 1989.

January 4, 1990

MEMORANDUM FOR: Hugh L. Thompson, Jr.
Deputy EDO for Nuclear Materials
Safety, Safeguards, and
Operations Support

FROM: Peter Crane

SUBJECT: PANEL REVIEW OF DIFFERING PROFESSIONAL OPINION ON THE STOCKPILING OF POTASSIUM IODIDE

I have received the report of the review panel that considered my DPO on potassium iodide. The first thing to be said is that the panel has obviously taken the assignment seriously, and has expended considerable time and effort coming up with its reevaluation of the costs and benefits of potassium iodide. Though as described below I believe that the panel has interpreted its charter with undue narrowness, that is not intended as a reflection on the competence or integrity of the analysis that the panel performed.

The panel finds that the ratio of costs to benefits is not 500 to 1 ($10,000,000 to $20,000), as the staff told the Commission in 1983, but perhaps as low as 6 to 1 ($7,500,000 to $1,200,000). It would be still lower but for the fact that (1) NUREG-1150 has reduced, by a factor of three, the estimated amount of iodine released in an accident, and (2) the panel calculates that 150,000,000 doses of KI would have to be stockpiled, a figure that strikes me as probably excessive. The review panel proposes to share this information with the states and other federal agencies.

To interpret the DPO as challenging the accuracy of the cost-benefit analysis in NUREG-CR-1433 is certainly correct. To interpret it as requesting no more than a recalculation of the cost-benefit analysis in that document is in large measure to miss the point, however. I had hoped to prevent just such a misunderstanding by itemizing my concerns in a brief supplementary memorandum to the members of the review panel, dated July 25, 1989.

I don't propose to rehash here everything in the DPO or the July 25 memorandum. Both those documents are in the package sent you by the review panel. Briefly, the crux of the DPO was the contention that the information on KI that was given to the Commission and the public in 1983, and was in part the basis of the Commissioners' policy decision, was baloney. If the panel does not deal with that contention it has only done part of its job.

The review panel states correctly: "A major point of this DPO ... appears to be that previous staff analyses neither explicitly noted nor adequately treated the fact that a fraction of the thyroid nodules produced as a result of an accidental release of iodine could result in cancers, with a small fraction of these predicted to result in fatalities." What I do not see is the panel's explicit finding as to whether this claim was valid. The revised cost-benefit calculation seems to imply agreement with the claim, but at the same time, the panel recommends that current Federal guidance, which among other things refers states and localities to the cost-benefit analysis of NUREG-CR-1433, should remain unchanged. Which is it? If nothing else, any further guidance the NRC puts out on the subject of potassium iodide ought to be clear.

I would also note that the panel's estimate rests on the supposition, derived from the Reactor Safety Study, that a large release will occur no oftener than once every thousand years (assuming 100 reactors). There is no discussion of the error bounds on that estimate -- in contrast to NUREG-CR-1433, which noted (1) that the Reactor Safety Study used error bounds of one-fifth and five, and (2) that the 1978 Lewis Committee concluded that those error bounds were "greatly understated."

The panel offers no satisfactory answer to the point made by the ACRS and OPE in 1983: that if the probability of a large release is so small, not only KI but other aspects of emergency planning -- sirens, drills -- might fail the test of cost-effectiveness. To say that KI is not cost-effective and recommend against it on that basis is to create the misimpression that other kinds of emergency preparedness do pass the cost-effectiveness test.

The panel notes that KI has to be administered before or a few hours after exposure to be useful. That is true; but it should be recalled that, as with the Poles after Chernobyl, some time may elapse between the release from the plant and the arrival of the plume at a particular populated area.

There is one other common sense point that is perhaps too obvious to need stating: that when you are talking about serious disease, a straight dollar-for-dollar balancing of the cost of prevention against the cost of treatment makes no sense at all. The cost-benefit analysis presented to the Commission in 1983 was premised, however, on the contrary notion: that it is not cost-effective for society to spend a penny more than $20,000 to prevent a case of disease that can be treated at a cost of $20,000. But what individual would consider having a serious illness, with someone else paying the bills, to be just as satisfactory as having good health? No one, of course. By the same token, therefore, why is it not reasonable for society to spend more on

preventing 100 cases of cancer than the precise dollar cost of treating those 100 cases if instead of being prevented they are allowed to occur?

Finally, there is a point contributed by Dr. David Becker of the American Thyroid Association, whom the panel consulted as part of their review of the DPO. He observed that if an accident occurs and competent authorities decide that use of KI is not warranted, that decision will have credibility only if there is a stockpile of KI that could be used.

In closing, I would like to go on record as stating that my DPO was handled in a competent professional manner and that the panel carefully addressed the basic technical issues that I raised. Although the panel still concludes that application of KI is not cost effective, I am gratified that the panel's conclusions support my assertion that the staff's prior characterization grossly understated the worth of KI. It is important that this significant change in the staff's technical assessment be reported to the Commission, and I agree with the panel's recommendation that the information developed by the panel be provided to the states and other interested federal agencies. (I assume that the panel contemplates making the information available to the public at the same time.) One means of providing this information would clearly be to revise NUREG-CR-1433, but this might be unduly time-consuming. I would leave it to the judgment of the Commission how best to assure that the record is promptly corrected.

cc: T. Speis
F. Congel
L. Soffer
A. Roecklein

Hugh --

attached is what I received from David Becker. He also informed me that the World Health Organization has been developing a position paper and recommendation on thyroid blocking with KI.

1988 1989

THE AMERICAN THYROID ASSOCIATION
GRAVES
1796 - 1853
INCORPORATED
FOUNDED 1923

27 November 1989

Alan Roecklein, M.D.
Radiation Protection-Health Effects Branch
USNRC
5650 Nicholson Lane
Rockville, MD 20852

Dear Dr. Roecklein:

The American Thyroid Association has for some time monitored the problem of potential radioiodine contamination of the atmosphere in the event of a nuclear reactor core melt accident. There has been concern about the possibility of radioiodine in the fallout accumulating in the thyroid gland and irradiating it, with the potential of causing thyroid neoplasms and hypothyroidism.

Potassium iodide (KI), by blocking radioiodine uptake by the thyroid gland, has a radioprotective effect. However, there are a number of significant difficulties in using KI for this purpose.

The American Thyroid Association has re-examined the issues involved in stockpiling KI for use in the event of a reactor accident. The attached statement is an update of a previous published analysis of this complex situation (Journal of the American Medical Association, 1984; 252:659). It is hoped that this statement will generate renewed consideration of this complex problem.

Sincerely yours,

John Wilber, M.D.
President, A.T.A.

Leonard Wartofsky, M.D.
Secretary, A.T.A.

Chairman, Public Health Committee
David S. Cooper, M.D.
Johns Hopkins University

David Becker, M.D.
Cornell University

9403150043

2pp.

Statement on Potassium Iodide Stockpiling

American Thyroid Association

The recent reactor accident at Chernobyl in which large amounts of radioactive iodine were released into the atmosphere again raised questions about proposed methods of protecting those at risk of exposure. In a previous statement (JAMA 1984, 252:659), the American Thyroid Association (ATA) reviewed the scientific information available about the usefulness of potassium iodide (KI) as a blocking agent to prevent radioactive iodine from entering the thyroid gland of those exposed to fallout. It also reviewed available data about the possible effects on the thyroid of low level radiation from radioiodine as well as the potential toxic side effects of distribution of potassium iodide to large unsupervised populations.

It was concluded at that time that information necessary for the development of a suitable public health strategy required risk/benefit data (ratio of the risk of the hazards of radioiodine to those of stable iodine administration) but that such information was not then available. The ATA is aware of no new information altering the issues raised at that time.

It was concluded in that report that, although the general distribution of KI was not recommended except in special locations and under special circumstances, advanced planning for possible distribution was advisable and it urged that a national task force of specialists be convened to review the issues in KI distribution and to develop alternate national distribution strategies for consideration.

As best as can be determined at this time, no substantial stockpile of potassium iodide is available for public use. Despite the unlikely event of an emergency requiring its use, the ATA believes that the option of potassium iodide distribution should be available for consideration to those responsible for public health measures. To this end, the ATA believes that it would be prudent to have available at central locations a suitable stockpile of KI for possible distribution should its use be contemplated.

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

9403300313

PDR

SIP

"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.

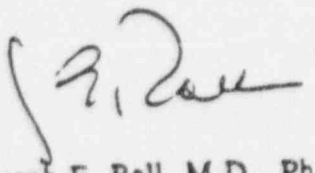
In our original comments NIH expressed the opinion that the implementation of the rule for NRC medical and medical research licensees could have an impact on patients and could result in an increase in mortality for both hyperthroidism and thyroid carcinoma. The NIH was not alone in expressing this opinion; 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