MINISTERE DE L'INDUSTRIE, DE LA POSTE ET DES TELECOMMUNICATIONS

GROUPE PERMANENT
CHARGÉ DES RÉACTEURS
NUCLÉAIRES

GPR/96-17

Fontenay-aux-Roses, May 7th, 1996

Mr John T. LARKINS
Executive Director

Advisory Committee on Reactor Safeguards
WASHINGTON D.C. 20555

Dear Mr LARKINS,

By a letter referenced January 17, 1996, the chairman of ACRS suggests to hold next October a Quadripartite Meeting of the Nuclear Safety Advisory Committees of France, Germany, Japan and USA, in the same way as the Quadripartite Meeting held in Luynes in October 1993.

The French Advisory Committee agrees to participate in such a meeting; nevertheless, for a good preparation of the meeting, it would be advisable to postpone it in 1997. It appears necessary to define first the issues to be developed during the meeting; the GPR proposes to include in these issues the safety of future PWR plants, the fuel behaviour under reactivity induced accident situations, the assessment of computerized instrumentation and control systems and the risks linked to shutdown situations. A preparatory meeting could be held between representatives of the four Advisory Committees before the end of 1996 to define the precise program of the meeting.

I send copy of this letter to Mr TOGO and to Mr BIRKHOFER.

Sincerely yours,

F. COGNÉ

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CEA-FAR - B.P. n° 6 - 92265 FONTENAY-AUX-ROSES CEDEX - TÉL. : (1) 46.54.73.01

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

April 22, 1996

MEMORANDUM TO: Carl J. Paperiello, Director
Office of Nuclear Material Safety and Safeguards

Edward L. Jordan, Director
Office of Analysis and Evaluation
of Operational Data

William T. Russell, Director
Office of Nuclear Reactor Regulation

James Lieberman, Director
Office of Enforcement

Richard L. Bangart, Director
Office of State Programs

William J. Olmstead, Associate General Counsel
for Licensing and Regulation
Office of the General Counsel

FROM: David L. Morrison, Director
Office of Nuclear Regulatory Research

SUBJECT: OFFICE REVIEW AND CONCURRENCE ON A RE-EVALUATION OF THE POLICY REGARDING USE OF POTASSIUM IODIDE AFTER A SEVERE ACCIDENT AT A NUCLEAR POWER PLANT

Your concurrence is requested on the attached Commission paper.

1. Title: Re-evaluation of the Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant.

2. Task Leader: Mike Jamgochian, DRA/RES, (415-6534)

3. Cognizant Individuals: Stuart Treby, OGC
Falk Kantor, NRR

4. Requested Action: Concurrence

5. Requested Completion Date: 30 days after signature

6. Background: In 1989, a Differing Professional Opinion (DPO) was filed by a member of the NRC's, Office of the General Counsel staff requesting a re-evaluation of the NRC policy regarding the use of potassium iodide (KI) after a severe accident at a nuclear power plant.

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In SECY-93-318 (November 23, 1993) and SECY-94-087 (March 29, 1994), the staff presented its recommendation to resolve the DPO. The staff's recommendation was that the NRC, in coordination with HHS and FEMA, revise current Federal KI policy to make KI available to the States. The revised policy would read: "Although a reactor accident requiring KI is unlikely and KI is only effective as a protective measure for the dose to the thyroid from radioactive iodine, the cost to purchase and stockpile amounts sufficient to administer to populations within 5 miles of operating nuclear power plants is relatively low. Consequently, it appears prudent to stockpile KI for limited populations located close to the operating nuclear power plants."

Additionally, the staff recommendation included a commitment that the NRC staff would work directly with FEMA and HHS to revise the Federal policy regarding stockpiling KI for possible use in a radiological emergency. The revised policy would state that KI will be purchased by the Federal Government (most likely the NRC or FEMA) and made available through FEMA to the States. While NRC would encourage the stockpiling of KI, the decision to stockpile, distribute, and use KI would be the responsibility of the individual States' emergency planning authorities. At the option of the States, procedures incorporating the use of KI in State emergency plans would be developed and coordinated through the Federal Radiological Preparedness Coordinating Committee.

The Commission's vote on the above staff recommendation was divided 2 to 2, and under NRC internal procedures, a tie vote on a proposal means that it fails. There was, therefore, no decision on the merits of the NRC staff's recommendation.

On September 9, 1995, a petition for rulemaking (PRM-50-63) was submitted to the NRC by Mr. Peter Crane (the same individual who filed the DPO in 1989) requesting a rulemaking to implement the recommendation of the President's Commission on the Accident at Three Mile Island (Kemeny Commission) that the United States stockpile the drug potassium iodide for thyroid protection during nuclear accidents.

On November 27, 1995, a Notice of Receipt of the Petition for Rulemaking was published in the Federal Register (60 FR 58256), requesting public comments by February 12, 1996. To date, 59 comment letters have been received and are evaluated in the attached Commission paper. In parallel with evaluating the merits of the petition for rulemaking (PRM-50-63), the staff has developed this Commission Paper that integrates and updates the information contained in SECY-93-318 and in SECY-94-087 and recommends the same Commission action. Therefore, in accordance with Chapter III of the Commission's internal procedures relating to voting, the staff requests the Commission to revisit the NRC policy regarding the use of potassium iodide.

7. Resources to implement this Policy are not included in the FY 1995 - 1999 Five-Year Plan. A copy of this concurrence package has been forwarded to the Office of the Controller for coordination of resource issues per the EDO memorandum of June 4, 1991.

Attachment:
Commission Paper w/atts.

cc w/atts.:
R. Scroggins, OC
L. J. Norton, OIG
J. Larkins, ACRS
E. Jordan, CRGR
F. Congel, AEOD

FOR: The Commissioners

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: EVALUATION OF POLICY REGARDING USE OF POTASSIUM IODIDE AFTER A SEVERE ACCIDENT AT A NUCLEAR POWER PLANT

PURPOSE:

To obtain Commission approval of a change in the NRC policy regarding the use of potassium iodide (KI) as a radioprotective agent for the general public.

BACKGROUND:

In 1989, a Differing Professional Opinion (DPO) was filed by a member of the NRC's Office of the General Counsel staff requesting a re-evaluation of the NRC policy regarding the use of potassium iodide (KI) after a severe accident at a nuclear power plant.

In SECY-93-318 (November 23, 1993) and SECY-94-087 (March 29, 1994), the staff presented its recommendation to resolve the DPO. The staff's recommendation was that the NRC, in coordination with HHS and FEMA, revise current Federal KI policy to make KI available to the States. The revised policy would read: "Although a reactor accident requiring KI is unlikely and KI is only effective as a protective measure for the dose to the thyroid from radioactive iodine, the cost to purchase and stockpile amounts sufficient to administer to populations within 5 miles of operating nuclear power plants is relatively low. Consequently, it appears prudent to stockpile KI for limited populations located close to the operating nuclear power plants."

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Contact:
Mike Jamgochian, RES
415-6534

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revised policy would state that KI will be purchased by the Federal Government (most likely the NRC or FEMA) and made available through FEMA to the States. While NRC would encourage the stockpiling of KI, the decision to stockpile, distribute, and use KI would be the responsibility of the individual States' emergency planning authorities. At the option of the States, procedures incorporating the use of KI in State emergency plans would be developed and coordinated through the Federal Radiological Preparedness Coordinating Committee.

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In parallel with evaluating the merits of the petition for rulemaking (PRM-50-63), the staff has developed this Commission Paper that integrates and updates the information contained in SECY-93-318 and in SECY-94-087 and recommends the same Commission action. Therefore, in accordance with Chapter III of the Commission's internal procedures relating to voting, the staff requests the Commission to revisit the NRC policy regarding the use of potassium iodide.

PUBLIC COMMENTS:

On November 27, 1995, a Notice of Receipt of the Petition for Rulemaking was Published in the Federal Register (60 FR 58256), requesting public comments by February 12, 1996. A total of 59 comment letters were received, of which 20 utilities, 9 State governmental agencies, 2 Utility interest companies, 1 letter signed by 12 health physicists, 2 State Universities and 1 member of the public were against the granting of the petition for rulemaking. Those letters in favor of granting the petition came from 5 Environmental groups, 18 members of the public (including one from the petitioner), the American Thyroid Association and one video tape which was an enclosure to the letter from one of the environmental groups.

None of the State governmental agencies that commented on the petition for rulemaking were in favor of granting the petition.

Opposition for granting the petition for rulemaking could generally be characterized by the following comments:

1. "There is simply no conceivable means to distribute potassium iodide to potentially affected members of the public within the appropriate time after initiation of a hypothetical nuclear accident. Predistribution is completely out of the question, since there would be no means to control misuses, overdoes, shelf life, etc."

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2. "A radioactive release from a nuclear power plant that results in a substantial thyroid dose would undoubtedly include a significant whole body dose as well. Potassium iodide offers no protection for this dose. If plans were in place to administer potassium iodide to the public, the potential would be created for evacuation orders to be ignored due to perceived protection by potassium iodide."

3. "The logistics for advanced distribution of KI to the general public within the plume EPZ would require a significant initial and at least annual commitment of resources for a small increase in any potential dose savings. There are many questions and problems associated with advanced KI distribution that would need to be addressed to ensure its availability in an emergency. How to ensure distribution to 100 percent of all households (permanent, seasonal, and transient)? Would the KI be kept in the households? Could they locate it in a emergency? What percentage of households would have retained the KI after three months? six months? one year? Would 100 percent distribution to all households have to be made each year to ensure that a supply is available? What percentage of households would have to demonstrate ready availability to satisfy federal requirements? Who would assume liability if the KI was used prior to the Governor ordering its use?"

4. "Potassium iodide is a drug with side effects, some of which are profound. The following contraindications are listed in the medical literature: hypersensitivity to iodides, acute bronchitides, hyperthyroidism, Addisons's disease, acute or chronic renal disease, tuberculosis acute dehydration. The following precautions are listed in the medical literature: use cautiously or avoid use in patients with a history of thyroid disease; use care during initial administration of potassium iodide because of risk of hypersensitivity; persons with goiter or autoimmune thyroid disease are at particular risk for adverse reactions; administration of potassium iodide during pregnancy may cause fetal harm, abnormal thyroid function and goiter."

5. "If the Nuclear Regulatory Commission adopts a policy of issuance of KI to the general public as a protective action recommendation, it will be considered as being contrary to state policy and <u>will not be accepted</u>. This will have the net result of negating much of the planning and preparedness effort of federal, state and local governments since Three Mile Island."

6. "The added function of distributing KI during an evacuation will increase the time required to complete the evacuation. This increase in evacuation time during a release from a nuclear power plant will result in an increased radiation exposure to evacuees and emergency workers."

Support for granting the petition for rulemaking could generally be characterized by the following comments:

1. "A host of countries--France, Germany, Belarus, Russia, Switzerland, Austria, the Czech Republic, Japan, Britain, Sweden, Slovakis, and others--protect themselves with stockpiles of KI. Soaring rates of thyroid cancer are appearing in children in the Soviet Union who were

exposed to the Chernobyl nuclear accident, but received too little potassium iodide, and too late."

2. "If the World Health Organization recommendation is followed, and the drug is stockpiled locally in firehouses, police stations, etc., it should be possible to get the drug to much of the affected population within a short time after an accident. The EPA Manual quotes the Food and Drug Administration as stating that potassium iodide "will have substantial benefit even if it is taken 3 or 4 hours after acute exposure.""

3. "The U.S. is currently engaged in a $15 million study of radiation-caused thyroid disease in the Ukraine. I firmly believe that it is money well spent, but I can imagine how Americans would react, if there were ever a nuclear accident in this country, on learning that our Government was willing to spend millions to study radiation-caused thyroid disease abroad, while balking at spending a fraction of that amount to prevent radiation caused thyroid disease at home."

4. "If stockpiled potassium iodide were available, it could be given to members of the public to protect them during the evacuation -- but the current federal policy assures that this will not even be an option."

5. "Just because there are other lethal radionuclides to which people may be exposed, why deny them the availability of KI, which can counteract the deadly effects of radioactive iodine? That's like saying, "Don't ever make flu vaccine available because there are so many strains and they can mutate from year to year.""

6. "Every drug has contraindications and the potential for allergic reactions. In an emergency as dire as a reactor accident where people risk illness and death, a possible adverse reaction to KI seems relatively minimal, and people absolutely should have the choice of making an informed decision and assuming possible risk."

DISCUSSION:

The current Federal guidance to State and local governments on the distribution of potassium iodide was promulgated in 1985 by the Federal Emergency Management Agency (FEMA), 50 FR 30285, in its capacity as Chair of the Federal Radiological Preparedness Coordinating Committee (FRPCC). As described in FEMA's regulation, 44 CFR Part 351, the FRPCC was established to coordinate all Federal responsibilities for assisting State and local governments in emergency planning and preparedness for peacetime radiological emergencies. Fifteen Federal agencies participate in the FRPCC: FEMA, NRC, EPA, DHHS, DOE, DOT, USDA, DOD, DOC, DOI, DOS, DVA, GAS, NCE, and NASA. The NRC, as an FRPCC member, contributed an analysis (NUREG/CR-1433, "Examination of the Use of Potassium Iodide (KI) as an Emergency Protective Measure for Nuclear Reactor Accidents," October 1980), which examined the costs and benefits of using potassium iodide as a radioprotective agent for the general public. This analysis stated that using KI to prevent radioiodine from accumulating in the thyroid gland could be an effective ancillary protective action during a nuclear power plant release. It further stated, however, that many factors made stockpiling or predistributing potassium iodide for the

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general public questionable. Therefore, the FRPCC recommended stockpiling or distributing during emergencies for emergency workers and institutionalized persons, but did not recommend requiring stockpiling or predistribution for the general public.

In 1989, a member of the NRC's OGC staff, filed a Differing Professional Opinion (DPO) which alleged deficiencies in the original cost-benefit analysis (NUREG/CR-1433) provided to the FRPCC by the NRC. The DPO suggested that the discussion by the staff at a November 1983 Commission briefing on KI could have left Commissioners and members of the public with insufficient understanding of the nature of the adverse consequences (thyroid disease) that the use of potassium iodide could avert. The DPO also suggested that the cost-benefit analysis, by simply balancing the dollar costs of a KI program against the dollar costs of treating radiation-caused thyroid illness, gave inadequate consideration to the nonmonetary costs of having an illness.

As reported to the Commission in SECY-91-321, the DPO panel developed a simplified analysis of the value and impact of the potassium iodide policy, including revisions to several factors used in NUREG/CR-1433. The panel concluded that no change in the Federal policy was warranted. However, in order to take into account all the issues raised by the DPO, and to incorporate new data currently available for several of the factors used in the analysis, the Office of Nuclear Regulatory Research was directed to perform a detailed update of the NRC's potassium iodide policy basis, taking into account both qualitative and quantitative factors.

In September 1989, the American Thyroid Association (ATA) submitted a letter to the Chairman of the FRPCC requesting that the committee reconsider the issues involved in stockpiling KI. In a statement attached to the letter, the ATA proposed that:

> 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.

On the basis of the ATA letter and statement, the FRPCC asked the Department of Health and Human Services (HHS) to review the medical and clinical status of the use of potassium iodide. In an initial response to this request, HHS reviewed current scientific literature on potassium iodide and its use as a blocking agent. In February 1990, HHS reported to the FRPCC that no new scientific data had been found that would affect the basis for the 1985 guidance to not stockpile or predistribute KI for the public. To ensure a comprehensive review, HHS also decided to solicit, from appropriate organizations and individuals, new data, scientific opinions, and reports on the experience of States concerning potassium iodide use and distribution.

HHS convened a meeting of experts on July 24, 1990 in Atlanta, Georgia. In attendance were representatives of the State and Federal agencies responsible for medical research, drug regulation, and radiological emergency response;

representatives of medical associations; and nationally recognized experts in the fields of endocrinology and nuclear medicine. The meeting was chaired by Daniel A. Hoffman, Ph.D, M.H.P., Assistant Director for Science, Center for Environmental Health and Injury Control, Centers for Disease Control.

Dr. David V. Becker, M.D., a signatory to the ATA petition, was the principal spokesperson for that organization at the meeting. His 1987 paper, entitled "Reactor Accidents, Public Health Strategies and Their Medical Implications," was distributed to participants. It contains the following statements in its conclusions:

> For maximum effectiveness, KI must be taken immediately before or at the time of exposure, a requirement producing major distribution problems. The logistics of KI distribution are complex and seem to limit its use to special situations. Significant side effects can occur from iodide ingestion, although they are not likely to be frequent with the KI dose proposed. In most accident scenarios, the overall gain from KI use seems to be marginal.
>
> In considering KI use as a public health measure, we are confronted by the problem of establishing sound public policy in the absence of sufficient scientific information and in the face of conflicting and often unrealistic perceptions.

In October 1990, HHS made the following recommendations to the FRPCC:

1. The 1985 FRPCC guidance need not be changed at this time since no compelling evidence to support a modification was presented.

2. Existing stores of KI should be inventoried. The FDA would determine the locations and size of KI supplies by identifying large customers of KI manufacturers. The FRPCC should request that the Conference of Radiation Control Program Directors identify appreciable supplies of KI within the States by surveying State Radiation Control Programs.

3. The FRPCC should establish a working group to address the issue of stockpiling. Group objectives should be to:

   - Review and catalog type, location, and expiration of existing suitable supplies of KI.
   - Review and determine feasibility of specific stockpiling recommendations made by meeting participants.
   - Make final recommendations to FRPCC on U.S. Government KI stockpiling policy

In April 1992, a report entitled "An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident" was completed by S. Cohen & Associates under the sponsorship of NRC's Office of Nuclear Regulatory Research. A summary of the report is given in "Summary of Assumptions Made by and Results of the Potassium Iodide-Stockpiling Cost-Benefit Ratio Reanalysis." Provided to J.A. Rabb (HHS) and V. L. Wingert

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(FEMA) by H. L. Thompson, Jr., letter dated June 10, 1993, available from the Office of the Secretary and the Public Document Room. This provides a discussion of the various assumptions made in the analysis, including the assumption that stockpiled potassium iodide can be distributed to the population surrounding a nuclear power plant before that population is exposed to radioactive iodine. The analysis shows that the cost benefit ratio for use of potassium iodide by the general public approaches a value of two for the small percentage of the exposed population within 5 miles of a nuclear plant. The results also show that the cost/benefit ratio remains from 50 up to 10,000 or higher for the exposed population further than 10 miles from a nuclear plant.

In June 1993, the April 1992 report was provided to the representatives of FEMA and HHS who co-chair the FRPCC Potassium Iodide Subcommittee. The subcommittee reported on the NRC-sponsored analysis at a meeting of the FRPCC in September 1993. It recommended initiating two studies to secure State input on implementation strategies for providing KI to the public: (1) request the Conference of Radiation Control Program Directors (CRCPD) to survey those States with nuclear power plants for opinions regarding Federal purchase and stockpiling of KI and regarding the feasibility of States providing KI to the public under emergency conditions and (2) request the International Atomic Energy Agency to provide information on existing plans and procedures from member States related to the storage, distribution, and dosage of KI. The first study, which consisted of a survey of States in connection with a Federal purchase and stockpiling of KI, was completed in mid-1994. All 32 States with nuclear power plants responded, as well as 11 States without plants. In general, the responses were as follows:

	Yes	No
Does your State favor a Federal KI Stockpile?		
- States with nuclear power plants	7	25
- States without nuclear power plants	3	8
Total	10	33

The primary reason given by States for not supporting a Federal purchase and stockpiling of KI was that the State policy did not include KI as a protective measure for the general public. Their use of KI was specified only for emergency workers and emphasizing the difficulty that the distribution of KI to the general public would pose in the event of a radiological emergency.

Of the 10 States that supported the Federal purchase and stockpiling of KI, one State preferred one centrally located national stockpile, 4 preferred Federal regional stockpiles, and 5 preferred a stockpile within their State.

The second study which involved the IAEA was never conducted.

In early 1995, the FRPCC subcommittee used the results of the above State survey, the 1992 NRC cost-benefit study, the lack of new data challenging the 1985 guidance on KI stockpiling, the lack of justification that the subcommittee could find for a Federal stockpile, and the lack of support for such an initiative by the States and the primary Federal regulatory agency (FEMA) to recommend:

1. The FRPCC Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent (50 FR 30258), should not be changed.

2. The Federal Government should not purchase and stockpile KI for use by the public.

Reexamination of Federal policy on the use of potassium iodide has been subject to considerable controversy, both inside and outside of the NRC. Because the 1992 NRC cost benefit study considers psychological costs, the assumptions and resulting uncertainties in the analysis have served to exacerbate rather than resolve this controversy. However, there are other factors (beyond those explicitly included in the revised analysis) that may influence the Commission's decision regarding potassium iodide.

The following considerations are in support of a continuation of the present policy, that State and local governments should consider stockpiling potassium iodide for use by emergency workers and institutionalized persons but not for the general public.

- **Perceived Contrast in Commission Policy on Need for Protection**

  To some members of the public, existence of a potassium iodide stockpile (like other kinds of emergency planning) may seem inconsistent with a Commission position that nuclear power plants are acceptably safe, even though the Commission requires KI tablets for emergency workers.

- **Correct Emphasis on Protective Measures**

  The use of potassium iodide could be an effective auxiliary protective measure for the general population under some conditions, but the primary protective measure for most individuals is, and should continue to be, evacuation.

- **Psychological Costs in the Regulatory Decisionmaking Process**

  The current Commission policy on potassium iodide focuses on the monetary costs of illness in the recognition that nonmonetary costs (discomfort, pain, anxiety, etc.) do not lend themselves to being quantified.

- **Inappropriate Sense of Protection**

  In the case of predistribution, self-administration of potassium iodide may lead to an inappropriate sense of protection (e.g., "I took potassium iodide so I don't have to evacuate").

- **Difficulty in Obtaining KI During an Emergency**

  The potential for personal injury or panic could arise when the public attempts to obtain the KI during an emergency.

- **Questionable Risks to the Public from Exposure to Low Levels of I-131**

  Several reports have surfaced that question the carcinogenicity of low-level exposure to I-131. The report from the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR 1994) stated that "A combined analysis of nearly 47,000 Swedish patients given ^{131}I for thyroid cancer, for hyperthyroidism or for diagnostic purposes (Holm 1989, 1991)....no clear association of cancer induction by radiation was evident in this analysis." Additionally, the National Council on Radiation Protection and Measurement (NCRP 1985) report, ... summarizes the then current state of knowledge:..." ^{131}I appears less carcinogenic in people on a rad-for-rad basis than external radiation. How much less is yet to be determined; in fact, available human data on low dose ^{131}I exposures have not shown ^{131}I to be carcinogenic in the human thyroid." It should be noted that the results of the studies referred to in the NCRP 1985 report do not statistically exclude the risk of thyroid cancer from ^{131}I. Further, the number of children in these studies was too small to draw any conclusions about children. The association of ionizing radiation with thyroid cancer is based almost exclusively on studies of people who were irradiated with x-rays in childhood.

  A recent case-control study of 107 cases of thyroid cancer in children in Belarus following the Chernobyl accident shows statistically significant correlation between thyroid dose and thyroid cancer incidence among the exposed children. Previous studies of the effect of radioiodine in children, principally ^{131}I, have been small and either inconclusive with respect to the carcinogenic effect of ^{131}I or suggestive of a reduced effect compared to x-ray or gamma-ray exposure. The incidence data for adults in Belarus suggests some excess cancer from the Chernobyl accident although relatively less than indicated for children.

  In Belarus, the major contribution to the thyroid dose is believed to have come from the ingestion of ^{131}I contaminated milk. Minor contributions to thyroid dose came from ingestion of leafy vegetables, inhalation of ^{131}I from the radioactive plume and inhalation of shorter-lived radioiodines (^{132}I and ^{133}I). The only statistically significant evidence previous to this study of the effectiveness of radioiodine for carcinogenicity in the juvenile thyroid comes from the experience of children from the Marshall Islands. Six cases of thyroid cancer were observed in children, compared to 1.2 expected. Those exposures involved a mixture of radionuclides, including short-lived radioisotopes of iodine, and external exposure in addition to exposure to ^{131}I. The only purely ^{131}I exposures derive from medical uses and involve very few pre-adolescent children.

  Although some data indicated a high threshold for carcinogenicity of I[illegible] in the thyroid, recent data from the Chernobyl accident indicates that there would be a benefit from the use of KI, especially in children.

The following considerations are in support of a change to the existing policy, which would encourage Federal, State, and local authorities to acqui[illegible]

potassium iodide reserves that could be made available during or before a nuclear emergency.

- **Efficacy of Potassium Iodide as Radioprotective Agent**

  Based on the ability of KI under optimal conditions to eliminate nearly all internal thyroid exposure use of potassium iodide as a thyroid-blocking agent is widely accepted.

- **Low Cost of Stockpiling**

  The absolute cost of stockpiling is very modest ($100,000 to a few $100,000 depending on the population radius to be protected, with a yearly maintenance cost somewhere around 20% of the initial cost). Costs in this range present no significant barrier to stockpiling and are probably less than the cost of the continued studies.

- **Policy Applies to the Populations Closest to a Nuclear Power Plant**

  The recommendation to exclude the general population from the existing potassium iodide policy is based on perceived lower risk to the general public, higher costs of stockpiling for a greater number of people, and the ability to evacuate the general public during an emergency. These considerations are less pronounced for populations closest to a nuclear power plant where the risk is highest and the number of people is relatively small.

- **Consistency with Some State and Some Foreign Governments Potassium Iodide Programs**

  Several States, including Alabama and Tennessee, and a number of foreign governments, (e.g., the Canadian provinces of New Brunswick, Ontario and Quebec; Austria; the Czech Republic; Poland; Slovakia; the former Soviet Union; and the United Kingdom) have plans to provide potassium iodide to limited portions of the general population near nuclear power plants.

- **Exceptations of the General Public**

  There is the perception that potassium iodide should be stockpiled as a measure consistent with general public expectation and belief that potassium iodide should and would be available if it were ever needed (or even thought to be needed, such as at Three Mile Island). Additionally, the stockpile may provide reassurance to the public that the Commission has taken appropriate measures to deal with remote contingencies.

OPTIONS:

The Commission may consider (1) making no change in existing NRC policy, (2) awaiting a request from the FRPCC to comment on or endorse any proposed FRPCC guidance before changing the current NRC policy, or (3) adopting a change in policy that would encourage the Federal emergency planning authorities to acquire potassium iodide reserves that could be made available during a nuclear emergency.

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1. **Make no change in existing NRC policy.**

   This option would result in continuation of the present policy that State and local governments should consider stockpiling potassium iodide for use by emergency workers and institutionalized persons but not for the general public. However, the public may consider the 1985 policy contradictory because on one hand it states that KI can be an effective ancillary protective action during a nuclear power plant accident, but on the other hand it does not support Federal stockpiling or predistribution of KI that could be made available to provide protection to members of the public.

2. **Await request from FRPCC to comment on or endorse any proposed new FRPCC guidance before changing current NRC policy.**

   This option is consistent with the established Federal process of waiting for the FRPCC to formulate Federal policy that is subsequently commented on or endorsed by member agencies. It would result in continuation of the present policy until the FRPCC evaluates the NRC's resolution of the KI Petition for Rulemaking (November 27, 1995). However, the current and longstanding Commission policy on stockpiling potassium iodide may be an impediment to the willingness of the FRPCC to propose policy changes. Furthermore, we are spending almost as much money continuing to study this issue as it would likely cost to establish potassium iodide stockpiles.

3. **Revise the current Commission policy now.**

   This option resolves the Differing Professional Opinion and resolves the overall concerns of the Petition for Rulemaking related to potassium iodide. This option represents an interoffice consensus and is recommended by the staff. It would result in the approval of the following position.

   Even though severe releases from potential accidents at NRC-licensed nuclear power plants are extremely unlikely, the Commission recognizes that in that unlikely event, potassium iodide could prove effective and useful under certain conditions. There also may be a benefit to the public in the immediate vicinity of the nuclear power plant in knowing that, in that unlikely event, a stockpile of potassium iodide will be available if needed.

   For these reasons, the Commission will support the Federal Emergency Management Agency, which has the appropriate statutory authority for such expenditure, if it wishes to promulgate a new Federal policy that includes maintenance of a potassium iodide stockpile. This stockpile could quickly be made available to State and local governments in the unlikely event of a severe release from a nuclear power plant, or (on a strictly voluntary basis) it could be made available to the State emergency planning personnel for stockpiling in the local vicinity of the nuclear power plant, if they so desire.

Therefore, the NRC, in coordination with HHS and FEMA, will revise current federal KI policy to make KI available to the States. The revised policy would read "Although a reactor accident requiring KI is unlikely and KI is only effective as a protective measure for the dose to the thyroid from radioactive iodine, the cost to purchase and stockpile amounts sufficiant to administer to populations within 5 miles of operating nuclear power plants is relatively low.[1] Consequently, it appears prudent to stockpile KI for limited populations located close to the operating nuclear power plants."

If the Commission chooses this option, the staff will work directly with FEMA and HHS to revise the Federal policy regarding stockpiling KI for possible use in a radiological emergency. The revised policy would state that KI will be purchased by the Federal Government (most likely the NRC or FEMA) and made available through FEMA to the States. While NRC encourages the stockpiling of KI, the decision to stockpile, distribute, and use KI would be the responsibility of the individual States' emergency planning authorities. At the option of the States, procedures incorporating the use of KI in State emergency plans would be developed with the assistance of FEMA. The details regarding this option would be developed and coordinated through the Federal Radiological Preparedness Coordinating Committee.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. The ACRS and CRGR agree with the staff's recommendation. The Offices of NMSS, NRR, AEOD, SP, and ADM have concurred in the staff's recommendation.

NOTE:

If the Commission agrees with the staff recommendation contained in this paper, it is the staff's intention not to continue evaluating the specific merits of the Petition for Rulemaking. This is because the specific remedy requested in the petition goes beyond the recommended policy change and could have significant additional cost implications that would be difficult to justify. The staff would notice in the Federal Register that the Petition for Rulemaking has been granted in part by the NRC actions to revise the FRPCC 1985 policy statement relating to the Federal Potassium Iodide Stockpiling Policy.

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[1] The unit cost to purchase KI is $0.05 per pill. Since a KI supply sufficient for one person consists of 10 pills, the cost to purchase a KI stockpile is $0.05 x 10, or $0.50 per person to be protected by that stockpile. There are 598,017 persons living within 5 miles of the 55 nuclear power plant sites listed in the cost-benefit re-evaluation report, including populous sites such as Indian Point, Zion, TMI, and Limerick. There are 72 nuclear power plant sites in the U.S. Thus, if all States were to request KI a conservative estimate of the total population within 5 miles of any U.S. nuclear power plant site (i.e., the number of persons proposed to be protected by the stockpile) is 598,017 x 72/55 = 782,859 persons, and the initial cost of providing a KI stockpile for those persons is $0.50 x 782,859 = $391,400. Since KI has a shelf life of at least 5 years, the yearly cost would not be expected to exceed $391,400/5 = $78,300 per year, which is equal to $0.10 per person per year. In fact, if only plume exposures are considered only one or two pills would likely be needed, reducing the cost even further.

RECOMMENDATION:

The staff recommends Option 3 in which the NRC, in coordination with HHS and FEMA, would revise current Federal KI policy to make KI available to the States.

James M. Taylor
Executive Director
for Operations

Enclosure:
1. Present NRC KI Stockpiling Policy

Present NRC-Endorsed Federal Potassium Iodide Stockpiling Policy

The present policy was established by the Federal Emergency Management Agency (FEMA), the chair agency of the Federal Radiological Preparedness Coordinating Committee (FRPCC), based upon the NRC-sponsored cost/benefit study "Examination of the Use of Potassium Iodide as an Emergency Protective Measure for Nuclear Reactor Accidents", NUREG/CR-1433, Sandia National Laboratories, March, 1980 (Reference 1).

The final Federal policy was published by FEMA in the Federal Register, Vol. 50, No. 142, July 24, 1985, cf. 30258, which states in part:

> "In summary, the policy recommends the stockpiling or distribution of KI during emergencies for emergency workers and institutionalized persons, but does not recommend requiring predistribution or stockpiling for the general public."

Prior to its publication in the Federal Register by FEMA, a draft of the proposed policy had been presented to the Commission for their negative consent by SECY-85-167, "Federal Policy Statement on the Distribution and Use of Potassium Iodide", May 13, 1985. In SECY-85-167, the Commission was informed that:

> "...The proposed Federal position with regard to the predistribution and stockpiling of KI for use by the general public is that it should not be required. The new draft policy statement observes that 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. The statement leaves the decision on the use of KI by the general public to the state and local authorities on a site specific basis. ..."

By a Memorandum to William J. Dircks, EDO, from Samuel J. Chilk, Secretary, "SECY-85-167 - Federal Policy Statement on the Distribution and Use of Potassium Iodide", June 11, 1985, the staff was informed that "...the Commission has not objected to your proposal to concur with the new draft Federal Policy Statement on Potassium Iodide."

As described in complete detail in SECY-85-167, the above-described approval by the Commission of the final form of the Federal potassium iodide policy (as published in the Federal Register, cf. 30258) followed a series of events during which the Commission had earlier stated that they favored inclusion of a recommendation against requiring the distribution and use of potassium iodide by the general public. This was later changed to reflect that the Commission favored inclusion of a statement that they believed "...this protective action is not worthwhile. ..." The final form of the policy, without such a statement, was approved by the Commission (as described above) following an OGC recommendation (SECY-84-161, April 17, 1984) that the Commission adopt a more neutral approach to the distribution and use of potassium iodide as a protective action.

From: William J Lindblad <lindblad.teleport.com@teleport.com>
To: TWD1.TWP2(tsk1)
Date: 5/15/96 8:38pm
Subject: Meeting schedules

Just lately, I saw a memo from Sam changing the meeting schedules for this summer in just the way that the entire Committee voted down in the March meeting. What gives? Sam said to bring problems with regard to this to him, but I consider that you are the one in charge. Is the Committee, in fact, independent of the staff or not?

William J. lindblad.teleport.com

CC: Sam Duraiswamy <sxd1@nrc.gov>

See me.
JTL

cy to JTL 4-22

4/21/96

One Page Fax to: John Larkins
From JCC
Subject: Item for the May P&P SC Meeting

The manner in which ACRS/ACNW interns are treated is a subject that has bothered me for some time. I would like to propose that interns be allowed and encouraged to attend all portions of ACRS/ACNW meetings in which they have an interest. This would enhance their learning experience while serving as interns.

When I first joined the Committee, I made a point of getting acquainted with each intern and discussing their work with them. As time went on, I fell out of this habit since no other Committee member seemed to be doing this. I believe that the Committee members should be encouraged to take the time to do some mentoring of this nature with our interns. Easy for me to say as a departing member.

Carroll 1/16

Janet/Patty Disk:Travel.Frm
9/9/94

ACRS SPECIAL TRAVEL ENDORSEMENT FORM

THIS FORM IS TO BE USED TO REQUEST ACRS ENDORSEMENT OF SPECIAL TRAVEL REQUESTS BY MEMBERS WHEN NRC SUPPORT FOR PARTIAL OR FULL REIMBURSEMENT OF EXPENSES AND/OR TIME IS DESIRED. THIS PROCEDURE IN NO WAY LIMITS THE FREEDOM OF A MEMBER TO PARTICIPATE IN A MEETING AS AN INDIVIDUAL AT PERSONAL EXPENSE. PLEASE SUBMIT THIS FORM TO THE PLANNING AND PROCEDURES SUBCOMMITTEE AT LEAST 60 DAYS PRIOR TO THE MEETING, IF POSSIBLE. SUPPLEMENTAL INFORMATION MAY BE ADDED AS DETAILS DEVELOP.

Member Name: T. S. Kress Date Submitted: May 23, 1996

Dates of Planned Trip: July 14-5, 1996 to Portland, Or

Destination: Portland, OR

Meeting or Facility to be Visited: Air Cleaning Conference

Purpose/Relevance to ACRS Business: Air Cleaning Conference deals with filtration technology and aerosol behavior - both of which are Severe Accident Issues

Participation (Invited Speaker, paper presented, etc.): As Chairman of ACRS, I have been asked to be the keynote speaker

Justification (Foreign Travel Only):

NRC SUPPORT REQUESTED

Air Fare: Yes ✓ No ____ Per Diem: Yes ✓ No ____ Days 1

Registration: $ N/A Compensation: Yes ____ No ✓ Days ____

Janet/Patty Disk Travel Frm
9/9/94

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Member Name: IVAN CATTON Date Submitted: 23 May 1996

Dates of Planned Trip: 16 June to 21 June

Destination: Hawaii

Meeting or Facility to be Visited: "International Symposium on Flow in Porous Media"

Purpose/Relevance to ACRS Business: Physical processes important to degraded core thermal hydraulics and ground water flow.

Participation (Invited Speaker, paper presented, etc.): Invited Speaker "Turbulent Flow and Heat Transfer in Highly Permeable Porous Media"

Justification (Foreign Travel Only):

NRC SUPPORT REQUESTED

Air Fare: Yes ____ No ✓ Per Diem: Yes ____ No ✓ Days ____

Registration: $ 0 Compensation: Yes ____ No ✓ Days ____

Janet/Patty Disk:Travel.Frm
9/9/94

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Member Name: G. Apostolakis Date Submitted: May 12, 1996

Dates of Planned Trip: Nov. 26, 1996 to Dec. 1, 1996

Destination: Berlin, Germany

Meeting or Facility to be Visited: Second International Conference on Human Factors Research in Nuclear Power Operations (ICNPO 2)

Purpose/Relevance to ACRS Business: Human factors are of great current interest. This conference will address themes that are treated very poorly in current studies, such as organizational structures, work ethic, safety philosophy, and safety culture.

Participation (Invited Speaker, paper presented, etc.): Invited to present paper on "Organizational Factors and NPP Safety."

Justification (Foreign Travel Only): This conference is the second in a series organized by the Institute of Social Research of the Institute of Nuclear Safety Systems (Japan) and the Technical University of Berlin. The German host is Professor B. Wilpert, a member of the German Reactor Safety Committee. The conference is conducted as a workshop (maximum number of participants: 35) so that free discussions can take place. Some of the invited guests are among the leading researchers in the field, e.g., Professor J. Reason from England.

NRC SUPPORT REQUESTED

Air Fare: Yes x No ____ Per Diem: Yes x No ____ Days 4

Registration: $? Compensation: Yes x No ____ Days 3

Technische Universität Berlin

TU Berlin · Sekr.

Institut für Psychologie · Dovestraße 1-5 · 10587 Berlin

FACHBEREICH 11
MASCHINENBAU
UND
PRODUKTIONS-
TECHNIK

Institut für
Psychologie

Unser Zeichen ☎ (030) 314-22715 Datum 7 February 1996

Dear Colleague,

The Institute of Social Research (ISR) of the Institute of Nuclear Safety System (INSS), Kyoto (Japan) and the FSS - Forschungsstelle Systemsicherheit of the Berlin University of Technology (Germany) jointly organized the most successful First International Conference on HF-Research in Nuclear Power Operations (ICNPO 1) in Berlin, 31 October - 2 November 1994. It was agreed among the organizing institutions to hold a sequel to this first event: the **Second International Conference on HF-Research in Nuclear Power Operations (ICNPO 2)**.

ICNPO 2 will take place again in Berlin

28 - 30 November 1996

The main objective of the conference is to build on the success of ICNPO 1 to gather dispersed social science and Human Factors (HF) - research in nuclear power operations (NPO) in various countries in order to improve safety and reliability of NPO. This time, its focus will be HF aspects under the general theme of

Understanding NPO in International Comparative Perspective

Among the subthemes which could be addressed under this theme are: Personnel Structure, Training of NPP-Personnel, Work Ethics, Organizational Structures, Regulatory Philosophy, Safety Philosophy, Safety Culture. These or similar subthemes may be treated either from systematic comparison studies or the presentation of studies of particular features within a given country.

We like to invite you to this event.

Maximally 35 participants will be invited to take part in the conference. Invitations will go to the members of the international network created by participants of ICNPO 1 and to additional, especially also young, researchers active in the field of the general theme. The invitation is conditional to submitting an abstract and a full paper prior to the conference.

To: wilpert@zrzsp3.gp.tu-berlin.de
From: George Apostolakis <apostola@mit.edu>
Subject: Re: ICNPO2
Cc:
Bcc:
X-Attachments:

Dear Professor Wilpert:

Thank you for your invitation. I have moved to MIT and receiving my mail from UCLA is not always efficient.

I could participate and give a talk on "Organizational Factors and NPP Safety."

I have to make a few arrangements first (November 28 is a major family holiday in the USA - Thanksgiving). Also, is there any financial support for travel?

I hope to finalize my participation in the next few days.

Sincerely,

At 03:34 PM 5/2/96 +0000, you wrote:
>Dear Profesor Apostolakis,
>On February 2 I sent you an invitation to participate in our second
>International Conference on HF Research in Nuclear Power Operations,
>Berlin, November 28-30, 1996. The conference is organized by my
>university in cooperation with the Kansai utilities' Institute of
>Nuclear Safety System - Institue of Social Research (Director:Juijy
>Misumi). The general top0ic will be "Understanding NPO in
>International Perspective.
>
>Knowing of the importance of your contributions to the field and the
>fact that you are now also member of the ACRS (I myself being member
>of the German equivalent: the Reactor Safety Commission) I know that
>your participation would greatly enhance the meeting's quality. Since
>we are now in the process of f nalizing the program I would
>appreciate if you could let me know whether we could count on your
>participation (among US participants are: Gene Rochlin, John Carroll,
>John Olson, Edwin Fleishman; James Reason will participate as well).
>
>Looking forward to your response,
>sincerely yours,
>Bernhard Wilpert
>

To: WILPERT Bernhard
From: George Apostolakis <apostola@mit.edu>
Subject: ABSTRACT
Cc:
Bcc:
X-Attachments:

ORGANIZATIONAL FACTORS AND NPP SAFETY

It is widely recognized that organizational factors (OFs) play an important role in NPP safety. For example, the IAEA International Nuclear Safety Advisory Group emphasizes that safety culture has two components: the organizational framework and the attitude of the staff. This work recognizes that NPPs are highly structured organizations ("machine bureaucracies"); the primary coordinating mechanism of work is the work process, i.e., a standardized sequence of tasks designed to achieve a specific goal. The Work Process Analysis Model (WPAM) that we have developed can be used in a number of ways: 1. To contribute to the assessment of the safety culture at the plant; 2. To expand root-cause analysis so that OFs contributing to the incident can be identified; 3. To include OFs into Probabilistic Safety Assessments. The structure of WPAM and its various applications will be discussed in this presentation.