

March 31, 1998

FOR: The Commissioners

FROM: L. Joseph Callan /s/
Executive Director for Operations

SUBJECT: STAFF OPTIONS FOR RESOLVING A PETITION FOR RULEMAKING (PRM-50-63 AND 50-63A) RELATING TO A RE-EVALUATION OF THE POLICY REGARDING THE USE OF POTASSIUM IODIDE (KI) BY THE GENERAL PUBLIC AFTER A SEVERE ACCIDENT AT A NUCLEAR POWER PLANT

PURPOSE:

To obtain Commission approval of an option to resolve a petition for rulemaking that requested the NRC to change its regulations regarding the use of KI by the public.

BACKGROUND:

On September 9, 1995, a petition for rulemaking (PRM-50-63) was filed with the NRC by Mr. Peter Crane. The petitioner requested that the NRC amend its emergency planning regulations to require that emergency plans specify a range of protective actions to include sheltering, evacuation, and the prophylactic use of KI.

On June 16, 1997, the staff forwarded to the Commission the Federal Radiological Preparedness Coordinating Committee's (FRPCC) proposed Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant in SECY-97-124 (Enclosure 1). The paper offered 3 options for the Commission's consideration with regard to the proposed FRPCC policy. In an SRM dated June 30, 1997 (Enclosure 2), the Commission approved Option 2 that endorsed the Federal offer to fund the purchase of KI for States at their request and endorsed the FRPCC recognition of the availability to State and local governments of the Federal stockpiling of KI. Under this option, the Federal government would provide funding for the purchase of KI, and State and local governments would be responsible for maintenance, distribution, and subsequent costs of KI. The SRM further stated that "NRC licensees should, as part of the emergency response planning, discuss this matter with State and local governments who make decisions on protective measures as part of their planning for responses to emergencies." The SRM also stated that the Commission's approval of Option 2 should not be viewed as a denial of, or Commission action on, the petition for rulemaking of Peter Crane (PRM-50-63), and requested that the staff submit an assessment of Mr. Crane's petition and of the comments on that petition to the Commission for its consideration.

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In SECY-97-245 (Enclosure 3), dated October 23, 1997, the staff provided three options for the Commission's consideration in order to resolve PRM-50-63. The first option would have granted the petition for rulemaking as requested by the petitioner. Under the second option, the Commission would have denied the petition for rulemaking, but would have developed guidance to address planning for KI distribution for those States that include KI in their planning basis. In the third option, the Commission would also have denied the petition for rulemaking but would have pursued a modification to the regulations to require licensees to address planning for KI distribution for those States that include KI in their planning basis.

On November 5, 1997, the Commission was briefed by the staff, the Federal Emergency Management Agency (FEMA), and the petitioner regarding the options available for resolving the petition for rulemaking. During the meeting, the Commission invited the petitioner to submit a modification to his petition in order to address views he discussed during the meeting. The Commission indicated, in an SRM dated November 25, 1997 (Enclosure 4), that it would defer action with respect to PRM 50-63 (SECY-97-245) and the draft Federal Register Notice on Federal KI Policy provided in COMSECY-97-028 (Enclosure 5) pending submission by the petitioner of a revision to his petition reflecting the petitioner's comments at the meeting and the staff's subsequent evaluation of the impact of the revised petition on the staff's recommendations as reflected in SECY-97-245. That evaluation is the subject of this paper.

On November 11, 1997, the petitioner submitted a revision to PRM-50-63 (Enclosure 6). The petitioner requested two things:

A statement clearly recommending stockpiling of KI as a 'reasonable and prudent' measure, and

A proposed rule change to 10 CFR 50.47(b)(10) by inserting the following sentence after the first sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate."

The petitioner also provided a marked-up version of the proposed Federal Radiological Preparedness Coordinating Committee (FRPCC) Federal Register Notice.

PUBLIC COMMENT ON THE AMENDED PETITION:

On December 17, 1997, the Commission published a request for public comment in the Federal Register (62 FR 66038). In response to several requests, the comment period was extended until February 17, 1998, by a Federal Register Notice published on January 21, 1998 (63 FR 3052). A total of 82 comment letters were received, of which 13 utilities, 3 State governmental agencies, 1 utility interest association, and 1 member of the public were

against granting the petition for rulemaking. The letters in favor of granting the petition came from 8 public interest groups, 46 members of the public (including 1 from the petitioner), 3 physicians, 2 US Senators, and 1 State Representative. Enclosure 7 contains a summary of the public comments.

DISCUSSION:

The staff has prepared a technical assessment entitled, "Assessment of the Use of Potassium Iodide (KI) as a Public Protective Action During Severe Reactor Accidents," (Enclosure 8) to assist the Commission in reviewing the staff options for resolving the petition. The staff's assessment presents information on severe accidents and how NRC's emergency planning regulations address severe accidents, the health effects from exposure of the thyroid to radiation and from the use of KI, information on experiences in Belarus and Poland in the aftermath of the Chernobyl accident, and international practice on the use of KI. The insights and conclusions are drawn from the staff's technical assessment and are contained in the Executive Summary of Enclosure 8.

In light of the petitioner's revisions to the petition and the staff's further study, the original options presented in SECY-97-245 were reconsidered by the staff as follows.

In the revised petition, the petitioner requested that consideration be given to including KI as a protective measure for the general public. This is a change from the original petition in which the petitioner requested that the regulations be amended to require emergency plans to include KI as a protective measure. In both the original and amended petitions, the proposed rule language lists sheltering and evacuation as protective measures along with KI. The planning standards in 10 CFR 50.47(b)(10) currently do not identify any specific protective actions, but indicate that a range of protective actions should be developed and included in emergency plans.

The petitioner submitted a draft statement of considerations to accompany the proposed rule change. The draft statement proposes that the Commission state that it believes stockpiling of KI to be a reasonable and prudent measure. The petitioner would further have the Commission recommend, but not mandate, the stockpiling of KI as a protective measure for the public.

The petitioner also submitted a markup of the proposed FRPCC Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant. The staff has not addressed that markup in this paper. Instead, the staff will consider the markup following resolution of the petition, as appropriate.

Two options are now identified by the staff. The first option is similar to the first option in SECY-97-245, in that it would grant the petition. The second option is similar to the second option in SECY-97-245, in that it would deny the petition. The third option in SECY-97-245 was to require licensees to address planning for KI distribution. It does not appear in this paper because the revised petition calls for a consideration of including KI as a protective measure rather than requiring inclusion of KI. Thus, requiring a licensee to address planning for KI distribution would not be appropriate.

Option 1

Grant the amended petition for rulemaking by initiating a rulemaking for the purpose of revising the regulations to include a sentence in 10 CFR 50.47(b)(10) that reads, "In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate." Further, the statement of considerations accompanying the proposed rule would include a statement that the Commission finds the stockpiling of KI to be reasonable and prudent.

Option 1 Implications

The rulemaking process would afford the public an opportunity to comment on the issue of KI stockpiling for the use of the general public.

The effect of the rule proposed by the petitioner would be to require NRC licensees to work with State and local governments to ensure that KI is considered as part of the emergency planning process.

It would be necessary to provide guidance on what constitutes compliance with the requirement to give consideration to evacuation, sheltering and the prophylactic use of KI. The current emergency preparedness practice is provided in FEMA's requirements in 44 CFR 350 and the NRC-FEMA MOU, dated September 14, 1993 (58 FR 47996). The guidance on what constitutes compliance is provided in NUREG-0654, a joint NRC/FEMA document. Thus, revision of the NRC rule would require an NRC/FEMA modification of this NUREG, and conforming changes to FEMA's regulations. Further, the NRC-FEMA MOU would have to be reviewed to see if conforming changes were necessary.

By virtue of the NRC making a change in a planning standard in 10 CFR 50.47, NRC would have to work with FEMA to decide how a determination of the adequacy of offsite emergency preparedness would be made. This determination would have resource implications for licensees, FEMA, NRC, and States. In addition, the NRC would need to decide what sanctions it is prepared to invoke in the event compliance with the new rule is not achieved.

The revision to the rule would put the use of KI, sheltering, and evacuation on an equal footing. This action would therefore go beyond what the Commission has already endorsed in its June 30, 1997, SRM, in that the best technical information indicates that evacuation and in-place sheltering provide adequate protection for the general public, and that use of KI should only be used as a complement to evacuation and sheltering. Thus, if this option is chosen, the Commission position on the proposed Federal Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant would need to be revised.

In addition to rulemaking, the petitioner requested that the Commission make a statement recommending stockpiling as a reasonable and prudent measure. Staff has considered the meaning of the terms "reasonable and prudent." Although the staff did not identify any specific meaning of these terms in NRC parlance, the dictionary definition of "prudent" includes caution in the face of risk. A policy stating that the use of KI is reasonable and

prudent may be interpreted by State and local governments as tantamount to a requirement for its use.

The petitioner asserts that a change in NRC's regulations would not consume significant resources. It is difficult to predict the exact amount of time that would be required, but the staff believes that it would take substantially more resources than the petitioner predicts, and based on the interactions with FEMA that would be required, it would take more than 2 FTE and more than the standard 19 months to complete a rulemaking. Further, the resources needed to develop guidance and verify compliance would need to be determined.

Option 2:

Deny the petition for rulemaking, but endorse the proposed 1997 FRPCC policy statement discussed in COMSECY-97- 028. That policy states in part:

The Federal policy is that KI should be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies. In developing the range of public protective actions for severe accidents at commercial nuclear facilities, the best technical information indicates that evacuation and in-place sheltering provide adequate protection for the general public. However, the State (or in some cases, the local government) is ultimately responsible for the protection of its citizens. Therefore, the decision for local stockpiling and use of KI as a protective measure for the general public is left to the discretion of State (or, in some cases, local government.)

In addition, note that consistent with the Commission's decision in the June 30, 1997, SRM the Federal government (most likely NRC) is prepared to fund the purchase of a stockpile of KI for the States upon request.

Option 2 Implications

The benefits afforded by public involvement in rulemaking, articulated in Option 1, would not be realized. The resource costs of Option 1 would also not be realized.

Anticipated promulgation of the FRPCC position has encouraged State and local governments [Maine, Ohio, and New York] to actively consider the use of KI. Formal promulgation of the policy is expected to cause additional governments to do likewise.

This option provides support for the use of KI, but as a complement to the range of protective actions that State and local governments have already considered.

Staff Position:

The staff carefully considered Mr. Crane's petition, the information in the enclosed technical paper (Enclosure 8), the public comments received on the revised petition, and the discussion section provided above, and found that arguments can be made for and against requiring the consideration of KI as a protective measure for the public, and in stating that such use is "reasonable and prudent."

On balance the staff does not find a compelling basis to support Option 1. Based primarily on the fact that Option 2 maintains evacuation and sheltering as the primary protective actions and would require a lower level of NRC and FEMA resources to implement, the staff recommends that the petition be denied (option 2).

RESOURCES:

The resources needed to resolve this petition in accordance with Option 2 are included in the current budget. Resources to conduct rulemaking in accordance with Option 1, as well as resources to purchase KI, have not been included in the current budget. Cost considerations of purchasing KI were discussed in SECY 97-124 and range from \$48K to \$1.3M, as described in the analysis in attachment 2 to that paper.

COORDINATION:

The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. The Office of the General Counsel has no legal objection.

RECOMMENDATION:

That the Commission:

Approve the staff's recommendation that the petition be denied (option 2).

L. Joseph Callan
Executive Director for Operations

Enclosures: As stated

Summary of public comments

Of the 82 comment letters received on the amended petition, the majority (63) were in favor of granting the petition. Forty-six letters came from members of the public. Of the others, there were letters from 8 public interest groups, 3 physicians, 2 US Senators, 1 State representative, a

manufacturer of KI, the US Pharmacopeia Convention, and the American Thyroid Association.

Comments from those in favor of granting the petition:

A. Mandatory requirement vs. optional requirement:

1. Many commenters would prefer that the wording of the original petition be used, including 2 US Senators. These commenters stated that: "The prophylactic use of KI for the general public should be a mandatory emergency planning requirement and should not be merely an optional consideration." The reason given by most that supported this approach was that, if given the choice, many States may not adequately protect their citizens.
2. One commenter stated that a reason for wanting NRC to require KI is that "without a federal mandate for stockpiling KI, the nuclear industry will simply shift its fight against the policy to the state and local levels."
3. One commenter stated that "this should be implemented on a federal level with uniformity of policy for all the states."

Staff response - The proposed FRPCC policy leaves the decision on the stockpiling of KI for the public to the States. An NRC requirement that it be included in emergency planning would not support the existing or proposed policy that the use of KI should be as a complement to evacuation and sheltering. The best technical information indicates that evacuation and in-place sheltering provide adequate protection for the general public, and that use of KI should only be used as a complement to evacuation and sheltering.

B. Logistics:

1. Several commenters stated that logistical issues associated with the distribution are all solvable.
2. One commenter that supported a mandatory requirement also believed that Federal agencies should assist States in addressing logistical issues in distributing KI.

Staff response - The staff analyzed the situations that would likely be present during a severe reactor emergency and concluded that the main concern was associated with the timing of administration. State and local officials are ultimately responsible for public health and safety. They are therefore responsible for decisions on appropriate public protective actions and their implementation. This issue is more fully addressed in Section IV of Enclosure 8.

C. Consequences from accidents:

1. There were 10 identical letters, all expressing the view that the NRC should decide favorably for the petition because emergency responders have a stockpile available, citizens should also have it, and many other nations already stockpile KI and the US should have no less protection. In addition to these points, 4 additional letters stated that KI has been proven effective if taken in a timely manner, that the Kemeny Commission and the American Thyroid Association recommended stockpiling, and that arguments that people will be evacuated in a timely manner do not take into account snowstorms or the potential for evacuees to be traveling with the radioactive wind.
2. "The concern about significant toxicity from potassium iodide in emergency blocking doses has been made moot by the extensive Polish experience where 18 million individuals received prophylactic potassium iodide with overall toxicity of 2.5% (mostly nausea) but with only a fraction of 1% having serious side-effects."
3. One physician urged that the Commission adopt the petition to protect against thyroid cancer.
4. The petitioner provided comments on the incidence of thyroid cancer in the US, and indicated that, of the approximately 16,000 Americans diagnosed with thyroid cancer annually, about 1200 are expected to die from the disease.

Staff response - The staff reviewed the experiences in Belarus and Poland following the Chernobyl accident, and observed that the primary source of exposure was likely due to the ingestion of contaminated foodstuffs. The staff's analysis can be found in Section III of Enclosure 8, and specifically identifies some of the medical concerns associated with the use of KI by the general public.

D. Costs:

1. Several commenters stated that the cost of a KI pill is only 10 cents, many nations stockpile KI, and that our protection should not be less than that afforded by other nations.
2. Several commenters stated that since KI is so inexpensive it makes sense to stockpile it for the public.
3. One commenter stated: "Facing and making the dreaded decision to evacuate, with all of its ramifications, will require much more nerve than the valiancy or sensibility of funding the stockpiling of a 10 cents pill. Put the decision and ability to protect our thyroids into our own hands."

Staff response - The staff evaluated the costs and benefits of using KI in NUREG/CR-630, and concluded that the benefits did not outweigh the costs. While the cost to purchase a supply of KI is modest, the cost of implementing a KI program can be significant. Additional information concerning this

issue can be found in Section III of Enclosure 8.

E. Efficacy of KI :

1. The American Thyroid Association continues to endorse the stockpiling of KI based on Chernobyl experience that thyroid cancer is a major result of reactor accidents and that since the exposure can continue for days the institution of KI blocking at any time is beneficial, that the Polish experience shows that deployment of KI is safe, that shelf life is extremely long, that the advantage of having a supply on hand outweighs moderate cost, and that problems attendant on predistribution are immaterial for the matter of creating a stockpile.
2. US Pharmacopeia wrote that the long-term viability of the drug was tested and found that 11 years after manufacture and eight years after the expiration date, the tablets were assayed at 99.1% of the labeled content of KI.
3. "An agency which does not aggressively promote - through all the means at its disposal - a cheap and effective remedy to a potential problem under its regulatory authority should seriously re-examine its legal and ethical responsibilities."
4. One commenter was concerned that the premature aging of reactor components, the economics of utility restructuring, and the long-term storage of high level waste at reactor sites all contribute to the need for KI stockpiling.
5. One commenter stated: "especially around the Seabrook Nuclear Plant, during the summer tourist season especially, it can be predicted that evacuees will be forced to wait in traffic queues for great lengths of time, . . . and that if KI predistribution were accomplished and accompanied by a thorough and vigorous program of public education, one might reasonably expect that many instances of cancer, hypothyroidism and other thyroid disorders might be avoided . . ."
6. 21 of the comment letters came from residents around Three Mile Island. Almost all stated that the Kemeny Commission supported stockpiling KI, and that the Commission should fulfill an earlier NRC commitment to do so.

Staff response: - The lessons learned from Chernobyl showed that, had evacuation and interdiction of consumption of contaminated foodstuff taken place, the public health consequences would have been reduced significantly. The staff reviewed information on policies and practices used in other countries, many of which do recommend predistribution of stable iodine. The staff concluded that one difference between Europe and the US is that transboundary issues are more of a concern in Europe than in the US. For many, the Chernobyl accident demonstrated that a nuclear power plant in a different country could have a significant impact. A more complete analysis of this issue can be found in Section VI of Enclosure 8.

In any event, the staff does not dispute that stockpiling KI can have benefits and the staff supports the FRPCC proposed policy that will result in the Federal Government funding the purchase of KI for those States that choose to stockpile KI for use by the general public.

Comments against granting the petition:

Of the comments against the petition 14 were from licensees, 3 were from State governments, 1 was from the Nuclear Energy Institute, and 1 was from a member of the public.

Comments from industry:

1. "The petitioner fails to provide any new evidence that stockpiling or predistribution of potassium iodide as a protective action will add significant public health and safety benefit to the adequate level of protection currently provided by existing emergency planning at and around commercial nuclear power plants."
2. "Evacuation is generally feasible and is more effective at dose reduction because it reduces dose to all organs, not just the thyroid as with the use of KI."
3. "State and local authorities should be left free to determine whether stockpiling is needed for a particular site."
4. "Risk due to thyroid dose is of significantly less concern relative to the risk associated with external radiation from noble gases"
5. "One of the major impediments with distribution of KI to school children is coordination and administration of the program, e.g., the actual decision making process to administer KI or evacuate, parental approval, and record keeping, identification, and documenting allergic reactions, and the availability of a qualified medical professional to administer the potassium iodide."
6. The events at Chernobyl and Europe do not really apply to the US situation, because the conditions that occurred in Europe as a result of the accident (exposure to releases over an extended period) generally are not applicable to the US, because evacuation is feasible.

Staff response - Responses provided to comments in favor of the petition summarize the staff views on the issues raised by industry. (See staff response under Section A and B of this enclosure.) The staff analyzed the issues represented by these comments and a fuller discussion of each can be found in Enclosure 8.

Comments from States:

1. "Evacuation is more feasible and practicable, stockpiling has logistical problems that render the idea impracticable and unmanageable. It should

be noted for the record that the federal government's KI stockpiles established for nuclear, biological and chemical (NBC) terrorism incidents also lack an established distribution mechanism that would ensure disbursement of KI to the general public in a timely manner."

2. Radioactive iodine is not the predominant nuclide expected to be released from a nuclear plant in the event of an accident.
3. Radioiodines can be filtered quite effectively prior to a release of radiation from a nuclear plant.
4. Any delays in evacuation which contribute to acute exposure to other long-lived radionuclides will have more significant health effects and possibly terminal cancers.
5. Giving KI to the general public "will instill a false sense of security in individuals that ingest the drug."

Staff response - Responses provided to comments in favor of the petition summarize the staff views on the issues raised by the States. (See staff response under Sections A, B, and C of this enclosure.) The staff analyzed the issues represented by these comments and a fuller discussion of each can be found in Enclosure 8.

Comments from a member of the public:

1. "The NRC should not be agreeing to provide or administer a potentially lethal drug to the general populace without sound medical advice, if at all."

Staff response - The staff reviewed the side effects associated with use of KI and Section III. F. of Enclosure 8 provides a full discussion of what was learned from this review.