October 23, 1997

FOR: The Commissioners
FROM: L. Joseph Callan /s/

Executive Director for Operations

SUBJECT: STAFF OPTIONS FOR RESOLVING A PETITION FOR RULEMAKING (PRM-50-63) RELATING TO A RE-EVALUATION OF THE POLICY

REGARDING USE OF POTASSIUM IODIDE (KI) 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 changing the NRC regulations regarding emergency planning.

BACKGROUND:

On September 9, 1995, a petition for rulemaking (PRM-50-63) was submitted to the NRC by Mr. Peter Crane. The petitioner requested that the NRC amend its emergency planning regulations to include a requirement that the range of protective actions include the prophylactic use of potassium iodide as well as sheltering and evacuation. The specific request was to amend one of the 16 planning standards in 10 CFR 50.47 to assure that the option of using potassium iodide be included in emergency plans. The planning standards currently do not identify specific protective actions that must be included in emergency plans prepared by licensees or the States.

The current Federal guidance to State and local governments on the distribution of KI was promulgated in 1985 by the Federal Emergency Management Agency (FEMA) in its capacity as Chair of the Federal Radiological Preparedness Coordinating Committee (FRPCC) (50 FR 30285; July 25, 1985) and as the Federal agency charged with establishing policy and providing leadership via the FRPCC (44 CFR 351 Subpart C). The FRPCC was established to coordinate all Federal responsibilities for assisting State and local governments in emergency planning and preparedness for peacetime radiological emergencies. On June 16, 1997, the Commission was provided a proposed revision to the Federal policy regarding the use of potassium iodide (SECY-97-124). The Commission approved the staff's option of endorsing the FRPCC recommendations. The Commission informed the staff not to view its approval of this option as a denial of the petition for rulemaking (PRM 50-63) and directed the staff to prepare an assessment of the petition and submit it to the Commission for its consideration.

DISCUSSION:

On November 27, 1995 (60 FR 58256), a Notice of Receipt of the Petition for Rulemaking was published in the Federal Register requesting public comment. A total of 63 comment letters were received, of which 20 utilities, 9 State governmental agencies, 2 utility interest organizations, 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, 22 members of the public (including 1 from the petitioner), and the American Thyroid Association. None of the State governmental agencies that commented on the petition for rulemaking supported granting the petition. (See the Enclosure 1 for a detailed analysis of the public comments.)

The petitioner requested that the "planning standard" in 10 CFR Part 50, section 50.47(b)(10) be revised to read.

(10) A range of protective actions including sheltering, evacuation, and prophylactic use of iodine, have been developed for the plume exposure pathway EPZ [emergency planning zone] for emergency workers and the public. Guidelines for the choice of protective actions during an emergency, consistent with Federal guidelines are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed.

The petitioner also requested that "the NRC also issue, either on its own or in conjunction with other agencies, a policy statement declaring that KI stockpiling is a sensible and prudent measure, necessary to assure that the drug will be available in the event of a major accident. This statement would make clear that KI, while no panacea, can be used in conjunction with evacuation and sheltering to maximize protection to the public." (1) The full text of the petitioner's request can be found in Enclosure 2.

The staff has evaluated the various options for addressing the petitioner's concerns and is providing three options for the Commission's consideration in resolving this petition. The first option would grant the petition as requested by the petitioner. The second option would deny the petition for rulemaking. However, the NRC in coordination with the States and other Federal agencies would develop guidance to address planning for KI distribution for those States that include KI in their planning basis, consistent with the FRPCC policy. In the third option the staff proposes to deny the requested petition for rulemaking but would pursue a modification to the regulations to require licensees to address planning for KI distribution for those States that include KI in their planning basis.

Option 1:To grant the petition for rulemaking strictly in accordance with the petitioner's request.

The petitioner proposed that section 50.47(b)(10) be amended to read as follows:

A range of protective actions including sheltering, evacuation, and prophylactic use of iodine, have been developed for the plume exposure pathway EPZ

[emergency planning zone] for emergency workers and the public. Guidelines for the choice of protective actions during an emergency, consistent with Federal guidelines are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed. [the underlined text would be added to the existing standard in 50.47]

Pros:1. Would resolve the issue as requested by the petitioner. Advantages of this option as identified by the petitioner are: a.) would establish a uniform Federal policy on KI and b.) would ensure that emergency plans address the prophylactic use of KI.

Cons: 1. By requiring KI as a protective measure this option would contradict the June 30, 1997, SRM and the 1997 proposed FRPCC recommendations that States should have the option of using KI as a protective measure.

- 2. Revising the regulation as requested by the petitioner would mean that licensees and States would be required to incorporate all three protective actions into their emergency plans. Failure to do so by a State would result in a situation where a State's decision would conflict with the new requirement.
- 3. May give the appearance that the use of KI, as a protective measure, could be equated to the use of evacuation and sheltering.
- 4. Would require NRC and FEMA resources to revise the regulations and guidance documents, and to review revised plans and procedures.
- 5. The Rulemaking required by this option would be protracted in that extensive coordination with the States, other affected Federal agencies, licensees and the public would be required prior to adoption as a final rule.
- 6. During the public comment period, state governments identified significant implementation problems associated with this option.

Option 2: Deny the petition for rulemaking as requested by the petitioner. However, NRC in coordination with the States and other Federal agencies would develop guidance to address planning for KI distribution for those States that include KI in their planning basis.

Pros:1. Would be consistent with the June 30, 1997, SRM endorsing the draft FRPCC policy discussed in SECY-97-124 to fund the purchase of KI for States at their request.

- 2. The proposed FRPCC policy addresses some of the petitioner's concerns. This is based on the following aspects of the proposed policy: 1) regional stockpiles will be made available to the States that request them in the event of an emergency, and 2) the Federal government will purchase KI for any State requesting it.
- 3. No NRC and FEMA review of a State's decision would be required.
- Cons: 1. Does not resolve the petition in the manner requested by the petitioner.

Option 3: Deny the petition for rulemaking as requested by the petitioner. However under this option a modification to the regulations would be pursued to require licensees to address planning for KI distribution for those States that include KI in their planning basis.

Pros:1. Would be consistent with the current and proposed federal policy on KI, that States should have access to KI as a protective measure.

- 2. Retains the States' prerogative to incorporate the use of KI into their emergency protection measures in the event of an accident.
- 3. Codifies the relief given in Option 2.

Cons: 1. The rulemaking required by this option may be protracted in that extensive coordination with the States, other affected Federal agencies, licensees and the public would be required prior to adoption as a final rule.

2. Would require NRC and FEMA resources to revise the regulations and guidance documents, and to review revised plans and procedures.

Staff position:

It is the staff's position that a revision to the regulations is not necessary to assure that KI, as a protective measure for the public, is available for use by the States. This position would support the Commission decision in its SRM dated June 30, 1997 to endorse the draft FRPCC policy on the distribution of KI.

The staff favors Option 2 because it is consistent with proposed Federal policy as endorsed by the Commission and addresses the overall policy change requested by the petitioner, i.e., the willingness of the Federal government to provide a stockpile of KI to the States upon request. This would be accomplished without the burden of a rulemaking.

Nonetheless, the staff has developed Option 3 should the Commission wish to codify these proposed policy changes in a rulemaking, which would involve coordination with the States, other Federal agencies, licensees and the public.

RESOURCES:

The resources needed to resolve this petition in accordance with Option 2 are included in the current budget. Resources to conduct rulemaking (Options 1 and 3) as well as resources to purchase KI have not been included in the current budget.

Under any of these options the Commission must make a determination that NRC funding for purchases of KI at the request of States would make a direct contribution to fulfilling the NRC's regulatory responsibility to protect the public health and safety during a radiological emergency. This determination provides the necessary legal basis for NRC expending appropriated funds for the purchase of KI. The NRC would also have to obtain Congressional reprogramming approval.

Additionally, the cost considerations of purchasing KI were fully discussed in SECY 97-124.

COORDINATION:

The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. A copy of this paper was sent to the ACRS and the CRGR for information.

RECOMMENDATION:

That the Commission:

Approve an option to resolve the Petition for Rulemaking (PRM-50-63).

L. Joseph Callan
Executive Director
for Operations

CONTACT: Mike Jamgochian, RES/DRA

(301) 415-6534

Enclosures: As stated

^{1.} The petitioner further stated that, "I am not proposing house-to-house predistribution of KI, which I think would be ineffective and a source of confusion during an actual emergency. Rather, I am suggesting that state and local authorities have ready access to supplies of the drug so that they can administer it if it is needed."