SECY-00-0037

February 11, 2000

FOR:	The Commissioners
FROM:	William D. Travers /RA/ Executive Director for Operations
SUBJECT:	STATUS OF POTASSIUM IODIDE ACTIVITIES

PURPOSE:

To inform the Commission of the status of NRC activities related to the use of potassium iodide (KI) as a supplemental protective measure for the general public in the event of a severe reactor accident, and to request Commission approval to pursue the inclusion of KI in the "National Pharmaceutical Stockpile (NPS)" being established by the Centers for Disease Control (CDC EXIT) and Prevention for use in response to large-scale disasters.

BACKGROUND:

NRC regulations, in 10 CFR 50.47(b)(10), require that emergency plans for nuclear power reactors include a "range of protective actions" for the plume exposure pathway emergency planning zone (EPZ) for emergency workers and the public.

On September 9, 1995, a petition for rulemaking (PRM 50-63) was filed with the NRC. 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 November 27, 1995 (60 FR EXIT 58256), a "Notice of Receipt of Petition for Rulemaking and Request for Public Comment" was published in the Federal Register (FR) requesting public comment. On November 5, 1997, the NRC staff, FEMA EXIT, and the petitioner briefed the Commission regarding the petition. During the meeting, the Commission invited the petitioner to submit a modification to his petition in order to address the views he discussed during the meeting.

On November 11, 1997, the petitioner submitted a revision to his petition, PRM 50-63A. The revised petition requested amendment of the regulations to provide for consideration of KI rather than requiring its use along with evacuation and sheltering as protective actions for the public. The petitioner also requested that the NRC make a statement clearly recommending stockpiling of KI as a reasonable and prudent measure. In addition, as part of the petitioner's comments on the proposed rule, the petitioner also stated that his original petition was incorporated by reference and resubmitted because the amended petition was based in part upon the June 30, 1997, Commission decision to fund State supplies for those States that request it.

On December 17, 1997 (62 FR 66038), the Commission published a "Notice of Receipt of Petition for Rulemaking and Request for Public Comment" on the amended petition in the Federal Register. In a June 26, 1998 SRM, the Commission directed the staff to proceed with rulemaking. The staff provided the Commission with a proposed rulemaking package on November 10, 1998, in SECY-98-264.

On April 22, 1999, in an SRM on SECY-98-264, the Commission directed the staff to publish a proposed rule for a 90-day public comment period. The Commission also voted to (1) direct the staff to amend the draft Federal Register Notice on KI policy to conform to the SRM, (2) not fund State stockpiles of KI; (3) direct the NRC staff to work with FEMA to establish and maintain regional stockpiles of KI; and (4) support NRC funding of the initial purchase and resupply of regional stockpiles of KI.

The proposed rule on the consideration of KI in emergency plans was published in the Federal Register on June 14, 1999 (64 FR 31737), with a request for public comment by September 13, 1999.

The current Federal guidance to State and local governments on the distribution of KI was issued in 1985 (50 FR 30258) by the Federal Emergency Management Agency (FEMA) in its capacity as Chair of the Federal Radiological Preparedness Coordinating Committee (FRPCC). The 1985 Federal policy recommends providing KI to emergency workers and institutionalized persons, but does not recommend stockpiling or pre-distribution for the public.

DISCUSSION:

There are four principal activities associated with the agency's KI efforts. They are (1) the development of the final rule on the

use of KI for the general public; (2) issuance of the KI guidance document; (3) determination of how to make KI available; and (4) reevaluation of the Federal policy on KI. Each of these activities is discussed below.

1. Final Rulemaking on the Use of KI for the General Public

A final rulemaking package on the use of KI for the general public is being submitted to the Commission concurrently with this SECY paper. That rulemaking responds to two petitions for rulemaking (PRM 50-63 and PRM 50-63A), to public comments on the proposed rule, and to Commission directives. The final rule would require that the prophylactic use of KI be considered as a protective measure for the general public as a supplement to evacuation and sheltering, as appropriate. The final rule, however, would not require that KI be made available; that decision would be made by State and local governments. The SECY paper and the Federal Register Notice (FRN) for the rulemaking package discuss the final rule in detail.

2. Issuance of KI Guidance Document

In an SRM issued on June 26, 1998, the Commission directed the staff to proceed with rulemaking on the use of KI and to issue draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) as a Public Protective Action During Severe Reactor Events," for public comment.

In an SRM issued on September 30, 1998, the Commission directed the staff to withdraw draft NUREG-1633, and to reissue a substantially revised document taking public comments into account and making the following changes:

> The reissued document should include an improved discussion of how the practical problems in KI stockpiling, distribution, and use are handled in States which already use KI as a supplement and in the numerous nations who use KI as a supplement. A discussion, in some detail, of the various guidance documents of the World Health Organization (WHO) and International Atomic Energy Agency (IAEA), as well as the U.S. Food and Drug Administration (FDA), would be very useful to state and local decisionmakers. The guidance document should be consistent with the policy adopted by the Commission in response to the petition for rulemaking and should fairly discuss the factors that need to be weighed in the state and local decisions. The revised document should be submitted to the Commission as a SECY information paper.

The staff formed the "KI Core Group" to accomplish the revision directed by the Commission. The "KI Core Group" consisted of: representatives from those States that have KI as a supplemental protective action (Alabama, Tennessee, and Arizona); Connecticut (two representatives, one from the State and one from the Town of Waterford); the Conference of Radiation Control Program Directors (CRCPD); the National Emergency Management Association; the FDA; the U.S. Environmental Protection Agency (EPA); and FEMA. The revised draft NUREG-1633 discusses various aspects of the use of KI during nuclear power plant emergencies and reflects the experience gained from the States that currently plan to use KI as a supplemental protective action for the public as well as the guidance and policies of other countries, WHO, and IAEA.

Completion of the guidance document is dependent upon guidance being developed by the FDA, the Federal agency responsible for determining the exposure action levels and proper dosage of KI. The FDA is currently reevaluating the guidance that it issued in 1982 on the use of KI as a thyroid-blocking agent in a radiation emergency. In particular, the FDA is reviewing the data from the Chernobyl accident to determine what, if any, changes should be made to its guidance. The staff understands that a draft of the FDA's revised guidance will be available for public comment early in 2000. When the FDA's draft revised guidance is available, it will be incorporated into the revised draft NUREG-1633. Then, the revised draft NUREG-1633 will be submitted to the Commission for approval to be published for a 60-day public comment period. The final NUREG-1633 will reflect consideration of the public comments received. The staff also intends to develop a KI public information brochure based on the final NUREG-1633.

3. Reevaluation of the Federal Policy on KI

In an October 23, 1997, memorandum to the Commissioners, the staff forwarded FEMA's draft FRN entitled, "Federal Policy on Use of Potassium Iodide as an Emergency Preparedness Measure for Nuclear Power Plant Accidents." In its June 26,1998, SRM, the Commission directed the staff to revise the FEMA draft FRN to include a statement that State and local decisionmakers, provided with proper information, may find that the use of KI as a protective supplement is reasonable and prudent for specific local conditions. In addition, the Commission reaffirmed its support for the Federal government's purchase of KI for States upon their request and indicated that the Federal funds would most likely be provided by the NRC. The Commission directed the staff to work with other Federal agencies to establish procedures to enable effective and timely use of KI by the States that have not established local stockpiles and wish to make use of the national stockpiles in the event of a severe nuclear power plant accident.

In a September 30, 1998, SRM, the Commission approved a revision of the draft FRN on Federal Policy on KI and directed the staff to provide it to FEMA for review by the Federal Radiological Preparedness Coordinating Committee (FRPCC). The staff forwarded the revised draft FRN to FEMA and, on November 5, 1998, discussed it at a meeting of the FRPCC.

In the April 22, 1999, SRM, the Commission approved issuance of the proposed rule. In addition, the Commission directed the staff to revise the draft FRN on KI Federal Policy that the staff had provided to FEMA and the FRPCC to conform to the revised Commission direction, including the Commission decision not to fund State KI stockpiles. A proposed revised Federal KI policy that meets Commission direction as stated in the April 22, 1999, SRM has not yet been offered to FRPCC. If the Commission

approves the recommended approach of making KI available through the National Pharmaceutical Stockpile as discussed below, the NRC staff will continue to work to develop that option. Once that option is sufficiently developed, the NRC can present a proposed revision of the KI policy to the FRPCC for its consideration. If progress is as expected, the decision on the policy changes should be reached by mid-2000.

The April 22, 1999, SRM also directed the staff to work with FEMA to establish and maintain regional KI stockpiles that could be used in the event of a severe nuclear power plant accident. The Commission supported NRC funding of the initial purchase and resupply of regional KI stockpiles "to the extent that this cannot be covered by FEMA under its initiatives, and to the extent that there is no Economy Act constraint on FEMA's receiving money from NRC for this purpose."

In a letter to the Commission dated April 29, 1999, James Lee Witt, Director of FEMA, expressed "strong opposition" to the unilateral reversal of the Commission's position on funding of State KI stockpiles. He also indicated that FEMA lacks authority and appropriations for acquisition of KI and stated that FEMA opposes regional stockpiles noting that, in FEMA's view, such stockpiles "would complicate, not strengthen radiological emergency preparedness."

In a June 15, 1999, reply to Director Witt, then-Chairman Jackson indicated that the NRC supports Federal funding of Federal regional stockpiles possibly collocated with pharmaceutical stockpiles being established by FEMA, and that the NRC supports initial NRC funding of such stockpiles to the extent there are no constraints on FEMA receiving money from the NRC for this purpose.[(1)] In addition, the Chairman indicated that Federal regional stockpiles of KI seem appropriate in that many States may not have stockpiles of their own irrespective of whether the Federal government offered to pay for the stockpiles. The Chairman expressed confidence that the NRC and FEMA staffs would successfully resolve the KI issue.

In accordance with the Memorandum of Understanding (MOU) between NRC and FEMA, the NRC staff provided copies of the draft pre-decisional Federal Register Notice on the final rule to FEMA in November 1999 and on January 10, 2000. On January 12, 2000, FEMA sent a letter with comments on the NRC's draft final rule package sent in November 1999. That letter, signed by Ms. Kay Goss, Associate Director for Preparedness, Training, and Exercises, reiterated Director Witt's concerns noted in his April 29,1999, letter with regard to the Commission decision not to fund State stockpiles of KI and urged the NRC to reconsider its decision on this matter. The letter also reiterated that "FEMA continues to maintain that Federal regional stockpiles will not enhance local emergency preparedness for responding to commercial nuclear power plant accidents because of the complex logistics associated with its storage and distribution."

4. Proposal for Making KI Available

In the April 22, 1999, SRM, the Commission directed the staff to work with FEMA to establish regional stockpiles of KI. As noted above, however, FEMA has stated in two letters that it opposes regional stockpiles as proposed by NRC.

Therefore, the staff is proposing to stockpile KI and make it available through the NPS being established by the Department of Health and Human Services (HHS) through CDC. The mission of the NPS is to maintain a national repository of life-saving pharmaceuticals, supplies, and equipment that will be delivered to the site of a bioterrorism event or site of an overwhelming technological or natural disaster in order to reduce morbidity and mortality in civilian populations. Under this approach, CDC would deliver medical material within 12 hours or less to any site in the continental U. S. and would hand over these supplies to a designated State representative in accordance with the Federal Response Plan. The system would include pre-crated packages ready for immediate shipment located strategically throughout the U. S. and the ability to augment these supplies with vendor-managed inventories.

The NRC staff proposal for making KI available through the NPS was developed in a series of four meetings with representatives of FEMA and CDC. In these meetings, the CDC was represented by a Senior Emergency Response Coordinator. The NRC staff recognized that the NPS could be used to enhance the existing radiological emergency preparedness programs by providing an infrastructure for KI stockpiling and delivery. If medical recommendations change (e.g., the FDA determines different doses than currently recommended), then the stockpiling requirements would be revised accordingly. There would be no need for NRC to establish and maintain regional stockpiles at multiple locations across the country nor would there be a need for NRC to monitor and replace expired stocks at these various locations since KI would be an item in the formulary of the NPS.

The next step would be a formal request from NRC to include KI in the NPS. CDC National Pharmaceutical Stockpile management have been informed that the NRC may be making such a request. The NRC staff informed the CDC that the decision to propose to CDC that they include KI in the NPS formulary would be made by the Commission.

The staff recommends that the Commission approve making a formal proposal to CDC to make KI available through the NPS. The staff believes that using the infrastructure of the NPS could be more efficient than creating and maintaining an independent infrastructure for the stockpiling and distribution of KI.

RECOMMENDATION:

That the Commission:

Approve the staff proposal to pursue the inclusion of KI in the National Pharmaceutical Stockpile (NPS) and direct the staff to prepare a formal request to CDC for its inclusion.

William D. Travers
Executive Director for Operations

Contact: Frank Congel, IRO
301-415-7476

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1. In its January 12, 2000 letter FEMA pointed out that the Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC), and the Public Health Service (PHS) are responsible for establishing the NPS, not FEMA.