POLICY ISSUE
(Notation Vote)

November 21, 2001 SECY-01-0208

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: STATUS OF POTASSIUM IODIDE ACTIVITIES

PURPOSE:

To provide the Commission with an update regarding the status of Potassium Iodide (KI) activities and to request that the Commission approve the purchase of an initial supply of KI for distribution prior to issuance of final Food and Drug Administration (FDA) guidance.

BACKGROUND

In a Staff Requirements Memorandum (SRM) reflecting approval of a final KI rule (SRM: SECY-00-0037 and SECY-00-0040, Affirmation on December 22, 2000), the Commission decided to fund State, and in some cases local, supplies of KI, subject to certain restrictions and limitations. Those restrictions include limiting funding to initial stockpiles of KI for one to two doses of KI for individuals within the plume exposure pathway emergency planning zone (plume EPZ). The Commission also directed the staff to accompany funding of KI with appropriate disclaimers for NRC and its employees.

On June 29, 2001, the Commission issued an SRM on SECY-01-0069 “Status of Potassium Iodide Activities.” In this SRM, the Commission directed the staff to make revisions to draft NUREG-1633, to resubmit draft NUREG-1633 prior to publication for public comment, and to await the publication of the final FDA guidance prior to publication of NUREG-1633. In addition, the Commission directed the staff to ensure, to the extent possible, that Commission funds allocated for stockpiles go toward purchasing actual KI tablets rather than administrative costs and that the contract with the pharmaceutical company for KI tablets includes direct distribution to requesting States.

The NRC**,** together with the Federal Emergency Management Agency (FEMA), has formed a subcommittee to develop and implement a program for an initial supply of KI to States which decide to include KI in their range of public protective actions. The use of KI would

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supplement other protective measures, such as evacuation and sheltering. The NRC/FEMA KI subcommittee has been meeting approximately monthly since January 2001 to develop procedures, processes, and guidance for KI program implementation. The subcommittee had planned to await the issuance of final FDA guidance on dosage and intervention levels prior to implementing the NRC KI supply program. FDA published its draft guidance in January 2001 (66 FR 801).

The NRC formally requested that a Federal Radiological Protection Coordinating Committee (FRPCC) subcommittee on KI be formed with representatives from the FDA and the Environmental Protection Agency (EPA), as well as the NRC and FEMA. The purpose of the FRPCC KI subcommittee is to expedite review and revision of the Federal KI policy, encourage the finalization of FDA guidance, and coordinate KI implementation issues. That subcommittee had its initial meeting on September 25, 2001. Additionally, as requested by the NRC through the FRPCC, FEMA Director Allbaugh sent a letter to the U.S. Department of Health and Human Services (HHS) Secretary Thompson requesting expedited completion of the FDA guidance on the use of KI.

Since the events of September 11, 2001, there has been greater public interest in the use of KI. The staff has received many phone calls and e-mails from members of the public, State and local officials**,** and the news media regarding the NRC's plans for the supply and distribution of KI. The FRPCC KI subcommittee is being used as a forum to discuss and develop recommendations regarding the impact of the September 11 events on the Federal KI policy, and KI stockpiling and distribution issues.

DISCUSSION

The staff has explored the option of purchasing an initial supply of KI for the States in advance of the FDA final guidance. NRC discussed this option with cognizant FDA and FEMA personnel who stated they support the NRC in the purchase of KI prior to issuance of FDA final guidance.

The FDA has stated that dosing guidelines and recommended intervention levels will not change between the draft and final guidance. The FDA expects to publish its final guidance by the end of November 2001. It is expected that if the Commission approves moving forward with purchasing KI at this time, the final FDA guidance would be available for use by the States at the time the KI is available for distribution. Should the final FDA guidance not be available, the dosage and intervention levels from the draft FDA guidance will be used based upon the fact that these guidelines will not be revised.

FEMA staff is prepared to support this NRC effort for purchase and distribution of KI and will prepare guidelines and expectations for States' use. FEMA also has agreed to allow sufficient time for the States to modify their emergency plans to incorporate the use of KI for the public.

Should the Commission approve the option to purchase KI at this time, the staff will negotiate a two-year commercial contract with FDA-approved manufacturers, as well as distributors for the purchase of KI. The contract will require the contractor to ship KI to specified addresses and provide NRC proof of delivery.

KI is commercially available in 130 mg tablets, scored to be split into two pieces**,** and is packaged in lots of 14 tablets. There are two FDA-authorized manufacturers of KI: MedPointe Inc. (MedPointe), and Anbex Inc. (Anbex). The commercial price per pill for large quantities has not yet been determined. Based on market research, the commercially available minimum price, including shipping and handling, is as low as $0.23 per tablet. MedPointe-manufactured KI is currently available in bottles of 14 pills while Anbex sells its KI as individually wrapped tablets. The shelf life for MedPointe is five years; Anbex shelf life is five years, with a pending FDA application for a two-year extension up to a seven-year shelf life. Based on market research, it is possible for the contractor to make its first shipment of KI within 30 days of contract award.

There are approximately three million people in the 10-mile EPZs of all NPPs. About six million tablets would be needed in order to supply up to two doses per person in the 10-mile EPZs, assuming that all States request an initial supply of KI. With the available funding of $800,000, at commercial prices, approximately 3.4 million tablets could be purchased. The staff has requested additional funds for KI purchases as part of the terrorism response emergency funding request.

Should the Commission approve KI purchase at this time, the staff has prepared the attached draft letter to the States informing them of the availability of KI which includes instructions on how to obtain KI from the NRC. This letter will include the following five attachments: 1) FDA guidance on use of KI; 2) FEMA implementation guidance; 3) Statements of Consideration published in support of the final KI rule; 4) optional KI application form; and 5) NRC Disclaimer. The FEMA guidelines will be prepared after any Commission approval of the commercial purchase of KI.

COORDINATION

The Office of the General Counsel has reviewed this Commission paper and has no legal objection to its content.

The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections.

The staff has also coordinated this Commission paper with FDA and FEMA.

RECOMMENDATION

The staff recommends that the Commission approve purchase and distribution of KI tablets as discussed in this paper.

/RA/

William D. Travers
Executive Director
for Operations

Attachment: As stated

LETTER TO STATES
DRAFT

As you know, the NRC has amended its emergency planning regulations to require that consideration be given to including the prophylactic use of potassium iodide (KI) as a protective measure for the general public in the plume exposure pathway Emergency Planning Zone (EPZ) that would serve as a supplement to sheltering and evacuation. Concomitant with this action, the NRC will provide funding for an initial supply of KI for States with population within the plume exposure pathway EPZ that choose to incorporate KI for the general public in its emergency plans. The term States includes local governments that have been designated by the State to request such funding and federally recognized Native American governments.

Together with the Federal Emergency Management Agency (FEMA), the NRC formed a subcommittee to develop and implement a program to provide KI to requesting States. The subcommittee had been awaiting the issuance of final Food and Drug Administration (FDA) guidance on dosage and intervention levels, prior to implementation of the NRC KI program.

The NRC, in coordination with FEMA and the FDA, is developing the means to provide KI to States. Within approximately 30 days, the NRC will be positioned to supply KI to States upon request. The following information is attached to this letter for your consideration and use: FDA guidance on use of KI (Attachment 1); FEMA guidelines for KI program implementation (Attachment 2); NRC Statements of Consideration published in support of the final KI rule (Attachment 3); optional KI application form (Attachment 4); and NRC Disclaimer (Attachment 5). States are encouraged to begin their process for considering the use of KI as early as possible, recognizing that the NRC's resources for this purpose will be limited. NRC will provide KI to requesting States on a first come, first serve basis.

When your State has completed its consideration process, concluded that incorporating KI for use by the general public is appropriate for your specific local situation, and that requesting KI from NRC is desired, the NRC requests that you respond by letter addressed to: Kathy Halvey Gibson, Chief, Emergency Preparedness and Health Physics Section, U.S. NRC, Washington, D.C. 20555. Your letter must provide the following information: the nuclear power plant (NPP) site(s), the population in the NPPs' 10-mile EPZ for which you are responsible, the contact person authorized to receive the KI, and the "Ship to" address for KI delivery. Upon receipt of this information, the NRC will validate the data and make arrangements to have KI shipped to your designated contact/address. The NRC will supply two KI tablets for each person in the 10-mile EPZ(s).

The NRC requests that one consolidated request be submitted for each State or Native American government. If decisions about emergency planning and the use of KI are the responsibility of local, rather than State authorities, the NRC requests that the State consolidate the local requests and forward the consolidated request covering all NPPs within the State to the NRC.

Should you decide not to request KI, please respond to the NRC by letter stating that decision.

If you have questions or require assistance in this matter, please contact either Kathy Halvey Gibson, NRC, 301-415-1086 or Vanessa Quinn, FEMA, 202-646-3664.

Thank you for your consideration of this important issue.

ATTACHMENT