POLICY ISSUE
NOTATION VOTE

April 24, 2001 SECY-01-0069

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: STATUS OF POTASSIUM IODIDE ACTIVITIES

PURPOSE:

To provide to the Commission revised draft NUREG-1633 (Attachment 1), "Assessment of the Use of Potassium Iodide (KI) as a Supplemental Public Protective Action During Severe Reactor Accidents" for approval for public comment as directed in Staff Requirements - Affirmation Session, 10:15 A.M. Friday, December 22, 2000, Commissioners' Conference Room, One White Flint North, Rockville, Maryland (Open to Public Attendance) (Attachment 2). To provide information on the status of program development to implement KI funding for States. To provide the status of the revision to the Federal KI Policy.

BACKGROUND:

On December 22, 2000, the Commission approved a final rule amending 10 CFR 50.47(b)(10) 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. The final rule was published in the *Federal Register* on January 19, 2001 (66 FR 5427) with an effective date of April 19, 2001. Staff Requirements Memorandum (SRM), dated December 22, 2000, states that the Commission will fund State stockpiles of KI and work with the Federal Emergency Management Agency (FEMA) for the effective implementation of the distribution of KI. The Commission directed the staff to recommend consideration by FEMA of revisions to the Federal Policy on KI and keep the Commission informed of FEMA's progress in producing the final draft. Additionally, the Commission directed that NUREG-1633 be revised pursuant to the Commission's decisions on KI and the final rule, and pursuant to Food and Drug Administration (FDA) draft revised guidance, and, when revised, be submitted to the Commission for approval prior to publication for a 60-day comment period.

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DISCUSSION:

There are three principal activities associated with implementing the Commission's decision on KI. They are (1) preparation of revised draft NUREG-1633, "Assessment of the Use of Potassium Iodide as a Supplemental Public Protective Action During a Severe Reactor Accident"; (2) development and implementation of a KI tablet/funding program; and (3) publication of revised federal policy on the use of KI. The status of each of these activities is discussed below.

1. NUREG-1633 "Assessment of the Use of Potassium Iodide as a Supplemental Public Protective Action During a Severe Reactor Accident"

In SRM, COMSECY-98-016, issued on September 30, 1998, the Commission directed the staff to withdraw the existing draft version of 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 which use KI as a supplement. A discussion, in some detail, of the various guidance documents of the World Health Organization (WHO) and the International Atomic Energy Agency (IAEA), as well as the U.S. Food and Drug Administration (FDA), would be very useful to state and local decision makers. 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 revised draft NUREG forwarded with this paper for Commission approval to be published for public comment, presents information that State and local decision makers could use to (1) decide whether KI should be incorporated into their current offsite emergency response plans; and (2) determine the best method to distribute KI to members of the public living within the 10-mile emergency planning zone (EPZ) of nuclear power plants. To this end, the staff considered the public comments and the comments of the 'KI Core Group', as well as the direction provided in COMSECY-98-016 and SRM dated December 22, 2000, in preparing the revised draft NUREG-1633. The revised draft discusses various aspects of the use of KI during nuclear power plant emergencies. The revised draft also contains direct input from those States that have KI as a supplemental protective action (Alabama, Tennessee, Arizona and New Hampshire). These States detailed the experiences they have had in the implementation as well as KI distribution phases of their programs. The international community also provided input on the programs that they have in place.

The revised draft FDA guidance is also included in its entirety as a chapter within revised NUREG-1633. The comment period on the draft FDA guidance ends on April 27, 2001. Revised NUREG-1633 relies heavily upon findings as presented in the draft FDA guidance. Should the FDA guidance change as a result of the public comments received, then the appropriate changes would also be made in NUREG-1633. The WHO recommendations are

included in an appendix to provide an international perspective on the use of KI. The IAEA guidance document has not been published in final form and therefore was not included in the NUREG.

2. Development and Implementation of a KI program

The NRC/FEMA Steering Committee co-chairs met on January 29, 2001 to discuss the expectations of the Commission on the implementation of a KI program as outlined in SRM dated December 22, 2000. At this meeting, it was determined that a KI subcommittee would be appointed, under the auspices of the NRC/FEMA Steering Committee, with staff from NRC and FEMA participating. Office of Nuclear Reactor Regulation (NRR) staff met with the Office of the General Counsel (OGC) on February 14, 2001 to request that an appropriately worded disclaimer, per the SRM and the Statements of Consideration (SOC) Issue H, be developed. OGC has drafted a proposed disclaimer which is attached (Attachment 3). FEMA will use a similar disclaimer.

A teleconference with the KI subcommittee was held on February 16, 2001, to discuss the SRM, proposed federal policy on KI, as well as the final rule SOC. The subcommittee met on February 27, 2001 to develop a charter and task list and discuss an implementation plan (Attachment 4). The charter and task list were presented to the NRC/FEMA Steering Committee at their March 1, 2001, meeting for approval. As an action item from the Steering Committee, the subcommittee met on March 14, and drafted a letter (Attachment 5) that was sent from both agencies steering committee co-chairs, to inform their regional offices about the rulemaking and program development.

NRC/FEMA staff roles and responsibilities for the KI program and a milestone schedule for program implementation are under development by the KI subcommittee and will be finalized pending the completion of FEMA staff's brief of their new Director. The subcommittee has developed three proposed application processes as well as three distribution options. These options are provided for information and are discussed below. The subcommittee decided that, while local governments may be designated by the States to request KI, all requests for KI should come through the appropriate State or Tribal government. An application form detailing the State's request for KI will be developed. The options are presented in the current order of preference of the KI subcommittee. The options detailing the application process assume NRC management of funds.

A. Application Process

Option 1. States apply to designated NRC HQ office. The requests are date-stamped and forwarded to FEMA HQ. FEMA HQ would then forward the application to the appropriate FEMA region for review and approval. The approved applications will then be forwarded, via FEMA HQ, to the NRC for release of KI tablets or funds. This process is similar to the process by which NRC and FEMA interact to coordinate the resolution of off-site Emergency Preparedness (EP) issues, such as allegations.

Option 2. States apply to FEMA HQ office. The requests are date-stamped and forwarded to FEMA region for review and approval. The approved forms would be forwarded from FEMA HQ to NRC for release of KI tablets or funds.

Option 3. States apply directly to FEMA regional offices for review and approval. The approved applications are then forwarded to FEMA HQ and in turn to NRC for release of KI tablets or funds.

B. Distribution Process

Option 1. NRC would purchase KI tablets in bulk and arrange direct shipment of KI tablets to States after approval of application by appropriate FEMA office. This option is preferred by the KI subcommittee because it enables bulk purchase of tablets for the lowest cost and ensures that the appropriated funding will be used only for the purchase of KI tablets. This option places minimal burden on FEMA and maintains NRC control of the program and expenditure of funds. The FDA guidance must be final prior to a statement of work and contract for bulk purchase of KI tablets to insure that the correct dosages and numbers of tablets are purchased.

Option 2. NRC would transfer funds to FEMA. FEMA would distribute either funds or tablets to the States after approval of the State's application. The program implementation for KI use in offsite EP would rest with FEMA, who is primarily responsible for offsite EP per NRC/FEMA Memorandum of Understanding. However, this option would reduce NRC control over the actual spending of the limited funds available for KI as well as increase the burden on FEMA.

Option 3. NRC would transfer funds directly to States for purchase of KI tablets by the States after completing the approval process. This may be the quickest option to get funding to the States. The disadvantages of this option are: 1) smaller orders for KI may result in higher costs for tablets; and 2) more NRC staff effort would be required to ensure that funds are used only for KI tablets and not funding of any State program costs.

These options will be presented to the NRC/FEMA Steering Committee for their consideration and recommendations.

The staff is developing a KI website to keep interested parties informed of the program development and subsequent implementation (Attachment 6). This will be updated regularly as the program development and implementation moves forward.

The staff met with the Office of Administration (ADM) contract specialist on March 9, 2001, to discuss various purchase options for KI, including bulk purchase of KI tablets, with direct shipment to the requesting states. The staff will continue to work with ADM to evaluate cost-effective options for purchase of KI tablets.

The staff has briefed the Office of Public Affairs (OPA) and the staff is working with OPA on answers to likely questions from the interested parties about the rulemaking, KI, and the implementation program. The Office of State and Tribal Programs (STP) was briefed during their regional counterpart meeting with State Liaison Officers. Representatives of NRR attended and made a presentation on KI, as well as participated in a panel on KI with FEMA and FDA, at the National Radiological Emergency Preparedness Conference held in Nashville, TN on April 2-5, 2001. Additionally, the staff regularly provides updates for the Chairman's Tasking Memorandum milestone schedule.

The next meeting of the KI subcommittee is scheduled for April 18, 2001 to continue development and implementation of the KI program. The NRC/FEMA Steering Committee will be briefed and provided the application and distribution options and the milestone schedule for their consideration and recommendations at their next meeting in June 2001.

3. Draft Federal KI Policy

The staff presented the Commission's recommended revision of the KI Federal Policy to the Federal Radiological Preparedness Coordinating Committee (FRPCC) for review and comment on January 17, 2001. FRPCC member agencies were requested to review the draft and provide comments to FEMA by February 16, 2001. As of the due date, FEMA had received comments from only two agencies. The staff participated in an FRPCC retreat held on March 7-8, 2001. At this retreat, the NRC staff requested a commitment from the FRPCC on timely approval of the Federal KI Policy. The FRPCC Chair committed to conduct a vote on approval of the draft Federal KI Policy at the next FRPCC meeting scheduled for May 8, 2001. However, the policy is still under review by FEMA. When FEMA sends its formal comments to the NRC, the staff will forward them to the Commission for its review and approval. FEMA has recognized that a special meeting of the FRPCC may need to be convened if the May 8 vote cannot be realized due to a delay in forwarding the comments to the NRC.

CONCLUSION:

The staff has followed the Commission's direction provided in COMSECY-98-016 and SRM dated December 22, 2000, in preparing the revised draft NUREG-1633 forwarded with this paper for Commission approval for publication for public comment. The issuance of NUREG-1633 as a final document and the implementation of the KI program is dependent upon the issuance of FDA's final guidance on the use of KI. The comment period on the draft FDA

guidance was extended from February 4, 2001 until April 27, 2001. It is unknown at this time, when the final guidance will be issued. The FDA's final guidance may impact draft NUREG-1633, which would need to be revised prior to publication, to accommodate any FDA guidance changes. The staff intends to develop a program structure to enable timely implementation of the program when the final FDA guidance is released.

RECOMMENDATION:

That the Commission approve the staff recommendation to publish draft NUREG-1633 for a 60-day public comment period.

COORDINATION:

The Office of the General Counsel has reviewed this paper, as well as draft NUREG-1633, and has no legal objection.

/RA/

William D. Travers
Executive Director
for Operations

Attachments:
1. NUREG-1633, Assessment of the Use of Potassium Iodide (KI) as a Supplemental Public Protective Action During Severe Reactor Accidents
2. Staff Requirements Memorandum, dated December 22, 2000, M001222
3. Draft Disclaimer
4. NRC/FEMA KI Subcommittee charter and task list
5. NRC and FEMA letters to Regional Directors on KI rulemaking
6. KI Website

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