RESPONSE, PLEASE
REFER TO: M001222

December 22, 2000

MEMORANDUM FOR: William D. Travers
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary /RA/

SUBJECT: 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)[1]

I. SECY-00-0037 - Status of Potassium Iodide Activities - and - SECY-00-0040 - Final Amendments to 10 CFR 50.47; Thereby Granting in Part Two Petitions for Rulemaking (50-63 and 50-63A); Relating to a Reevaluation of Policy on the use of Potassium Iodide (KI) for the General Public after a Severe Accident at a Nuclear Power Plant

The Commission approved a final rule amending 10 CFR 50.47 to grant one petition in part and grant the amended petition for rulemaking related to NRC policy and regulations concerning the consideration and use of potassium iodide as one of the elements in offsite emergency planning in the event of a severe reactor accident. The final rule amends 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 Emergency Planning Zone (EPZ) that would serve as a supplement to sheltering and evacuation.

The revised Federal Register notice (Attachment 1) should be reviewed by the Rules Review and Directives Branch in the Office of Administration and forwarded to the Office of the Secretary for signature and publication.

(EDO) (SECY Suspense: 1/26/01)

The Commission has decided to fund State stockpiles of potassium iodide (KI) and work with the Federal Emergency Management Agency (FEMA EXIT) for the effective implementation of the distribution of KI.[2] The Commission has determined that for a State that has decided to stockpile KI, NRC funding for purchases of KI for use by that State during a radiological emergency would make a direct contribution to fulfilling NRC's regulatory mission. This decision is consistent with the decisions of the Commission on June 30, 1997, and June 26, 1998, and reverses the April 22, 1999, decision to establish and fund regional stockpiles of KI. The Commission has also disapproved the staff's recommendation to pursue inclusion of KI in the National Pharmaceutical Stockpile (NPS) at NRC expense. However, the Commission does not discourage the inclusion of KI in the NPS if the Centers for Disease Control and Prevention, or any other government entity, deem it appropriate. To expedite the work with FEMA, which has the lead for drafting the Federal Policy on Potassium Iodide (Draft Policy), the NRC staff should recommend consideration by FEMA of the attached revisions in the Draft Policy reflecting the Commission's decisions in this SRM. The staff should ascertain FEMA's plans for finalizing the Draft Policy and keep the Commission informed of FEMA's progress in producing its final draft.

FEMA's Draft Policy currently provides that "[a]ny State, or in some cases, local government, that selects the use of KI as a supplemental protection measure for the general public may so notify the FEMA Regional Director from the FEMA Region in which the State is located, and may request funding for the purpose of purchasing a supply." Because the policy contemplates that requests for funding for stockpiles will be directed to FEMA, but will also provide that the Commission will be responsible for funding States' requests for KI supplies, the staff should work closely with FEMA to carry out the Commission's decision on funding. Accordingly, the staff should inform FEMA that in offering to fund State or in some cases local government stockpiles, the Commission intends only to fund supplies for one to two doses per individual for those within the 10-mile Emergency Planning Zone (EPZ) provided in NRC and FEMA Regulations. The Commission also only intends to fund purchases consistent with the anticipated revision of the Food and Drug Administration (FDA) recommendations on potassium iodide doses. After funding the initial purchases of KI, the Commission may consider extending the program to fund stockpile replenishment, but has made no commitments in this regard. The Commission also does not intend to fund any ancillary costs, including costs associated with storing stockpiles or distributing KI in the event of an emergency.

The Commission is anxious to work cooperatively with FEMA and other members of the Federal Radiological Preparedness Coordinating Committee (FRPCC) to bring this important issue to a conclusion. The Commission's expectation is that FEMA will only provide funding in response to requests by States, by local governments that have been designated by the State to request such funding and by federally recognized Tribal governments. The Commission believes that the funding scheme should be consistent with, and supportive of, the Commission's long-standing working relationships with Agreement States, non-Agreement States, and Tribal governments.

The staff should coordinate with FEMA the most efficient and cost-effective way to fund the stockpiles. The Commission expects a cost per dose of about 20 cents or less. Further, the staff and FEMA should consider purchasing KI in bulk to take advantage of volume acquisition at low cost, and therefore, effectively cap the amount the NRC will pay per recommended dose. The staff should inform FEMA that the Commission has budgeted $400,000 in FY 2001 for KI funding and will be requesting similar funding in FY 2002. The staff and FEMA should work out a fair policy for allocating the authorized funding to meet funding requests. Therefore, the States are encouraged to begin their process for considering KI as early as possible,

recognizing that the NRC's resources for this purpose will be limited. The staff should accompany any funding for KI with the appropriate disclaimers to ensure that the NRC and any of its employees are not to be held responsible for any activity connected with transporting, storing, distributing, administering, using, or determining the proper doses of KI for adults or children.

The Commission believes that substantial additional changes may be needed in the revised draft NUREG-1633 pursuant to the Commission's decisions on this paper and the final rule, and pursuant to FDA's draft revised guidance. The revised draft NUREG-1633, when it is available, should be submitted to the Commission for approval to be published for a 60-day public comment period.

(EDO) (SECY-Suspense: 90 days after FDA issues the draft revised guidance for public comment)

Attached are the Commission's revisions to the Statements of Consideration on the final rule and FEMA's Draft Policy.

Attachment 1: Revised Federal Register for Final Rule in SECY-00-0040
Attachment 2: Revised draft FEMA Federal Register Notice

cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
CIO
CFO
OCAA
OCA
OIG
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR - Advance

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1. Section 201 of the Energy Reorganization Act, 42 U.S.C. Section 5841, provides that action of the Commission shall be determined by a "majority vote of the members present." Chairman Meserve and Commissioners Dicus and McGaffigan were present in the Conference Room. Commissioners Diaz and Merrifield participated in the meeting via speakerphone.

2. In limited circumstances, the Commission will provide funding for local stockpiles as discussed below.