FRPCC KI SUBCOMMITTEE
MEETING SUMMARY

MEETING DATE: September 27, 2001
10 am

LOCATION: NRC HQ
One White Flint North
Rockville, MD

ATTENDEES: Don Thompson,FDA
Bill McNutt, FEMA
Craig Howard, FEMA
Kathy Halvey Gibson, NRC
Glenn Tracy, NRC
Patricia Milligan, NRC

MEETING SUMMARY:

1. PURPOSE: The purpose of the FRPCC subcommittee is to expedite review and revision of the Federal KI Policy, encourage finalizing FDA guidance, and coordinate KI implementation issues**.**

2. CURRENT EVENTS

a. HHS/CDC: The Center for Disease Control is investigating including KI in their National Pharmaceutical Stockpiles. The CDC requested population information for the 10 and 50 mile EPZs surrounding nuclear power stations.

b. IAEA/WHO: The International Atomic Energy Agency convened a technical committee to discuss the possible modification of the Safety Standards on recommended intervention levels for use of KI. Due to the terrorist attacks of September 11, 2001 and the unavailability of international flights, the U.S. did not send representatives from NRC or EPA, however, the U.S. position was faxed to the meeting chairman for inclusion into the meeting minutes. The meeting concluded with the recommendation to leave the intervention level for KI prophylaxis at 10 Rem, with wording to be included to recognize that individual countries may adjust this level to best meet the needs of their populations and specific local conditions.

3. STATUS OF NRC KI ACTIVITIES

a. NRC/FEMA KI SUBCOMMITTEE: The subcommittee is working to develop a KI implementation program for States that wish to include KI prophylaxis in their range of public protective actions and request funding from NRC.

b. NUREG-1633: This document is under revision prior to publication for public comment. The completion and publication of the document is dependent upon the FDA guidance being finalized.

c. **LETTER TO STATES/APPLICATION:** The NRC/FEMA steering committee KI subcommittee is developing a process by which States can apply for KI.

d. **RFPA FOR KI:** The RPFA is waiting final FDA guidelines prior to issue to insure that the appropriate drug dose/tablets are purchased.

4. STATUS OF OTHER AGENCY ACTIVITIES

a. **FDA GUIDANCE**: The comment review is completed and the draft is being worked to address the stakeholder comments. The draft will be circulated throughout FDA for concurrence prior to final publication. This guidance will supercede the 1982 FDA Federal Policy on the use of potassium iodide.

b. **EPA PAGS**: The status of the EPA PAG revision was not discussed as the EPA representative was unable to attend this meeting.

5. KI FEDERAL POLICY

a. **1982 FDA POLICY:** The present FDA KI policy will be superceded by the revised FDA guidelines, see 4a.

b. **1985 FRPCC POLICY:** The current policy does not recommend KI for members of the public and requires revision.

c. **NRC PROPOSED REVISED POLICY:** The NRC proposed revised wording for the KI federal policy in SRM-00-1222, attachment 2. The FRPCC subcommittee members will review this policy, the existing federal policy and the proposed policy written by Bill McNutt, FEMA, for discussion at the next meeting.

6. ACTION PLAN/SCHEDULE

a. **ISSUES FOR CONSIDERATION FOR NEXT MEETING:**

i. Should revised policy be issued before or after FDA guidance finalized?
ii. What level of detail is appropriate in the policy?
iii. Will CDC activities have impact on policy?
iv. Should funding be discussed in policy?
v. Should reference/discussion of EPA PAGs be included in policy or referenced as supplemental information?
vi. Should reference/discussion of FDA guidance be included in policy or referenced as supplemental information?
vii. Should reference/discussion of NRC rule be included in policy or referenced as supplemental information?
viii. Is the existing federal KI policy, with minor changes, adequate?

b. **NEXT MEETING DATE:** to be determined.

7. NRC WEBSITE: http://www.nrc.gov/NRC/REACTOR/KI/index.html

8. BACKGROUND INFORMATION: On May 23, 2001, members of NRC staff met with FEMA representatives to discuss the history, roles and responsibilities, process, and time line for revising the Federal KI Policy per the NRC Staff Requirements Memorandum dated December 22, 2000. The meeting was prompted by a FEMA letter to NRC dated May 4, 2001, in which FEMA stated that the revised policy should not be issued until after the FDA guidance is finalized. FEMA affirmed that the role of the FRPCC was an advisory body to FEMA and that FEMA would ultimately approve and issue any revisions to the Federal KI Policy. NRC and FEMA representatives agreed

that an FRPCC subcommittee should be reconvened to foster timely and efficient revision of the policy.

NRC formally requested that FEMA form an FRPCC subcommittee on KI with representatives from EPA and FDA, as well as NRC and FEMA. At an FRPCC meeting on August 1, 2001, the FRPCC accepted NRC's recommendation to form an FRPCC subcommittee on KI with representatives from NRC, FEMA, EPA and FDA. The purpose of the FRPCC subcommittee is to expedite review and revision of the Federal KI Policy, encourage finalizing FDA guidance, and coordinate KI implementation issues. At the request of NRC through the FRPCC, FEMA Director Albaugh sent a letter to HHS Secretary Thompson requesting expedited review of the FDA guidelines on the use of KI.

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