POLICY ISSUE
NOTATION VOTE

May 22, 2002 SECY-02-0089

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: REVISED DRAFT NUREG-1633 AND PUBLIC INFORMATION BROCHURE ON POTASSIUM IODIDE (KI) FOR THE GENERAL PUBLIC

PURPOSE:

In accordance with Staff Requirements Memorandum (SRM), SECY-01-0069 – "Status of Potassium Iodide Activities" dated June 29, 2001, the staff is submitting revised draft NUREG-1633 to the Commission for review prior to publication for public comment. This paper also provides the text of a proposed public information brochure for Commission review and comment.

BACKGROUND:

On June 29, 2001, the Commission issued Staff Requirements Memorandum (SRM), SECY-01-0069 - "Status of Potassium Iodide Activities." The SRM directed the staff to revise the draft NUREG-1633, "Consideration of the Use of Potassium Iodide During Severe Nuclear Reactor Accidents," to include the comments and direction provided in the SRM and to resubmit the draft to the Commission for comment prior to publication. A staff commitment to provide a public information brochure was made in SECY-00-0037, "Status of Potassium Iodide Activities."

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DISCUSSION:

The staff revised draft NUREG-1633 as follows:

1. The Food and Drug Administration (FDA) has published the final guidelines on the use of potassium iodide (66 FR 64046). The final FDA guidelines are provided as Attachment 2 of draft NUREG-1633.

2. A discussion of the history of the international KI guidance has been included in the main body of the draft NUREG. Section 3.3 discusses the recommendations of the World Health Organization (WHO) and Section 3.4 includes the recommendations of the International Atomic Energy Agency on stable iodine prophylaxis.

3. The NUREG has been modified to be consistent with the Statements of Consideration for the final rule on KI published in the Federal Register (66 FR 5247) January 19, 2001, with one exception. The Statements of Consideration for the final rule states that "KI would help prevent thyroid cancers in the unlikely event of a major release . . . " In fact, according to the FDA and WHO, potassium iodide, when used correctly, reduces the risk of thyroid cancer. This is a subtle but important distinction. The draft NUREG now states specifically "the Commission finds that KI is a reasonable, prudent and inexpensive supplement to evacuation and sheltering for specific local conditions" (Preface, Executive Summary and Conclusions). Section 4.2 includes the paragraph as directed in item 3 of the SRM on SECY-01-0069.

4. The discussion on alternative source terms was revised per the direction in the SRM. The guidance regarding the use of alternative source terms from Regulatory Guide 1.183 was included (section 1.3.1).

5. Chapter 2 was revised to delete duplicative information. The sections on Chernobyl thyroid cancer incidences and the Polish KI experience were relocated to Chapter 3. Chapter 3 clarifies that the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) report is consistent with and supportive of the guidance issued by WHO and FDA.

6. In accordance with Commission direction to make this NUREG a more useful document, only States with actual implementation experience/lessons learned were included. Consequently, Chapter 5 on the States' experiences was revised. The Commonwealth of Pennsylvania and the State of Ohio's programs, at this time, are still in the development process. The State of Ohio specifically requested that the NRC not publish any details of Ohio's proposed draft program until it has been finalized. The response from Ohio is attached. The State of Maine had developed a policy but had no program implementation experience to share with other States. The policy developed by the State of Maine does not specifically address nuclear power plant accidents nor emergency planning zones. The policy covers residents in the entire State of Maine. The staff was concerned that inclusion of the Maine policy may be considered by some

stakeholders to be an endorsement of expanded (i.e., 20-mile or 200 mile) emergency planning zones when considering the use of potassium iodide as contrasted to Commission direction to provide one to two doses of potassium iodide for residents within the 10 mile EPZ of a nuclear power plant. The Maine policy is publicly available and is attached for your information.

Connecticut's program of KI use for institutionalized persons and emergency workers is consistent with the guidance of NUREG-0654/FEMA-REP-1, page 63, "provisions for the use of radioprotective drugs, particularly for emergency workers and institutionalized persons within the plume exposure EPZ whose immediate evacuation may be infeasible (sic) or very difficult. . ." All states with nuclear power plants within their borders or those with populations within the EPZs of nuclear power plants adhere to this guidance, which was first published in 1980. Connecticut's program is, therefore, not included in this draft NUREG.

There are four states that have long included KI prophylaxis for the general public. These states are Tennessee, Alabama, Arizona and New Hampshire. Their programs and logistical experiences are included in this draft NUREG.

7. International experience in Chapter 6 was revised. The French program was updated to reflect the most recent changes, i.e., door-to-door distribution. The experiences of the Czech Republic, Hungary, Belgium and the Slovak Republic were added. These countries responded to staff requests and sent useful details of their programs.

8. The information provided by the States and the international community is current as of the date of this report. The lessons learned and experience gained by the States and the international community, as discussed in Chapters 5 and 6, are summarized in Chapter 7, Section 7.2, Pre-Accident Distribution and Section 7.3, Post-Accident Distribution.

9. A discussion of the various methods of KI distribution, as well as the pros and cons of each method is also included in Chapter 7. The "pros" were labeled and discussed as "objectives accomplished" while the "cons" are labeled as "elements that need to be considered." This designation was used because a "con" for one reactor site may, in fact, be a "pro" for another specific local condition. Further, the use of these labels has the additional advantage of avoiding potential reader bias.

10. The staff requested FDA to address KI prophylaxis for individuals more than 40 years of age under the postulated circumstances of a reactor accident. However, the final FDA guidance was published without changes to recommendations regarding prophylaxis for the population more than 40 years of age under specific reactor accident conditions. Therefore this item is not addressed at this time.

11. Attachment A to the SRM on SECY-01-0069, item 8, requests that the staff delete the first sentence and add the following "The Commission intends to fund initial supplies for

one or two doses per individual, consistent with FDA guidance, for those within the 10-mile EPZ as provided in NRC and FEMA regulations." This change was not included because the NRC program to fund KI purchases, is not at this time, consistent with FDA final guidance on potassium iodide. In SECY-01-0208, the staff stated that the contract to provide KI would be awarded only to an FDA-approved vendor. The FDA-approved vendors are, at this time, only able to supply KI as 130 mg tablets in packages of 14 tablets, with dosage guidelines that are not consistent with the final FDA guidance.

The revised Federal Policy was published in the Federal Register, January 10, 2002 (FR Vol. 67, No. 7). The staff has signed a contract with a vendor for KI distribution. To date, twelve states have requested KI from the NRC.

The staff worked with FEMA and FDA on the public information brochure and the text is included for review and comment as Attachment 6. FEMA may also publish some version of this text for its purposes. Upon Commission approval of the text, the NRC staff will make the brochure available to the States for their use.

CONCLUSION:

The staff has completed the Commission direction provided in its June 29, 2001, SRM on SECY-01-0069. The revised draft NUREG-1633 is forwarded with this paper for Commission approval.

RECOMMENDATION:

That the Commission approve the staff recommendation to publish NUREG-1633 for a 60-day public comment period and approve the KI public information brochure.

RESOURCES:

The resources for moving forward, upon Commission approval, with publication of the draft NUREG-1633 are included in the current budgets for FY 2002 and FY 2003.

COORDINATION:

The Office of General Counsel has reviewed this paper, as well as draft NUREG-1633 and the draft public information brochure, 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 during Severe Reactor Accidents
2. Staff Requirements –SECY-01-0069-Status of Potassium Iodide Activities dated June 29, 2001
3. State of Ohio Draft KI Policy e-mail
4. State of Maine Protocol on the Distribution and Administration of Potassium Iodide Dated April 27, 1997
5. Discussion of Maine Policy on KI e-mail
6. Public Information On Potassium Iodide (KI)

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