June 29, 2001

MEMORANDUM TO: William D. Travers
Executive Director for Operations

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

SUBJECT: STAFF REQUIREMENTS - SECY-01-0069 - STATUS OF POTASSIUM IODIDE ACTIVITIES

The Commission has directed the staff to revise Draft NUREG-1633 subject to the changes provided in the attachment and the following comments. The revised draft NUREG should be provided to the Commission prior to publication for comment.

1) Publication of Draft NUREG-1633 should await the publication of the final FDA guidance, which should be included in the NUREG. While awaiting the publication of the final FDA guidance, the staff should undertake a global review of the scope and contents of the NUREG to make it a more consistent and useful document.

2) A discussion of the history of international KI guidance should be included in the main body of the report. The WHO document should not be included as an attachment but both WHO and IAEA documents should be appropriately referenced.

3) The NUREG should be consistent with the statements of consideration in the final rule. Wherever possible, the Commission-approved statements and responses to public comments on the final rule should be reiterated in the NUREG. For example, Section 4.2 (Consideration of the Use of KI) and Section 4.3 (Funding of KI) of the NUREG should more closely reflect the responses to Issue E (Requiring versus Considering Use of KI) and Issue F (Funding), respectively. Likewise, the recommendations of health organizations on using KI to reduce the risk of thyroid cancer should be reiterated clearly to help the States with their decision making. Also, the staff should modify the discussion of the Commission's findings with respect to KI. The SOC states, "[t]he Commission finds that KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering <u>for specific local conditions</u>." Final Rule: Consideration of Potassium Iodide in Emergency Plans, 66 Fed. Reg. 5427, 5430 (Jan. 19, 2001)(underline added). The draft NUREG repeats a portion of this finding in numerous places, but in every instance leaves off underlined language. The staff should modify the draft NUREG to include the entire quote each time it is repeated. The quote should also always be put in context. For example, in the SOC the quote is directly followed by the following discussion in responding to a commenter:

> Through its decision to require that the use of KI be 'considered' (rather than being required), the Commission is acknowledging that the efficacy of any protective measure will depend upon a number of factors, including those noted by the commenter, that can vary not only between countries but in individual States. Thus, the Commission concluded that decisions on the use of KI need to be resolved on a case-by-case basis. As part of this consideration, State and local governments can weigh all relevant factors. 66 Fed. Reg. at 5430 (emphasis added).

This discussion, or a slightly modified version, should be added to the various places in the NUREG that repeat the quote.

4) The discussion of the alternative source terms in Chapter 1 appears to be stated more categorically than other source term documents, and may not be necessary or relevant to this guidance document. The staff should consider deleting it. If retained, it should be expanded or revised to correct the deficiencies.

5) Chapter 2 duplicates much of the FDA guidance in Chapter 3 and should be simplified to remove the repetitious material or eliminated. If Chapter 2 is retained, it needs to be clarified that the UNSCEAR 2000 report is consistent with and supportive of both WHO's and FDA's guidance.

6) In Chapter 5, with the permission of the States, include the experience of the States of Ohio and Maine, both of which have moved toward inclusion of KI in their emergency plans (although in Maine's case the closure of Maine Yankee meant the policy was never implemented). Remove the discussion of Pennsylvania since it has not completed its process and the discussion does not reveal how the practical problems of KI distribution are handled. If available, add additional information from States such as Connecticut where current emergency plans have long provided for KI prophylaxis for certain members of the public at institutions within emergency planning zones, such as hospitals and prisons, whose evacuation would be delayed.

7) In Chapter 6, correct the information on France, using, at a minimum, the information available on the DSIN web page.

8) The NUREG should include the most up-to-date information available concerning the experience, both pro and con, of States and foreign governments in the distribution of KI.

9) A discussion of the pros and cons of various KI distribution logistics should be included in the NUREG.

10) The staff should urge FDA to address in its final guidance document the issue of KI prophylaxis for those over 40 years of age under the postulated circumstances of a reactor accident. To document this concern, the staff may want to refer the CRCPD question to FDA for resolution.

The staff should ensure that to the maximum extent possible, Commission funds allocated for

stockpiles go toward purchasing actual KI tablets, rather than toward administrative costs.

The staff should convey to its FEMA counterparts the importance to Federal KI policy of FEMA's leadership role in finalizing and carrying out necessary implementing functions of a Federal KI policy.

The staff should explore the option of the federal government negotiating a contract with a pharmaceutical company to supply all stockpiles of KI, for any state that requests it, at a certain price that will include distribution. Under such a contract the federal government would not be responsible for physically storing KI, in anticipation of State requests, or distributing KI, but would be able to benefit from bulk purchase pricing. This may eliminate or reduce some of FEMA's concerns about purchasing and distribution.

The Commission should be informed promptly of any issues requiring Commission resolution.

Attachment: Changes to NUREG-1633 in SECY-01-0069

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

Attachment

Changes to NUREG-1633 in SECY-01-0069

1. On page iii, delete the line for Appendix A.

2. On page vi, paragraph 2, revise line 5 to read ' ... contains final ~~draft~~ guidance from ....' In line 6, insert a period after 'agent' and delete the remainder of the sentence.

3. On page vii, last paragraph, revise line 1 to read ' ... document presents information and discusses the ....' Delete the second sentence (This document presents ... general public.) Revise line 4 to read '~~This guidance begins with a brief discussion of t~~ The basis for ....' Revise line 6 to read ' ... source terms are briefly discussed.' Revise the last 2 lines to read ' ... terms are discussed. In addition, t~~T~~his guidance document contains a discussion of ....'

4. On page viii, revise lines 2 and 3 to read ' ... also included ~~guidance documents of the World Health Organization (WHO) and~~ the final guidance document from U.S. Food ....' Revise the last line to read ' ... State decision makers, as well as references to other international documents, such as those of the World Health Organization (WHO) and the International Atomic Energy Agency (IAEA) to assist the States in their decision-making process.'

5. On page 4, paragraph 1.3.2, in line 6 delete 'and'. Revise line 7 to read ' ... quantities of radioiodine and the importance of evacuation, sheltering and embargoing of food stuffs.'

6. On page 9, paragraph 2, revise line 1 to read ' ... gland is the largest ~~biggest~~ gland in the neck ....'

7. On page 15, paragraph 3.2, in line 9, revise the reference to the FDA guidance document to reflect the final guidance. Do likewise throughout NUREG-1633.

8. On page 31, paragraph 4.3, delete the 1st sentence (The Commission ... of KI.) Add the following sentence in its place. '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 provided in NRC and FEMA regulations.'

9. Delete Appendix A