UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

CHAIRMAN

March 9, 2000

Cys: Travers
Paperiello
Miraglia
Norry
Blaha
Congel, IRO
Collins, NRR
G19990582
EDO R/F
OIG

The Honorable Edward J. Markey
United States House of Representatives
Washington, D.C. 20515-2107

Dear Congressman Markey:

I am responding to your letter of November 10, 1999, expressing concerns about the U.S. Nuclear Regulatory Commission's (NRC's) responses to your questions on potassium iodide (KI) stockpiles associated with the hearing on July 21, 1999, on the Fiscal Year 2000 NRC Authorization Act before the Subcommittee on Energy and Power. In particular, you refer to a letter from Mr. Peter Crane, dated October 15, 1999, concerning alleged misrepresentations by the NRC of the Federal Emergency Management Agency (FEMA) position on regional KI stockpiles, alleged intentionally inaccurate testimony on the cost of buying KI, and an alleged misleading representation of the money NRC has spent studying KI.

I do not believe that the NRC misrepresented FEMA's position on regional KI stockpiles. In a letter from FEMA Director James L. Witt, dated April 29, 1999, (Enclosure 1) to the Commission, Director Witt stated, among other concerns, that FEMA did not support establishment of regional KI stockpiles. Former Chairman Jackson's reply (Enclosure 2), dated June 15, 1999, included a statement that she was confident that the NRC and FEMA staffs would be successful in resolving the KI issue. The NRC's responses to the post-hearing questions reflected that NRC and FEMA were undertaking this effort and NRC's belief that the agencies would reach a successful outcome. The NRC never stated nor intended to imply that FEMA had indicated any change in its position. As a result of former Chairman Jackson's letter to Mr. Witt and Commission direction to the NRC staff, the NRC and FEMA staffs have been meeting to identify options for stockpiling KI.

On January 12, 2000, the NRC received a letter from FEMA, signed by Ms. Kay Goss, Associate Director for Preparedness, Training, and Exercises (Enclosure 3). The letter reiterates the concerns expressed by Mr. Witt in his letter of April 29, 1999, including the statement that FEMA does not support regional stockpiles. (We note that this letter addresses predecisional issues and therefore has not been released to the public.) We will provide you a copy of the NRC response. We have no communications from FEMA to the effect that it has changed its position on regional stockpiles and, as noted above, NRC did not mean to imply that FEMA had modified its position.

Originated by:
F. Congel, IRO

You also requested "updated and accurate figures detailing the cost of buying potassium iodide," including "the cost per pill and the expected shelf-life for KI tablets." The basis for the cost figures presented in our response to the referenced Congressional correspondence is described in Attachment 2 to NRC SECY-97-124, dated June 16, 1997, (Enclosure 4) and updated in SECY-98-264, dated November 10, 1998 (Enclosure 4a). The estimate provided in post-hearing question 16a was based on the distribution of two pills, costing 25 cents each, to 80,000 people in the vicinity of each site. The total cost for 70 sites was estimated in the response at $3.25 million. However, we note that there was an error in the calculation, and the correct estimate should have been $2.8 million. Obviously, the overall cost for funding the purchase of KI depends, among other factors, on both the current market price of KI tablets and the number of States that would establish stockpiles.

The U.S. Food and Drug Administration (FDA) is currently reevaluating its 1978/1982 KI guidance. If FDA proposes KI dosages other than the current ones, the cost for KI could change. Nonetheless, in response to your request, we can estimate the cost of KI tablets when purchased in large quantities (greater than about 500,000 tablets). Mr. Crane references correspondence from a Swedish firm that offers KI in bulk at 6 cents per pill, with a stated 10-year shelf-life (Enclosure 5). The Swedish company, RECIP AB, provided costs that ranged from 11.5 cents per tablet for 1,000,000 tablets to 6 cents per tablet for 50,000,000 tablets. These cost estimates are for 65 mg tablets, whereas the current recommended FDA KI dosage for adults and children over the age of 1-year is 130 mg of KI per day. The cost per 130 mg dose is twice the cost per tablet and would therefore range from 23 cents to 12 cents per 130 mg dose. This stated cost does not include shipping nor any costs associated with RECIP AB obtaining FDA approval of this KI product for use in the United States.

In the United States, two companies advertise KI tablets that have received FDA approval for sale to the general public. ANBEX charges $10 per package of 14 KI tablets (130 mg dose) plus $4.00 for shipping up to 10 packages. The shelf-life is stated by ANBEX to be "indefinite." Based on the staff's informal inquiry, the company indicated that the cost could be reduced to about $2.50 - $2.60 per package of 14 tablets in quantities of about 1,000,000 tablets, resulting in a cost of about 18 cents to 19 cents per tablet. Carter-Wallace Laboratories sells Thyro-Block Tablets, a 130 mg KI tablet. The tablets are sold in a 98-day supply (98-130 mg tablets) for individuals at a cost of $42.95 or in a case of 100 bottles of 14 KI tablets (130 mg) per bottle for $560. This is about 40 cents to 43 cents per tablet. The company estimated that purchasing a million or more tablets at a time could reduce the price to about 20 cents per tablet. In sum, we believe that the cost estimate used in our response -- 25 cents per tablet -- is an appropriate (albeit perhaps slightly conservative) estimate.

You also requested that NRC provide an accurate account of the actual expended costs of studying the KI issue. In our answer to the hearing question, we estimated that our spending to study the KI issue exceeded $2.6 million over the period from October 1989 to August 11, 1999. The sum for the individual items listed came to $2.64 million. This estimate is based on information available in the internal work tracking system and estimates of staff and management overhead costs. The specific costs are detailed in the enclosed response to Mr. Crane (Enclosure 6).

If you would like additional information, please do not hesitate to contact me.

Sincerely,

Richard A. Meserve

Enclosures:

1. Letter to NRC Commission fm J. L. Witt, FEMA, dtd April 29, 1999
2. Letter to J. L Witt, FEMA fm Chairman S. Jackson, NRC dtd June 15, 1999
3. Letter from Ms. Kay Goss, FEMA, dtd January 12, 2000
4. NRC SECY-97-124, dtd June 16, 1997 - Proposed Federal Policy Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant

4a. NRC SECY 98-264, dtd November 10, 1998 - Proposed Amendments to 10 CFR 50.47; Granting of Petitions for Rulemaking (PRM 50-63 and 50-63A) Relating to a Reevaluation of Policy on the Use of Potassium Iodide (KI) After a Severe Accident at a Nuclear Power Plant

5. E-mail fm Swedish firm, dtd December 17, 1998 re KI SUPPLIER
6. Letter to P. Crane fm W. Travers, NRC

cost figures presented in our response to the referenced Congressional correspondence is described in Attachment 2 to NRC SECY-97-124, dated June 16, 1997, (Enclosure 3) and updated in SECY-98-264, dated November 10, 1998, (Enclosure 3a). At this time, the U.S. Food and Drug Administration (FDA) is currently reevaluating its 1978/1982 KI guidance. If FDA proposes KI dosages other than the current ones, the cost for KI could change. It is not practical or possible at this time to provide an exact total cost of KI.

Notwithstanding these limitations, in response to your request, the cost of KI tablets, when purchased in large quantities (greater than about 500,000 tablets), can be estimated. Mr. Crane references correspondence from a Swedish firm that offers KI in bulk at 6 cents per pill, with a stated 10-year shelf-life (Enclosure 4). The Swedish company, RECIP AB, provided costs that ranged from 11.5 cents per tablet for 1,000,000 tablets to 6 cents per tablet for 50,000,000 tablets. It should be noted that these cost estimates are for 65 mg tablets whereas the current recommended FDA KI dosage for adults and children over the age of 1-year is 130 mg KI per day. The cost per 130 mg dose is twice the cost per tablet and would therefore range from 23 cents to 12 cents per 130 mg dose. Additionally, this stated cost does not include shipping nor any costs associated with RECIP AB obtaining FDA approval of this KI product. In the United States, there are two companies advertising KI tablets for purchase by the general public that have received FDA approval. ANBEX charges $10 per package of 14 KI tablets (130mg dose) plus $4.00 for shipping up to 10 packages. The shelf-life is stated by ANBEX be "indefinite." Based on the staff's informal inquiry to the company, it was indicated that the cost could be reduced to about $2.50 - $2.60 per package of 14 tablets in quantities of about 1,000,000 tablets, resulting in a cost of about 18 cents to 19 cents per tablet. Carter-Wallace Laboratories sells Thyro-Block Tablets, a 130 mg KI tablet. The tablets are sold in a 98-day supply (98 130 mg tablets) for individuals at a cost of $42.95 or in a case of 100 bottles of 14 130 mg KI tablets per bottle for $560. This is about 40 cents to 43 cents per tablet. It is estimated that purchasing a million or more tablets at a time could get the price down to about 20 cents per tablet.

You also requested that NRC provide an accurate account of the actual expended costs of studying the KI issue. In our answer to the hearing question, we estimated that our spending to study the KI issue exceeded $2.6 million in period from October 1998 to August 11, 1999. The precise sum for the individual items listed came to $2.64million. We do not have a more precise estimate of the spending because our internal work tracking system does not capture much of the effort expended on the KI issue. Much work on KI did not have a specific tracking number and was recorded under categories such as "analytical methods," "technical review," "management," and "support to other organizations." Therefore, it was necessary for us to estimate the staff time spent.

A copy of the response to Mr. Crane's letter of October 15, 1999 is attached (Enclosure 5).

Sincerely,

Richard A. Meserve

Enclosures: See next page

Distribution:

CPaperiello PNorry JBlaha IRO R/F

SBurns SCollins KCyr File Center/ADAMS EDO R/FG1999990582

DISK/DOCUMENT NAME: G:\congel\markey-ki-new-ver3.wpd

To receive copy, indicate: "C" = Copy w/o attachment/enclosure; "A" = Copy with attachment/enclosure; "N" = None. NO MARK = NO COPY!!!

OFC	D:IRO		NRR		OGC		DERP		EDO		OC	
NAME	FCongel		CCarpenter via E-mail		JGray S.Treby		FMiraglia		WTravers		RAMeserve	
DATE	02/15/00		02/21/00		02/21/00		02/16/00		02/16/00		02/ /00	

OFFICIAL RECORD DOCUMENT

ENCLOSURE 1

Federal Emergency Management Agency

Washington, D.C. 20472

APR 29 1999

Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Madam Chairman and Commissioners:

I read in the April 24, 1999 New York Times and in your press release that you voted to withdraw your commitment to fund the purchase of potassium iodide for States that elect to stockpile it for use by the general public in the event of a radiological release from a nuclear power plant. In addition to deciding that the NRC would not pay for State stockpiles, you announced that FEMA should pay for both regional and state stockpiles. I strongly oppose this unilateral decision that reverses your previous position and adversely affects the implementation of the policy proposed by the Federal Radiological Preparedness Coordinating Committee (FRPCC). The policy provides that if a State chooses to add potassium iodide as a supplement to its evacuation and sheltering protective actions, the State will inform FEMA and we will forward that request to the NRC to support the purchase.

Your abrupt retreat from repeated promises to the Federal community, states and the public is apparently based on a misapprehension of FEMA's authorizing legislation and a disregard of our view—and that of other FRPCC agencies—that regional potassium iodide stockpiles will not enhance local radiological emergency preparedness. On funding, we stand fast on our position that FEMA lacks authority and appropriations for acquisition of potassium iodide and thus, cannot and will not assume the NRC financial commitment to the States.

Based on concerns expressed by States, FEMA has always opposed the notion that Federal regional stockpiles of potassium iodide would be effective in the event of a release from a nuclear power plant. The complex logistics of storage and distribution far outweigh the usefulness of such a stockpile. Regional stockpiles of potassium iodide would complicate, not strengthen radiological emergency preparedness.

NRC and FEMA must work together with the States to implement the FRPCC policy. As you may recall, this proposed policy would leave the option to the State on whether it would use potassium iodide as a supplemental protective measure for the general public. If a State opted to incorporate its use as a protective measure for the general public, and the NRC fulfills its commitment, funds will be provided for such a purchase.

In light of the significance of this issue, and the concerns being raised by the States, I would appreciate a response to this letter by May 28, 1999.

Sincerely,

James Lee Witt
Director

Attachments: NRC Potassium Iodide Funding Commitments
Federal Radiological Preparedness Coordinating Committee proposed policy and scheme for potassium iodide request & funding

cc: William Travers, EDO
FRPCC Agencies

ENCLOSURE 2

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D C 20555-0001

CHAIRMAN

June 15, 1999

The Honorable James Lee Witt, Director
Federal Emergency Management Agency
500 C Street, SW.
Washington, D.C. 20472

Dear Mr. Witt:

I am responding to your letter of April 29, 1999, to the U.S. Nuclear Regulatory Commission (NRC) in which you commented on the NRC's recent action concerning the possible use of potassium iodide (KI) as supplemental protection for the public in case of a severe accident at a nuclear power plant. As indicated in a staff requirements memorandum (SRM) (a copy is enclosed for your information) to the NRC staff on April 22, 1999, and in a press release on April 23, 1999, the NRC is proposing to revise its emergency preparedness regulations to add KI to the protective actions that must be considered, along with evacuation and sheltering, in nuclear power plant emergency plans. The Commission also has decided not to fund State stockpiles of KI. We regret that we did not inform the Federal Emergency Management Agency (FEMA) sooner of our KI decision.

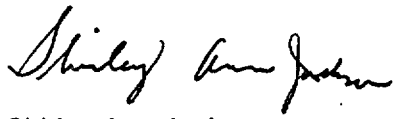
A related issue that recurs in the debate on the use of KI as a protective action for nuclear power plant accidents has been the role of the Federal government, in particular the NRC, in funding the purchase of a stockpile of KI for those States that may wish to include KI in their emergency plans. As previously discussed by the Commission in the Federal Register notice on emergency planning (45 FR 55402, August 19, 1980) under the section on funding, the Commission stated that "any direct funding of State or local governments solely for emergency preparedness by the Federal Government would come through FEMA." Notwithstanding earlier draft positions indicating that "the Federal Government (most likely the NRC)" would fund the purchase of State stockpiles of KI, this previously established NRC policy precludes NRC from funding such purchases. In addition, the NRC budget has continued to decrease and offers little margin for the Commission to divert resources to new initiatives.

According to your letter, the NRC announced that it expects the FEMA to pay for both regional and State stockpiles. This is not the case. Actually, the Commission supports the position that the Federal government should fund the purchase of KI for Federal stockpiles at appropriately located regional centers, possibly collocated with some of the three national and 27 regional stockpiles being established by FEMA to respond to possible nuclear, biological, and chemical (NBC) terrorism, discussed in the draft Federal Radiological Preparedness Coordinating Committee Policy Statement on KI. The Commission supports NRC funding of the initial purchase and resupply of KI for such regional stockpiles to the extent there are no constraints on the FEMA receiving money from the NRC for this purpose. The Commission believes that funding for State stockpiles of KI for States that elect to use it should come from the traditional sources of funding for State and local emergency response planning rather than the Federal government. Your letter also states that FEMA has always been opposed to regional stockpiles Although our staffs meet frequently and your staff has made presentations directly to the Commission, we did not understand that FEMA opposes regional stockpiles.

The Commission has directed the NRC staff to work with the FEMA staff to establish and maintain regional KI stockpiles to be used in the event that local stockpiles prove to be insufficient, or when a State without a stockpile elects to use KI on an ad hoc basis in the case of a nuclear emergency. In your letter, you indicate that FEMA opposes the concept of Federal regional stockpiles of KI and that the complex logistics of storage and distribution of KI from regional stockpiles far outweigh the usefulness of such stockpiles. We agree that the storage and distribution of KI are among the vexing problems associated with the use of KI in an emergency, but believe that under the current draft policy that provides for only extremely limited Federal regional stockpiles, it would be difficult, if not impossible, for the Federal government to respond to requests for KI in the event of a nuclear emergency. Irrespective of whether the Federal government offered to pay for KI stockpiles, because States are not required to stockpile, we believe it is reasonable to assume that many States will not have stockpiles of their own. Therefore, regional stockpiles seem appropriate.

The NRC and FEMA have worked together as partners in protecting the health and safety of the public since President Jimmy Carter directed the FEMA to assume the lead responsibility for State and local government emergency planning and preparedness for nuclear power reactors on December 7, 1979, eight months after the accident at the Three Mile Island facility. The role of the FEMA in the NRC regulatory process is recognized in both NRC and FEMA regulations and in a memorandum of understanding between the two agencies that became effective on January 14, 1980. Presently, the NRC, with the assistance of the FEMA, representatives from other Federal agencies, and several States and local governments, is developing a substantially revised version of a study related to KI and an associated information document to assist State and local emergency planning officials in making decisions relative to the use of KI for the general public. I am confident that our two staffs, working together in a spirit of cooperation and dedication similar to the ongoing FEMA strategic review of its radiological emergency preparedness program, will be successful in resolving the KI issue.

Sincerely,



Shirley Ann Jackson

Enclosure:
Staff Requirements Memorandum

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

OFFICE OF THE
SECRETARY

April 22, 1999

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: Annette Vietti-Cook, Secretary

SUBJECT: STAFF REQUIREMENTS - SECY-98-264 - PROPOSED AMENDMENTS TO 10 CFR 50.47; GRANTING PETITIONS FOR RULEMAKING (PRM 50-63 AND 50-63A) RELATING TO A REEVALUATION OF POLICY ON THE USE OF POTASSIUM IODIDE (KI) AFTER A SEVERE ACCIDENT AT A NUCLEAR POWER PLANT
and
COMJSM-98-002 - FUNDING FOR POTASSIUM IODIDE STOCKPILES

The Commission has approved issuance of the proposed rule for comments subject to the following comment and attached changes to the Federal Register Notice (FRN). The FRN should be revised and returned to SECY for signature and publication.
(EDO) (SECY Suspense: 5/31/99)

The staff should amend the draft Federal Register Notice on the federal KI policy provided to FEMA to conform to this SRM, particularly with respect to the Commission's decision not to fund State stockpiles.
(EDO) (SECY Suspense: 5/31/99)

The staff should work with FEMA to establish and maintain regional KI stockpiles to be used in the event of a severe nuclear power plant accident. The Commission supports the position that the federal government should fund the purchase of KI for federal stockpiles at appropriately located regional centers. The Commission supports NRC funding of the initial purchase and resupply of KI to the extent that this cannot be covered by FEMA under its initiatives, and to the extent that there is no Economy Act constraint on FEMA's receiving money from the NRC for this purpose.

If FEMA decides after working with the States to develop any formal funding request to Congress for a program of federally funded grants for State KI stockpiles, the NRC should assist FEMA in developing its funding request.

The section entitled "Analysis of Issues raised by Public Comments" represents technical responses to questions and statements and does not represent policy decisions by the Commission. Therefore, the statements that are currently attributed to the Commission in this section should be changed to indicate that the responses are those of the NRC staff.

On page 17, after the last sentence, insert 'The Commission has considered the KI policy question on numerous occasions since 1984. The voting history of the Commission shows that reaching consensus on this policy question has been an elusive goal. An important reason for this historical lack of consensus is that this policy question is not a clear cut one. Individual Commissioners, past and present, have differed in their views with respect to the relative importance to be given to factors bearing on the KI issue. These honest differences have led to divided Commission views on how to resolve the policy question. The Commission is agreed that its historical difficulty to reach consensus on the KI policy question underscores the reality that this policy question is not a simple one, is not one that is easily resolved and, as a result, has been the subject of protracted deliberation. With that relevant background, following are the Commission's views on specific issues raised by the Petition.'

The FRN should include reference to the fact that the staff is developing a final version of the NUREG related to KI and the associated development of an information document for State and local decision makers. On page 4, at the end of the second full paragraph, add a new sentence: NRC staff is preparing a technical report and an information brochure to enable State and local decision makers to make an informed decision in this matter.

Attachment:
As stated

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

Changes to the Federal Register Notice

1. On page 1, paragraph 2, sentence 2 should be revised to read "The proposed rule would amend the current regulations to require ~~indicate~~ that consideration shall be given to including potassium iodide (KI)~~, along with sheltering and evacuation~~, as a ~~supplemental~~ protective measure for the general public: that would supplement sheltering and evacuation. KI would help prevent thyroid cancers in the unlikely event of a major release of radioactivity from a nuclear power plant.

2. The FRN currently states incorrectly that the Commission granted two petitions (PRM 50-63 and 50-63A). PRM 50-63 was replaced by PRM 50-63A which the Commission has granted. Therefore, the FRN should be revised to clarify this fact. On page 2, paragraph 1 under Supplementary Information, revise to read "By undertaking this rulemaking, the Commission, while not adopting the exact language suggested by the petitioner, is proposing to grant a petition for rulemaking (PRM 50-63A) submitted by Mr. Peter Crane on November 11, 1997. That petition is a revision of a petition (PRM 50-63) that he submitted on September 9, 1995.

3. On page 3, line 5, insert a new sentence after 'conditions' as follows: When the Commission amended its emergency planning regulations on November 3, 1980, it stated that 'any direct funding of State or local governments solely for emergency preparedness purposes by the Federal government would come through FEMA.' Begin the next sentence with 'In its decision on June 30, 1997, the Commission ....' In lines 5 and 6, delete 'consistent with the Commission's decision on June 30, 1997,'.

4. On page 3, line 7 and 8, replace the sentence 'The NRC staff will ... KI is established.' with 'The Commission has determined that notwithstanding the June 30, 1997 intention that "most likely the NRC" would fund the purchase of State stockpiles of KI, the NRC budget has continued to decrease and offers little margin for the Commission to divert resources to new initiatives. Historically, funding for State and local emergency response planning has been the responsibility of those governments usually working with licensees. The Commission notes that the Petitioner has not requested the Federal funding of stockpiles of KI.' Start the next sentence as follows: 'In the alternative, the NRC will ....' On page 3, line 9, delete 'also'. In lines 9 and 10, replace 'procedures to enable the national' with robust, pre-positioned regional' and add an 's' to 'stockpiles'. In line 10, delete 'for terrorist activities'. In line 11, replace 'national' with 'regional'.

5. On page 4, first full paragraph, sentence 1, insert 'NRC staff's' before 'proposed'.

6. On page 4, second full paragraph, line 1, insert 'portion of the' before 'petition'. In line 2, replace 'by directing' with 'regarding'.

7. On page 6, last line, replace 'in favor of' with 'which favored'.

8. On page 15, at end of second full paragraph insert: However, FEMA recently reported that the federal stockpiles of KI are few and stocked only for first responders to terrorist action. As things stand now, needs of members of the public for KI on an *ad hoc* basis would have to be supplied from other sources. As stated above, the Commission intends to work with FEMA to assure that stockpiles contain adequate supplies of KI.

9. On page 17, before the Analysis of Issues raised by Public Comments insert a new paragraph as follows: On November 5, 1997, the Commission held a public meeting with its staff, FEMA representatives, and the author of the 1995 rulemaking petition to consider the petition and proposed changes to the Federal policy on the use of KI. In part as a result of the meeting, the petitioner amended his petition to ask for a rule that would require that consideration would be given in the formulation of emergency plans to the use of KI as a supplement to evacuation or sheltering, and on June 26, 1998, the Commission granted the amended petition, and directed the NRC staff to initiate the requested rulemaking. The Commissioners also decided that the FRPCC Federal Register notice on Federal KI policy should include a statement to the effect that the State and local decision makers, provided with proper information, may find that the use of KI as a protective supplement is reasonable and prudent for specific local conditions. On September 30, 1998, the Commission approved a draft Federal Register notice and directed that it be sent to the FRPCC.

10. On page 21, first full paragraph, line 1, insert 'thyroid' after 'excess'.

11. On page 22, second full paragraph, line 1, correct spelling of 'measures'.

12. On page 23, paragraph 2, add a footnote at end of second sentence, to read 'A "medically significant" reaction was one for which the person suffering the reaction consulted a physician more than once. Nauman and Wolff, "Iodide Prophylaxis in Poland After the Chernobyl Reactor Accident: Benefits and Risks," The American Journal of Medicine, Vol. 94, May 1993, p.530. About .02% of the population that received KI had "medically significant" adverse reactions to KI. Id. However, "[i]t should be pointed out that control values for these side effects in a population not receiving KI are not available." Id.' That is, it is not known what the incidence of such reactions would be in a population under similar stress, but not receiving KI, and thus it is not known to what extent these adverse reactions were the result of KI.

13. On page 24, under Conclusions from Polish Experience, line 1, insert 'In Poland' before '(1)'. In line 2, delete 'in Poland'.

14. On page 25, first full paragraph, line 1, insert 'In contrast to the Chernobyl experience,' before 'in the event'. In lines 2 and 3, remove the parentheses. In line 3 replace 'that would' with 'all of which'. In line 3, replace 'risk to' with 'risk of exposure of'. Also in line 3, insert 'to all radionuclides' after 'public'. In line 4, add 'or especially sheltering' after 'evacuation', and replace 'further' with 'resulting from exposure to one important group of radionuclides, the radioiodines.' That is why current NRC guidance discusses KI for plant personnel, emergency workers, and institutionalized persons unlikely to be evacuated promptly.

15. On page 25, delete the start of the second full paragraph (One public commenter ....) to the start of Issue 3 on the next page. Replace it with 'In this light, the Commission agrees that the use of KI may be determined by State and local emergency response planners to be a useful supplementary protective measure.'

16. On page 26, line 7 from the bottom, correct spelling of "nodules".

17. On page 27, under Commission Response, line 4, insert 'such as by making it available' after 'available'. In line 9, replace 'Other approaches' with 'Another approach' and replace 'could' with 'is to'.

18. On page 28, paragraph 1, replace with "The commenter is correct, in that it was difficult to obtain KI after the Three Mile Island accident. That is one reason why the Commission believes that planners should consider stockpiling KI, and why the Commission supports Federal stockpiles, so that States that have chosen not to stockpile KI could have access, albeit *ad hoc* and delayed, to an adequate supply in a radiological emergency at a nuclear power plant. As noted elsewhere in this notice, the Commission will work with other agencies to assure that there are Federal regional stockpiles that contain adequate supplies of KI. ~~However, with the limited Federal stockpile of KI for terrorist events and the willingness of the Federal Government to provide a stockpile of KI for any State that decides to use it as a supplemental protective measure for the general public,~~ Moreover, the general availability of KI is greater now than at the time of the TMI accident, partly because of the FDA's approval of KI as an over the counter drug. Some States have elected to incorporate KI into the emergency response plans and have obtained adequate supplies for this purpose. The Commission is not aware of any factors that would constrain the availability of KI for stockpiling purposes. The Commission believes that an adequate supply of KI could be obtained.

19. On page 32, line 7, replace the 'of' after 'State' with 'or'.

20. On page 32, line 2 from the bottom, replace' NRC staff' with 'Commission'.

21. On page 33, line 1, replace 'considers' with 'believes'. Delete the second full paragraph under the Commission Response.

22. On page 33, replace the Commission Decision with the following: 'KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering for specific local conditions. Therefore, the Commission's guidance on emergency planning has long taken KI into consideration (NUREG-0654/FEMA-REP-1, Rev. 1, p. 63, items e. and f.). However, since the last revision of that guidance, there has been experience with the mass distribution of KI during a radiological emergency, and though the record on that distribution is not complete, the indications thus far are that mass distribution is effective in preventing thyroid cancer and causes remarkably few threatening side effects. Moreover, many nations in Europe and elsewhere, nations as different in their circumstances, politics, and regulatory structures as France, Canada, and Japan, have stockpiled KI and planned for its use. So have some U.S. States. The World Health Organization and the International Atomic Energy Agency recommend its use. Therefore, in order the achieve greater assurance that KI will receive due attention by planners, it seems reasonable to take a small further step and, continuing to recognize the authority of the States in matters of emergency planning, explicitly require that planners consider the use of KI.

The proposed rule change should not be taken to imply that the NRC believes that the present generation of nuclear power plants is any less safe than previously thought. On the contrary, present indications are that nuclear power plant safety has improved since

the current emergency planning requirements were put in place after the Three Mile Island accident.

The use of potassium iodide is intended to supplement, not to replace, other protective measures. This rule change thus represents no alteration in the NRC's view that the primary and most desirable protective action in a radiological emergency is evacuation of the population before any exposure to radiation occurs, whenever that is feasible. (Evacuation protects the whole body, whereas potassium iodide protects only a single gland, the thyroid.) Depending on the circumstances, KI may offer additional protection if used in conjunction with evacuation and/or sheltering.

The NRC recognizes that the decision to stockpile KI presents issues of how best to position and distribute the medicine, to ensure, *e.g.*, that optimal distribution takes place in an emergency, with first priority given to protecting children; that persons with known allergies to iodine not take it; that members of the public understand that KI is not a substitute for measures that protect the whole body; etc. To date, these issues have been addressed in different ways in the numerous countries that currently stockpile KI. The NRC is working with States and localities to develop guidance on these and other points relating to the use of KI. The NRC believes that these implementation issues can be solved, given the level of expertise in the relevant Federal and State agencies, and the experience of numerous nations that have built KI into their emergency plans.

It is expected that States will inform FEMA and the NRC of the results of their consideration of whether to opt for stockpiling. This will enable the Federal government to engage in better contingency planning for States that decide against stockpiling KI.'

23. On page 34, first full paragraph, line 3, insert 'in part and denied in part' after 'granted'.

24. On page 34, under Commission Conclusions ..., line 1, replace 'agrees with many of' with ', having reviewed'. In line 2, replace the period with a comma and delete 'The Commission'. In item A., line 1, insert 'when determined by State and local emergency response planners and' after 'KI,'.

25. On page 34, line 7, replace 'noted' with 'finds' and replace 'consistent with the Commission's' with 'notwithstanding its'. In line 7, delete '(most likely the NRC)'. In line 8, replace 'will' with 'is not prepared to'. In line 9, replace 'The' with 'In the alternative, the' and replace 'also directed' with 'is directing'. In line 10, replace 'procedures to enable the national' with 'robust, prepositioned regional'. In line 12, replace 'the national' with 'regional'.

26. On page 36, in item E., line1, insert 'Although the cost of KI tablets has doubled,' before 'the Commission' and insert ', and other nations' experience,' after 'estimate'. In line 2, insert 'relatively' after 'is'. At the end of item E., add the following new sentence: 'However, the overall cost is minimal when placed in the context of emergency planning and should not be a deterrent to stockpiling KI for use by the general public should State and local decision makers determine that the prophylactic use of KI as a supplement to evacuation and sheltering is appropriate.' In item F., line 1, replace 'NBC medicinal' with 'robust, regional' and replace 'provide' with 'be established'. Replace lines 2 and 3 with 'to enable use by States that have not established local stockpiles and wish to make use

of KI in the event of a severe nuclear power plant accident.

27. On page 36, revise paragraph F to read "The Commission ~~believes~~ will work to assure that ~~medicinal~~ regional Federal stockpiles ~~should~~ will provide ~~assurance to States and local governments that a limited Federal stockpile of KI is available, if needed~~. enough KI to enable use by States that have not established local stockpiles and wish to make use of KI in the event of a severe nuclear power plant accident.

28. On page 36, replace 'Commission approval to fund KI' with 'Commission decision to fund KI'

29. On page 36, in the last paragraph, replace the last 2 sentences with: 'At that time it was believed that the NRC was the likely Federal agency to fund the stockpiling. Historically, funding for State and local; emergency response planning has been the responsibility of those governments usually working with licensees and, absent Congressional funding specifically for this purpose, NRC is not prepared to fund stockpiling of KI.

30. On page 38, paragraph 2 from the bottom, line 1, replace 'directed' with disagreed with' and replace 'in SRM 98-061 to grant' with 'recommendation to deny'.

31. On page 39, item II., line 2, replace 'SRM 98-06' with 'SRM 98-061'. In item IV., line 1, add an 's' to 'petitions' and replace 'require' with 'take'.

32. On page 41, paragraph 2 from the bottom, lines 1 and 2, replace 'grant the petition for rulemaking PRM-50-63A by revising' with 'revise'.

33. On page 42, second full paragraph, line 1, insert "that" after 'Given'.

34. On page 42, prior to the last paragraph, insert a new paragraph as follows: 'The Commission notes that when it amended its emergency planning regulations on November 3, 1980, the regulatory standards for emergency planning were a restatement of basic joint NRC-FEMA guidance to licensees and to State and local governments incorporated in NUREG-0654; FEMA-REP-1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants for Interim Use and Comment." This guidance was cited in the regulation and speaks to radioprotective drugs including their use by the general public including quantities, storage and means of distribution and State and local plans for decision making with respect to their use. The Commission removed the citations of the guidance from the regulation in 1987 but the guidance has continued in use for planning purposes and by the Federal agencies for evaluating emergency plans. As a result, it is believed that all of the affected States have at some point considered the use of KI. Some States have made the decision to stockpile KI. Thus, in practical terms, the projected costs will occur only in those States that have not elected to stockpile KI and choose stockpiling in light of the Chernobyl accident, recent international practice, and the NRC requirement to consider the use of KI.

35. On page 48, line 1, replace 'have' with 'has'.

ENCLOSURE 3

Federal Emergency Management Agency

Washington, D.C. 20472

JAN 12 2000

Annette Vietti-Cook, Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Ms. Vietti-Cook:

Enclosed is the Federal Emergency Management Agency's (FEMA) response to the Nuclear Regulatory Commission's (NRC) draft Final Rule, which proposes to include in 10 CFR 50.47(b)(10) "consideration of potassium iodide (KI)" as a supplemental protective measure in emergency planning and preparedness in support of commercial nuclear power plants.

I am taking this opportunity to reiterate Director Witt's concern expressed to former Chairman Jackson in an April 29, 1999, letter. The issue concerns NRC's reversal of its commitment to fund the purchase of potassium iodide (KI) for States that elect to stockpile it, locally or near the nuclear facility, for use by the general public in the event of a radiological release from a nuclear power plant. In light of the Federal policy developed and unanimously approved by the members of the Federal Radiological Preparedness Coordinating Committee (FRPCC), which includes the NRC, FEMA encourages the NRC to reconsider the Commission's reversal of its position on this matter. The policy would provide that if a State chooses to add KI as a supplement to its evacuation and sheltering protective actions, the State would inform FEMA and we would forward the request to the NRC to support the purchase. The NRC currently has the authority to efficiently carry out this policy and pass the cost on through its user fee.

In changing course on this matter, the Commission took the position that it would work with FEMA to establish and maintain Federal regional KI stockpiles. I would like to emphasize that, based on input from its State and local partners in emergency management, FEMA continues to maintain that Federal regional stockpiles of KI will not enhance local emergency preparedness for responding to commercial nuclear power plant accidents because of the complex logistics associated with its storage and distribution.

It appears that the NRC, the trade press and the public also have the mistaken impression that FEMA has a current role in establishing the regional pharmaceutical stockpiles for responding to acts of terrorism. I should clarify that the Department of Health and Human Services, the Centers for Disease Control and the Public Health Service are responsible for establishing these stockpiles and determining the location and composition of those resources.

I wish to thank the NRC staff for the opportunity to comment on the proposed final rule on KI. We look forward to continuing to work with the NRC to resolve this matter and in dealing with other issues affecting the health and safety of the public.

Sincerely,

Kay C. Goss, CEM®
Associate Director for Preparedness,
Training, and Exercises

Enclosure

FEMA RESPONSE AND COMMENT ON NRC DRAFT PREDECISIONAL FEDERAL REGISTER NOTICE ON KI RULEMAKING

This responds to the draft Federal Register Notice containing the final Rule that was sent to FEMA for review and comment.

The FEMA position remains that contained in Director Witt's April 29, 1999, letter to the Commissioners. In summary, the FEMA-stated position is:

(1) FEMA opposes Federal regional stockpiles as proposed by the NRC. In our judgment, they will not enhance local emergency preparedness because of the complex logistics of storage and timely distribution;

(2) the Federal Radiological Preparedness Coordinating Committee (FRPCC) unanimously approved an amended Federal policy reiterating the State's authority to decide whether to stockpile locally and distribute KI as a protective measure for the general public on a site-specific basis; and,

(3) the NRC should support the Federal KI policy and honor its commitment to provide funding for States that opt to establish local stockpiles of KI. FEMA lacks authority and appropriations for acquisition of potassium iodide and thus cannot and will not assume the NRC financial commitment to the States.

Although the NRC and FEMA staff have met for the purpose of reexamining earlier positions and policies, there have been no final agreements, and thus no decisions have been made. During our reexamination, the FEMA staff reiterated the agency position that the Commission reconsider its decision not to fund State stockpiles of KI.

Specific items are addressed below:

- The NRC states that agreements and procedures are in place through the establishment of Federal regional stockpiles, such as those under the scope of the HHS/CDC/PHS for establishing stockpiles, processes and procedures for responding to acts of terrorism. However, these regional stockpiles, and other means for acquiring pharmaceutical antidotes in response to possible terrorist activities, are only in the early stages of development by HHS. The NRC incorrectly expresses the FEMA position as supporting Federal regional stockpiles. This is reflected in the NRC's response to Issues 7 and 22.

  We suggest the following language, assuming the Commission decides to fund State stockpiles of KI: "FEMA and the NRC are working together to develop detailed guidance on how a State or local government could obtain KI in accordance with the FRPCC-revised Federal policy, which provides for the NRC funding of local stockpiles when requested by the State."

In Issue 22, we suggest: "You are essentially correct, HHS/CDC is supporting the establishment of a system that would provide pharmaceuticals to biological and chemical terrorist incidents. These pharmaceuticals, which may be available, are determined by each Metropolitan Medical Strike Team. These Strike Teams may choose not to include KI even if supplied by the NRC."

- In Issue 12, with respect to the FDA's development of possible new guidance on use of KI, i.e., dose per age group and intervention levels, it is clear that their draft guidance for publication in the Federal Register will not occur this calendar year. We must also assume that when FDA does publish its draft guidance, they will receive many comments. FEMA agrees that the revised NUREG-1633 should not be published in final until FDA has completed its work and provided its updated and completed guidance. However, we also believe that the **draft** NUREG-1633 could be published in the Federal Register for comment with the FDA updated guidance inserted before NUREG-1633 is issued in final. In addition, the NRC's language in the proposed Federal Register notice implies NUREG-1633 will be published in final in early 2000, when, in fact, it will first be noticed in the Federal Register as a draft for comment to anyone who is interested.

  We suggest the following language in the NRC's responses to Issues 2, 10, 16, 18, 19, and 21: "The Notice for comment should be published in early 2000, with the final version of NUREG-1633 published after the FDA final guidance is available."

- In Issue 14, we agree with the NRC's response to the commenter that the Rule only says a State must consider KI to be in compliance. However, it is clear that the effect of withdrawal of funding for local KI supplies could affect a State's decision on whether or not to provide a local supply or to add KI as a supplemental protective measure.

Thank you for the opportunity for FEMA to reiterate the agency's position and to comment on the draft Federal Register Notice.

ENCLOSURE 4

POLICY ISSUE
(Notation Vote)

June 16, 1997 SECY-97-124

FOR: The Commissioners

FROM: L. Joseph Callan
Executive Director for Operations

SUBJECT: PROPOSED FEDERAL POLICY REGARDING USE OF POTASSIUM IODIDE AFTER A SEVERE ACCIDENT AT A NUCLEAR POWER PLANT

PURPOSE:

To provide the Commission with options concerning a proposed change in the Federal policy regarding the use of potassium iodide (KI) as a protective measure for the general public during severe reactor accidents.

SUMMARY:

As part of the Federal effort to reevaluate the Federal policy on KI based on a request by a petitioner, the Federal Radiological Preparedness Coordinating Committee (FRPCC) adopted recommendations that would result in a revised Federal policy statement. NRC staff has participated in the FRPCC activities and has worked closely with the Federal Emergency Management Agency (FEMA) in this area.

There are three options that can be taken with regard to the FRPCC recommendations: (1) recommend no change in the existing Federal policy, (2) recommend the adoption of the FRPCC recommendations, with the added recognition of recent developments regarding medicinal stockpiles for nuclear, biological, and chemical events, or (3) recommend modifications to the FRPCC recommendations.

CONTACT: Frank J. Congel, AEOD
(301) 415-7476

NOTE: TO BE MADE PUBLICLY AVAILABLE WHEBN THE FINAL SRM IS MADE AVAILABLE

The staff recommends either option 2 or option 3(b). In light of the fact that this is a national policy issue, Commission guidance is requested.

BACKGROUND:

Federal Policy on KI (1985)

The current Federal guidance to State and local governments on the distribution of KI was promulgated in 1985 by FEMA in its capacity as Chair of the FRPCC (50 FR 30285) and as the Federal agency charged with establishing policy and providing leadership via the FRPCC (44 CFR 351 Subpart C). The FRPCC was established in accordance with 44 CFR Part 351 to coordinate all Federal responsibilities for assisting State and local governments in emergency planning and preparedness for peacetime radiological emergencies.

Federal agencies which participate in the FRPCC are: Federal Emergency Management Agency (FEMA), Nuclear Regulatory Commission (NRC), Environmental Protection Agency (EPA), Department of Health and Human Services (HHS), Department of Energy (DOE), Department of Transportation (DOT), Department of Agriculture (USDA), Department of Defense (DOD), Department of Commerce (DOC), Department of Interior (DOI), Department of State (DOS), Department of Veterans Affairs (DVA), General Services Administration (GSA), National Communication System (NCS), and National Aeronautics and Space Administration (NASA).

The 1985 Federal policy recommends the stockpiling or distribution of KI during emergencies for emergency workers and institutionalized persons, but does not recommend requiring pre-distribution or stockpiling for the general public. It recognizes, however, that options on the distribution and use of KI rest with the States. Hence, the policy statement permits State and local governments, within the limits of their authority, to take measures beyond those recommended or required nationally.

DPO (1989)

In 1989, Peter G. Crane, a member of the NRC staff, filed a Differing Professional Opinion (DPO) which alleged that there were deficiencies in the original cost-benefit analysis (NUREG/CR-1433) provided to the FRPCC by the NRC. The DPO suggested that the staff discussion at a November 1983 Commission briefing on KI might have left Commissioners and members of the public with insufficient understanding of the adverse consequences (thyroid disease) that the use of KI could avert. The DPO also suggested that the cost-benefit analysis, by simply balancing the dollar costs of a KI program against the dollar costs of treating radiation-caused thyroid illness, did not adequately consider the non-monetary costs of an illness.

In SECY-91-321, the DPO panel developed a simplified analysis of the value and impact of the KI policy, including revisions to several factors used in NUREG/CR-1433. The panel concluded that no change in the Federal policy was warranted. However, in order to consider all of the issues raised by the DPO and incorporate new data, the Office of

Nuclear Regulatory Research performed a detailed update of the NRC's KI policy basis, taking into account both qualitative and quantitative factors.

The staff presented its recommendation to resolve the DPO in SECY-93-318 (November 23, 1993) and SECY-94-087 (March 29, 1994). The staff recommended that the NRC, in coordination with HHS and FEMA, revise current Federal KI policy as a matter of prudency to make KI available to the States. The Commission's vote on the above staff recommendation was split 2 to 2 (SRM dated May 6, 1994). Thus, the policy remained unchanged.

American Thyroid Association's Request and Establishment of KI Subcommittee (1989)

In September 1989, the American Thyroid Association (ATA) submitted a letter to the Chairman of the FRPCC requesting that the Committee reconsider the issues involved in stockpiling KI. The ATA proposed that:

> "As best as can be determined at this time, no substantial stockpile of potassium iodide is available for public use. Despite the unlikely event of an emergency requiring its use, the ATA believes that the option of potassium iodide distribution should be available for consideration to those responsible for public health measures. To this end, the ATA believes that it would be prudent to have available at central locations a suitable stockpile of KI for possible distribution should its use be contemplated."

In response, the FRPCC established an Ad Hoc Subcommittee on Potassium Iodide and asked the HHS to review the medical and clinical status of the use of KI. In an initial response, HHS reviewed the then current scientific literature on KI and its use as a blocking agent. HHS reported to the FRPCC in February 1990 that no new scientific data had been found that would affect the basis for the 1985 guidance to refrain from stockpiling or predistributing KI for the public. To ensure a more comprehensive review, HHS also decided to solicit new data, scientific opinions, and reports on the experience of States concerning KI use and distribution.

HHS convened a meeting of experts on July 24, 1990 in Atlanta, Georgia. Representatives of the State and Federal agencies responsible for medical research, drug regulation, and radiological emergency response, representatives of medical associations, and nationally recognized experts in the fields of endocrinology and nuclear medicine attended. Daniel A. Hoffman, Ph.D, M.H.P., Assistant Director for Science, Center for Environmental Health and Injury Control, Centers for Disease Control chaired the meeting.

Following the experts' meeting, HHS made the following recommendations to the FRPCC in October 1990:

1. The 1985 FRPCC guidance need not be changed at this time since no compelling evidence to support a modification was presented.

2. Existing stores of KI should be inventoried. The FDA would determine the locations and size of KI supplies by identifying large customers of KI manufacturers[1]. The FRPCC should request that the Conference of Radiation Control Program Directors identify appreciable supplies of KI within the States by surveying State Radiation Control Programs.

3. The FRPCC should establish a working group to address the issue of stockpiling. Group objectives should be to:

   - Review and catalog type, location, and expiration of existing suitable supplies of KI.
   - Review and determine feasibility of specific stockpiling recommendations made by meeting participants.
   - Make final recommendations to FRPCC on U.S. Government KI stockpiling policy.

The FRPCC Subcommittee on KI followed up on these recommendations.

An Analysis of KI for the General Public in the Event of a Nuclear Accident

Under the sponsorship of NRC's Office of Nuclear Regulatory Research, S. Cohen & Associates completed a report entitled, "An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident" in April 1992. The analysis was updated and published in February 1995 (NUREG/CR-6310).

The analysis, whose central objective was to conduct a cost-benefit analysis of KI, assigned monetary values to thyroid health effects. The report addressed not only the scientific aspects of the use of KI but also the economic costs and benefits to society. The report indicated that a fair evaluation of KI cannot be limited to an assessment of the cost-benefit ratios, but must include a thorough understanding of how these ratios were derived.

[1] According to FEMA, the FDA inquiry conducted in late 1996 showed that Carter Wallace, one of the largest manufacturers of KI, had an inventory of 70 cases of KI. Each case contains 1000 bottles. Each bottle contains 14 tablets, a 14-day supply. According to this inquiry, Carter Wallace can manufacture 40-50 cases a day if necessary. Roxanne, another manufacturer of KI, has an unknown inventory of liquid KI in 30 ml bottles.

The analysis utilized the technical insights from both the National Academy of Sciences, BEIR V Committee (NAS 1990) and the National Council on Radiation Protection and Measurements (NCRP 1987) regarding iodine and thyroid dosimetry.

The analysis also addressed the effectiveness of KI. According to the analysis, given the rapid uptake of iodine (radioactive or stable), there is a limited benefit of KI administration following exposure to radioiodines. For KI to serve as an efficient blocking agent, the report continued, it must be administered in sufficient quantities before or concurrently with radioiodine exposure.

This report estimated the cost/benefit ratio of stockpiling KI prophylaxis as a function of estimated population within radial distances from a plant. The results of this analysis showed that the cost-benefit ratio ranged from 2.22[2] for populations within 5 miles to 81.8 for populations within 50 miles. This means that for the 0- to 5-mile population cell, $2.22 would be spent for stockpiling KI in order to avoid the economic equivalent cost of $1.00. For the 0- to 50-mile population cell, $81.8 would be spent to avoid the economic equivalent of $1.00. The cost-benefit ratios for population cells increased nearly exponentially with distance.

As basis for the cost-benefit analysis, the authors used four accident categories postulated for the Surry nuclear power plant as described in NUREG-1150. The analysis used the accident consequence code to calculate the thyroid dose to individuals as a function of age, gender, and distance. For the worst case that was analyzed, the whole body doses close to the plant at the plume centerline were high and likely to be fatal[3]. Doses decrease with distance and away from the plume centerline. Within 5 miles, where the cost-benefit ratio for stockpiling KI was estimated to be 2.22, the whole body doses may still exceed thresholds for early health effects[4] for which administration of KI is ineffective. It was precisely such insights that led to the NRC's recommendation for prompt evacuation of areas close to the plant and five miles downwind as the preferred protective action. This guidance is contained in NUREG-0654 Rev. 1 Supp. 3 entitled Criteria for Protective Action Recommendations for Severe Accidents published in July 1996.

State Survey (1994)

In June 1993, the April 1992 report was provided to the representatives of FEMA and HHS who co-chaired the FRPCC Potassium Iodide Subcommittee. The subcommittee reported on the NRC-sponsored analysis at a meeting of the FRPCC in September 1993. It recommended initiating two studies to secure State input on implementation strategies for providing KI to the public: (1) request the Conference of Radiation Control Program

---

[2]In SECY-94-087, the staff applied correction factors to the cost-benefit ratios and produced a modified ratio of 11 instead of 2.2.

[3]Assuming no protective actions, such as evacuation or sheltering.

[4]The health effects include nausea, fatigue, vomiting, epilation, diarrhea, and hemorrhage.

Directors (CRCPD) to survey those States with nuclear power plants for opinions regarding Federal purchase and stockpiling of KI and regarding the feasibility of States providing KI to the public under emergency conditions and (2) request the International Atomic Energy Agency to provide information on existing plans and procedures from member nations related to the storage, distribution, and dosage of KI. The latter study, which involved the IAEA, was never conducted. The first study, which consisted of a survey of States in connection with a Federal purchase and stockpiling of KI, was completed in mid-1994. All 32 States with nuclear power plants responded, as well as 11 States without plants. In general, the responses were as follows:

	Yes	No
Does your State favor a Federal KI Stockpile?		
- States with nuclear power plants	7	25
- States without nuclear power plants	3	8
Total	10	33

The primary reason given by States for not supporting Federal purchase and stockpiling of KI was that the State policy did not include KI as a protective measure for the general public. The State use of KI was specified only for emergency workers. Many States emphasized that the distribution of KI to the general public would be difficult in the event of a radiological emergency. The difficulty stems from logistical challenges presented for timely distribution of KI to permanent and non-permanent populations and the liabilities associated with the misuse of KI.

Of the 10 States that supported the Federal purchase and stockpiling of KI, one State preferred one centrally located national stockpile, four preferred Federal regional stockpiles, and five preferred a stockpile within their State.

In early 1995, the FRPCC subcommittee was prepared to recommend that:

1. The FRPCC Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent (50 FR 30258), should not be changed.

2. The Federal government should not purchase and stockpile KI for use by the public.

The basis for these recommendations were:

1. The results of the State survey,

2. The 1992 NRC cost-benefit study,

3. The lack of new data challenging the 1985 guidance on KI stockpiling,

4. The lack of justification that the subcommittee could find for a Federal stockpile, and

5. The lack of support for such an initiative by the States and the primary Federal regulatory agency (FEMA).

However, FEMA did not issue the results of these findings because of a petition for reconsideration.

Petition for Rulemaking (1995)

On September 9, 1995, Mr. Crane, who filed the DPO, filed a petition for rulemaking (PRM-50-63) with the NRC as a private citizen. He requested that the NRC amend its emergency planning regulations to require that emergency planning protective actions include sheltering, evacuation, and the prophylactic use of KI. The request would amend one of the 16 planning standards in 10 CFR 50.47, which licensees' and offsite agencies' emergency plans are required to meet, in order to assure that the option of using KI is included in emergency plans.

The staff's resolution of the petition is currently under consideration. The implications of the policy options on the petition are discussed later.

Stockpile of Medicinal Supplies for Nuclear, Biological, and Chemical Agents (1995)

In June 1995, the White House issued Presidential Decision Directive 39 (PDD-39) on US Policy on Counterterrorism. The PDD-39 directed the Federal agencies to take a number of measures to reduce vulnerability to terrorism, to deter and respond to such acts, and to strengthen capabilities to prevent and manage the consequences of terrorist use of nuclear, biological, and chemical (NBC) weapons including weapons of mass destruction. The PDD-39 assigned to FEMA the task of ensuring that the Federal Response Plan (FRP) was adequate to respond to the consequences of terrorism.

FEMA, in coordination with the Catastrophic Disaster Response Group (CDRG)[5], developed a draft report to the President entitled, "An Assessment of Federal Consequence Management Capabilities for Response to Nuclear, Biological or Chemical (NBC) Terrorism," dated June 12, 1996. The report recommended, among other things, that the Federal government purchase and stockpile thyroid blocking agents (KI) for the general public that could be used in the event of a nuclear terrorist event. The NRC was a member of the Core Group which generated the recommendations and was instrumental in adding KI to the list of medicinal supplies to be stockpiled nationally.

[5]The CDRG is the headquarters-senior-level coordinating group which addressees policy issues regarding the Federal Response Plan (FRP). The CDRG is chaired by FEMA and comprises representatives of Federal departments and agencies with responsibilities under the FRP. The NRC is represented by the Incident Response Division Director.

The Core Group concluded that as the result of recent events, significant threats over the past few years, and the increased availability and proliferation of nuclear, biological, or chemical materials, there is an increasing concern for the potential of terrorist incidents. NBC events, the report continued, may occur as a local event with potentially profound national implications. In responding to these events, the first responders must be able to provide critical resources to the victims. These include, but are not limited to, chemical nerve antidotes, vaccines for anthrax, and antibiotics[6]. It was therefore determined that there is a need to purchase and preposition stockpiles of adequate medical supplies at the Federal, State, and local level. While KI was not considered as vital as chemical nerve antidotes and vaccines, the NRC staff was successful in getting KI included with other medicinal supplies for NBC events because of the unusual characteristics of these events:

1. NBC events are unpredictable with many unquantifiable parameters. In contrast to nuclear power plant accidents, NBC events can occur in major metropolitan areas. The group postulated NBC scenarios for which evacuation and sheltering were not effective or even possible.

2. NBC events can have consequences ranging from low to disastrous. Some may not escalate beyond the threat stage while others may occur without a threat stage with devastating consequences, with everything in between.

3. Even with the significant amount of planning at the Federal, State, and local level, NBC events still have potential for mass casualties.

Because of the special characteristics of NBC events, the Core Group recommended a broader range of protective actions. The NRC concurred in the findings of the report by letter from AEOD Director to FEMA Director dated September 25, 1996. The report was subsequently presented to the President in February 1997 and approved for distribution in May 1997.

The staff believes that such a stockpile of KI substantially addresses the issue raised by the American Thyroid Association.

FRPCC Subcommittee on KI (1996)

In parallel with petitioning the NRC, Mr. Crane also requested that FEMA review his petition and reconsider the Federal policy. In early 1996 the FRPCC convened an Ad-Hoc Subcommittee on Potassium Iodide to request and review new information on this matter from interested parties. The subcommittee conducted a public meeting on June 27, 1996. The subcommittee evaluated all comments from the June 27 public meeting and concluded in its report to the FRPCC that "while the viewpoints presented at the public meeting were

[6]Some of these medicines can save lives only when administered urgently. The timely distribution remains an issue.

compelling, the 1996 Subcommittee on Potassium Iodide heard no new information that seriously challenges the bases for the 1985 recommendation concerning public use of KI." However, the Subcommittee made the following recommendation regarding the Federal KI policy:

1. Without changing the Federal policy by interceding in the State's prerogative to make its own decisions on whether to use KI, the Federal government (NRC, or through FEMA) should fund the purchase of a stockpile for a State that decides to incorporate KI as a protective measure for the general public;

2. The Subcommittee believes the language in the 1985 policy should be softened to be more flexible and balanced. For example, the problem many intervenors observe with the Federal policy is the italicized statement "The Federal position with...potassium iodide for use by the general public is that it should not be required." It would not be as negative if the last phrase were reworded to state "it [potassium iodide for use by the general public] is not required, but may be selected as a protective measure at the option of the State or, in some cases, local governments."

3. The subcommittee recommends that local jurisdictions who wish to incorporate KI as a protective action for the general public should consult with the State to determine if such arrangements are appropriate. If local governments have the authority or secure the approval to incorporate KI as a protective measure for the general public, they would need to include such a measure in their emergency plans.

Proposed Federal Policy on KI (1996)

The full FRPCC endorsed the subcommittee's recommendations with some modifications and plans to publish a revised Federal policy statement on distribution of KI. Because of the NRC's interest and recognized expertise in emergency planning around nuclear power plants, NRC staff agreed to work closely with FEMA to propose language that would integrate the FRPCC subcommittee's recommendations, the FRPCC's endorsement, and the recent developments in the areas regarding preparedness for terrorism.

FRPCC and Interagency Assignments

Under 44 CFR 351, the FRPCC is the Federal coordinating body responsible for assisting FEMA in providing policy direction for the program of Federal assistance to State and local governments in their radiological emergency planning and preparedness activities. FEMA, as chair of the FRPCC, establishes policy and issues guidance to State and local governments. The FRPCC member agencies jointly review and evaluate the status of emergency planning periodically. Part 351.21 (f) requires the NRC to assist FEMA in developing and promulgating guidance to State and local governments for the preparation of radiological emergency plans. Part 351.21 (i) requires the NRC to provide representation to and support for the FRPCC. The NRC has fully participated in FRPCC activities. Because of its special interest in emergency planning for nuclear power plants,

the NRC staff worked closely with FEMA and other Federal agencies in developing the proposed KI policy. The staff recognized the importance of working closely with health agencies such as HHS and DVA regarding the use of KI by the general public. Throughout this process, the staff worked collegially with other key Federal agencies to ensure a broader consensus on the Federal policy.

The NRC's representative to the FRPCC has agreed to propose language that integrates what was already recommended and endorsed by various Federal committees and working groups. By virtue of its regulatory functions, the NRC staff had to consider some additional fine points. For example, the NRC staff considered the licensing implications of the proposed KI policy, the need for additional guidance to the licensees or States, and the potential impact on FEMA's responsibilities in offsite emergency planning.

If accepted by the FRPCC, the proposed policy will be noticed in the *Federal Register*. Since FEMA chairs the FRPCC, it assumes the responsibility for this publication.

Options

Option 1. **Recommend no change in existing policy.**

This option would result in continuation of the present policy, i.e., stockpiling KI for use by emergency workers and institutionalized persons but predistribution or stockpiling of KI for use by the general public should not be required.

This option would require that NRC staff request that the FRPCC reconsider its current recommendations and not consider the existing Federal stockpile for NBC events. The staff does not believe that other key Federal agencies on the FRPCC would be receptive to this option because of the activities that have taken place since 1985.

This option does not update the current policy to reflect the recent developments. The staff believes that the time is appropriate to update the present policy. A Federal stockpile of KI, among other medicinal supplies, already was available for the Olympics and the national political conventions. There is a new national impetus for expanding the Federal preparedness to include medicinal supplies for NBC events. While the FRPCC determined that there is no new information that seriously challenges the basis of the current policy regarding reactor accidents, it did recommend that the Federal government fund the purchase of KI for any State upon their request and soften the language in the present policy.

Option 2. **Recommend the adoption of the FRPCC recommendations recognizing the recent developments in preparation for NBC events.**

This is one of the options favored by the staff. As pointed out in option 1, the staff believes that the present policy should be updated. Attachment 1 contains a proposed Federal policy on KI that reflects the key elements of this option. It incorporates changes recommended by the FRPCC's Subcommittee on Potassium Iodide, acknowledges the

developments in the area of NBC events regarding KI but does not alter the current emergency planning requirements. The principal differences between option 2 and the 1985 version are the addition of the willingness of the Federal Government to purchase a supply of KI for States at their request, and the establishment of a Federal stockpile.

The highlights of option 2 proposed policy are as follows:

- KI should be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies. In developing the range of public protective actions for severe accidents at commercial nuclear facilities, the best technical information indicates that evacuation and in-place sheltering provide adequate protection for the general public. However, the State (or in some cases, the local government) is ultimately responsible for the protection of its citizens. Therefore, the decision for local stockpiling and use of KI as a protective measure for the general public is left to the discretion of the State or, in some cases, the local government.

- The Federal government will establish funding for the purchase of a supply of KI. It is recognized that the State or the local government, within the limits of their authority, can take measures beyond those recommended or required. The availability of KI as a protective measure for the general public supplements other options for public officials responsible for protective action decisions. A few States have indeed included KI as a protective action for the general public. The FRPCC does not want to usurp the State prerogative to incorporate the use of KI as a protective measure for the general public. Therefore, to ensure that States have available to them the option to use KI if they so elect, the Federal government will be prepared to provide funding for the purchase of a supply of KI. Any State or local government which selects the use of KI as a protective measure for the general public may notify FEMA and request funding for the purpose of purchasing a supply of KI. Guidance would have to be developed in this area jointly with FEMA.

- A stockpile of KI is being established by the Federal government. The Federal government is required to prepare for a wider range of radiological emergencies[7]. To that end, and as an added assurance for radiological emergencies in which the location and timing of an emergency are unpredictable and for which, unlike licensed nuclear power plants, there is little planning possible, a stockpile of KI is being established by the Federal government. This Federal stockpile will be available to any State for any type of radiological emergency at any time.

---

[7]In response to new threats, the Federal government broadened the scope of emergency response preparedness to include terrorism involving nuclear, biological, and chemical agents. As a result, and in support of State and local governments, new resources were identified to be needed in response to such events. About two dozen Metropolitan Medical Strike Teams (MMST) are being established for response to such events. Medical supplies, including KI, are being stockpiled nationally for the use by MMSTs in three locations: East coast (Washington, DC), Central (Denver), and West coast (Los Angeles). The quantity of supplies stockpiled uses a planning basis of 100,000 people for a period of two days.

- Those States or local governments which opt to include KI for the general population will be responsible for the maintenance, distribution, and any subsequent costs associated with this program.

- The incorporation of a program for KI stockpiling, distribution, and use by any State or local government into the emergency plans will not be subject to Federal evaluation. This is based on the recognition that the use of KI by the State for the general public is a supplemental protective measure, and that the existing emergency planning and preparedness guidance for nuclear power plants are effective and adequate to protect the public health and safety.

Analysis of Option 2 Proposed Policy

To ensure that the KI policy adheres to the principles of good public policy, NRC staff identified key factors that should be taken into account:

1. The preeminent role of State and local governments in the protection of offsite public health and safety;

2. The application of good science to the development of any new guidance regarding KI;

3. The value added of any new guidance in the context of existing planned protective measures;

4. The recognition that KI is not without side effects which have been discussed at length throughout the past years. Before the NRC actually participates in the purchase and supply of KI, it will prepare through consultation with HHS, a suitable product warning to be used by the State and local governments.

5. The implementation challenges of any new guidance.

The NRC staff considered these factors in developing the proposed Federal policy on KI. Furthermore the staff believes that the proposed policy does the following:

1. Integrates the subcommittee's recommendations with the recent developments in the area of preparedness for NBC events, namely the establishment of national medicinal stockpiles, including KI;

2. Recognizes the central role of State and local governments in protecting public health and safety, and honors the State's prerogative to determine whether it wishes to add KI as a supplemental protective measure for the general public;

3. Does not encumber the States and local governments who choose to retain their existing plans if they believe that the implementation of a KI program may reduce

the effectiveness of implementing prompt evacuation as a preferred protective action for the general public;

4. Provides added assurance to those States and local governments that a Federal stockpile of KI is available, should it be needed;

5. Is consistent with the recently published draft guidance (NUREG-0654 FEMA-REP-1 Rev. 1 Supplement 3) by NRC and FEMA on "Criteria for Protective Action Recommendation for Severe Accidents;"

6. Does not result in a rule change which is a two-year process and may require a backfit analysis;

7. Maintains the foundation of offsite emergency planning by confirming that the existing guidance and requirements are adequate.

The proposed policy is also strengthened by the already existing stockpile of KI that was available for the Olympics and the national political conventions. The staff believes that given these stockpiles, unlike the TMI experience, KI could be made available in a more timely manner if needed in the future.

This option has some fiscal implications for the NRC associated with its offer to purchase KI for any State that requests it.

Fiscal Implications of Proposed KI Policy

The option 2 proposed Federal policy contains an offer by the Federal government (most likely the NRC) to fund the purchase of a supply of KI for any State that chooses to add KI to its options of protective actions in response to an emergency at a NRC licensed nuclear power plant. To fulfill this proposed obligation, staff's estimate of the range of NRC costs is given in three scenarios in Attachment 2. Currently, resources are not budgeted for the purchase of KI and funds would have to be reprogrammed should a State (or States) request funding through FEMA.

The cost estimate does not include the administrative costs associated with the KI purchase. The more likely scenario is that several sites may request funding each year for a few years. In that case, the estimate is about $50,000 each year for a period of three years and repeated every seven years, thereafter.

Option 3. **Recommend modifications to the FRPCC recommendations.**

There are a number of possible modifications to the FRPCC recommendations that can be recommended. The staff has prepared a limited number of cases to scope the wide range of possibilities.

a) **Endorse FRPCC recommendations without the offer to fund the purchase of KI.**

> There are already two States which have KI for the general public under the current policy. The staff is not aware of any cases where funding to purchase a supply of KI is the obstacle for adding KI as a protective measure for the general public. The staff believes that the costs associated with a KI program could be significant when activities such as public education and the logistics associated with the distribution are added to the cost to purchase KI supplies. The FRPCC's offer to fund the purchase of KI is intended to demonstrate a good faith effort on behalf of the Federal government to assure that if any State wishes to add this supplemental measure, there is no implicit discouragement from the Federal government.

If this option is selected, the staff would have to request that the FRPCC reconsider its recommendation regarding Federal funding for the purchase of KI.

b) **Recommend that the staff, in coordination with HHS and FEMA, revise current Federal KI policy to make KI available to the States.**

This was recommended by the staff in SECY-94-087. The revised policy would state that:

> KI will be purchased by the Federal government (most likely by the NRC) and made available through FEMA to the States. While the NRC encourages the stockpiling of KI, the decision to stockpile, distribute, and use KI would be the responsibility of the individual States. At the option of the State, procedures incorporating the use of KI in State emergency plans would be developed with the assistance of FEMA. The details regarding this option would be developed and coordinated through the FRPCC.

This option contains some of the essential elements of option 2 and is the other option favored by the staff. For example: (1) it is a State option to determine whether it wishes to include KI in its plans, and (2) the Federal government (most likely the NRC) will purchase KI for the States. This option could have fiscal implications up to scenario 3 in option 2. The principal difference with option 2 is that in this option the Federal government openly encourages the stockpile of KI by States for prudency.

The States may perceive the NRC encouragement to stockpile KI by the States as going beyond what is necessary. This is based on the statements presented by States' representatives at the public meeting conducted by the subcommittee on KI in 1996. Not only were they not convinced that there is a benefit to a KI stockpile, but believed that it may hamper the implementation of prompt evacuation which is the preferred protective measure. Indeed, it was after these testimonies and a careful examination of issues and information presented to the subcommittee, that FRPCC recommended a position that reflected a more subtle encouragement (as reflected in option 2).

SECY-94-087 was silent on cases where States did not opt to have a local stockpile of KI. In today's environment, those States could rely on the NBC stockpile to use KI on an ad hoc basis if needed.

This option was favored by the staff in 1994 and, in recognition of the NBC development, remains one of the two recommended options today.

c) **Direct the staff to effect a rule that requires KI as a protective measure for the general public.**

This option is based on the presumption that stockpiling KI for limited populations located close to operating nuclear power plants, if not cost-beneficial, is, nonetheless, prudent.

The option would require that emergency plans be revised to include a KI distribution system for the public and the criteria for its administration in an accident.

This option would be at odds with the FRPCC recommendations and according to the polls, the States would not view this option favorably. The FRPCC recommendations were, in part, based on the notion that the State or local governments are ultimately responsible for the decisions regarding protective actions and their implementation. To have a national stockpile of KI allows the States to use KI on an ad hoc basis if needed.

This option would also have wide-spread implications for emergency planning. It would require the States and local governments to make significant changes to their plans and procedures in order to ensure that KI can be distributed to the public (permanent and transient populations) in a timely manner, preferably without reducing the effectiveness of prompt evacuation if necessary. It would require that Federal agencies develop additional guidance for FEMA evaluation of the changed plans. The NRC and staff would have to revise the existing Federal guidance on protective actions for severe accidents, such as Supplement 3 to NUREG-0654. The State and local officials would have to conduct public training for public use of KI. Public health officials and school officials would need specific instructions for dispensing KI to the general public and school children.

For the purpose of placing this option in perspective using the two States which currently stockpile KI for the general public, the staff contacted officials from Alabama and Tennessee. In each case, KI supplies would be made available at reception centers following an accident. Under the direction of the Health Officer, KI tablets would be administered to members of the public reporting to these centers. Neither State has a planned distribution system to provide KI to the members of the public in case evacuation would not be feasible. Under these circumstances, KI would be distributed on an ad-hoc basis.

In short, this option has the potential to undo the web of emergency planning without any significant added benefit.

Implications of Options on the Petition for Rulemaking

Before discussing the implications of the options on the Petition for Rulemaking, the contributions of Mr. Peter Crane of the NRC, the petitioner, should be recognized for their value in illuminating all aspects of this issue. He has persevered, over many years and in the face of technical disagreement on intangible issues, in keeping this important issue before the agency and without his efforts even the policy changes recommended in this paper would not likely have been made.

Option 1: No change to existing policy.

If this option were approved, then the petition would be denied. The staff could still grant part of the petition by referencing the NBC developments which will result in a Federal stockpile.

Option 2: Endorse FRPCC recommendations recognizing the recent developments in preparation for NBC events.

If the proposed Federal policy is accepted, there will be no rule change to amend 10 CFR 50.47 to require that KI be included in the emergency plans. Thus, the petition would be denied. However, the staff believes that the Federal offer to fund the purchase of KI for the States at their request and the Federal stockpile of KI for NBC events[8] substantially addresses the fundamental concerns behind the petition, without requiring changes in State and local emergency plans.

There are currently two States which stockpile or distribute KI for the general public around nuclear power plants. More States may choose to add KI to their protective actions for the general public.

Option 3 (a): Endorse option 2 with no funding.

The petition would be denied. The Federal stockpile for NBC events partly addresses the fundamental concerns behind the petition.

Option 3 (b): In coordination with HHS and FEMA, revise current policy to make KI available to the States.

[8]As pointed out in the proposed Federal policy, the Federal stockpile of KI will be available to any State for any type of radiological emergency.

The petition would be denied. The availability of KI would substantially address the fundamental concerns behind the petition.

Option 3 (c): Effect a rule change.

This option would grant the petition by directing the staff to make the requested rule change.

Coordination

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer has no objection to the resource estimates contained in this paper.

RECOMMENDATION:

The staff requests that the Commission approve either option 2 or option 3(b).

L. Joseph Callan
Executive Director for Operations

Attachments:
1. Proposed Federal Policy on KI
2. Estimation of Cost

Commissioners' comments or consent should be provided directly to the Office of the Secretary by COB Wednesday, July 2, 1997.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT June 25, 1997, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat shoudl be apprised of when comments may be expected.

DISTRIBUTION:

Commissioners	CIO
OGC	CFO
OCAA	EDO
OIG	REGIONS
OPA	SECY
OCA	
ACRS	

Billing Code 6718-06-P April 16, 1997

FEDERAL EMERGENCY MANAGEMENT AGENCY

DRAFT

Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent

AGENCY: Federal Emergency Management Agency.

ACTION: Issuance of Federal Policy on Potassium Iodide.

SUMMARY: The Federal Radiological Preparedness Coordinating Committee (FRPCC) is issuing this revised Federal policy concerning the purchase, stockpiling, and use of potassium iodide (KI) as a prophylaxis for the thyroid in the unlikely event of a major radiological emergency at a commercial nuclear power plant. Taken in time, KI blocks the thyroid's uptake of airborne radioactive iodine, and thus could help reduce thyroid diseases caused by such exposure.

The Federal policy is that KI should be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies. In developing the range of public protective actions for severe accidents at commercial nuclear facilities, the best technical information indicates that evacuation and in-place sheltering provide adequate protection for the general public. However, the State (or in some cases, the local government) is ultimately responsible for the protection of its citizens. Therefore, the decision for local stockpiling and use of KI as a protective measure for the general public is left to the discretion of State (or, in some cases, local government.)

ATTACHMENT 1

It is recognized that the State (or in some cases, the local government), within the limits of its authority, can take measures beyond those recommended or required. The availability of KI as a protective measure for the general public supplements other options for public officials responsible for protective action decisions. A few States have indeed included KI as a protective action for the general public. The FRPCC does not want to usurp the State prerogative to incorporate the use of KI as a protective measure for the general public. Therefore, to ensure that States have the option to use KI if they so elect, the Federal government is prepared to provide funding for the purchase of a supply of KI. Any State (or in some cases, local government) which selects the use of KI as a protective measure for the general public may so notify FEMA, and may request funding for the purpose of purchasing a supply of KI.

In addition, the Federal government is also required to prepare for a wider range of radiological emergencies[1]. To that end, and as an added assurance for radiological emergencies in which the location and timing of an emergency are unpredictable and for which, unlike licensed nuclear power plants, there is little planning possible, a stockpile of KI is being established by the Federal government. This Federal stockpile will be available to any State for any type of radiological emergency, at any time.

---

[1]In response to new threats, the Federal government broadened the scope of emergency response preparedness to include terrorism involving nuclear, biological, and chemical agents. As a result, and in support of State and local governments, new resources were identified to be needed in response to such events. About two dozen Metropolitan Medical Strike Teams (MMST) are being established for response to such events. Medical supplies, including KI, are being stockpiled nationally for the use by MMSTs in three locations: East coast, Central, and West coast. The quantity of supplies stockpiled uses a planning basis of 100,000 people for a period of two days.

The policy herein incorporates changes recommended by the FRPCC's Subcommittee on Potassium Iodide, and supersedes the 1985 Federal policy (50 FR 30258). The principal difference between this revised policy and the 1985 version are the addition of the offer of the Federal Government to purchase a supply of KI for States at a State's request and the establishment of a Federal stockpile. The Federal Emergency Management Agency (FEMA) chairs the FRPCC, thereby assuming the responsibility for this publication.

For Further Information Contact: William F. McNutt, Senior Policy Advisor, Room 634, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-2857; facsimile (202 646-4183.

Background

This policy on use of KI as a thyroidal blocking agent is the result of a Federal interagency effort coordinated by FEMA for the FRPCC. On March 11, 1982, FEMA issued a final regulation in the Federal Register (47 FR 10758), which delineated agency roles and responsibilities for radiological incident emergency response planning (44 CFR 351). One of the responsibilities assigned to the Department of Health and Human Services (HHS) and in turn delegated to the Food and Drug Administration (FDA) was providing guidance to State and local governments on the use of radioprotective substances and prophylactic use of drugs (e.g., KI) to reduce radiation doses to specific organs including dosage and projected radiation exposures at which such drugs should be used.

In the June 29, 1982 Federal Register (47 FR 28158), FDA published recommendations for State and local agencies regarding the projected radiation dose to the thyroid gland at which State and local health officials should consider the use of KI. The Federal policy on stockpiling and distribution of KI was published in the July 24, 1985 Federal Register (50 FR 30258). On September 11, 1989, the American Thyroid Association requested FEMA, as Chair of the FRPCC, to reexamine the 1985 policy and to revisit the issue of stockpiling and distribution of KI for use by the general public. In response, the FRPCC established an Ad Hoc Subcommittee on Potassium Iodide. On December 5, 1994, the FRPCC adopted the report and recommendations of the Ad Hoc Subcommittee on Potassium Iodide, which reaffirmed the Federal position as expressed in the 1985 policy.

On April 3, 1996, in connection with a September 9, 1995 Petition for Rulemaking submitted to the Nuclear Regulatory Commission (NRC) on this issue, the FRPCC established a new Subcommittee on Potassium Iodide to review current information. The Subcommittee conducted a public meeting on June 27, 1996. Based on the information collected, the Subcommittee concluded that there was no new information that seriously challenges the bases for the 1985 recommendations concerning public use of KI for radiological emergencies at nuclear power plants. However, several recommendations were made to the FRPCC. The Subcommittee's three recommendations were: 1) without changing the Federal policy by interceding in the State's prerogative to make its own decisions on whether or not to use KI, the Federal government (NRC, or through FEMA) should fund the purchase of a stockpile for any State that, hereinafter, decides to incorporate KI as protective measure for the general public; 2) The Subcommittee believes the language in the 1985 policy should be softened to be more flexible and balanced. For example, the problem many intervenors observe in the Federal policy is in the italicized statement "The Federal position with...potassium iodide for use by the general public is that it should not be required." It would not be as negative if the last phrase were reworded to state "it [potassium iodide for use by the general public] is not required, but may be selected as a protective measure at the option of the State or, in some cases, local governments." and 3) The subcommittee recommends that local jurisdictions who wish to incorporate KI as a protective action for the general public should consult with the State to determine if such arrangements are appropriate. If local governments have the authority or secure the approval to incorporate KI as a protective measure for the general public, they would need to include such a measure in their emergency plans.

The full FRPCC endorsed the subcommittee's recommendations with some modifications.

Policy on Distribution of KI Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent

The purpose of this document is to provide Federal policy and guidance with regard to distribution of KI, and its usage as a thyroid blocking agent, around operating nuclear power generating facilities. The issue has been addressed in terms of two components of the population that might require or desire KI use: (1) Emergency workers and institutionalized individuals close to the nuclear power plant site, and (2) the nearby general population. This guidance is for those State and local governments who, within the limits of their authority, need to consider these recommendations in the development of emergency plans and in determining appropriate actions to protect the general public.

The Federal policy is that KI should be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies. In developing the range of public protective actions for severe accidents at commercial nuclear facilities, the best technical information indicates that evacuation and in-place sheltering provide adequate protection for the general public. However, the State (or in some cases, the local government) is ultimately responsible for the protection of its citizens. Therefore, the decision for local stockpiling and use of KI as a protective measure for the general public is left to the discretion of State (or, in some cases, local government.)

It is recognized that the State (or in some cases, the local government), within the limits of its authority, can take measures beyond those recommended or required. The availability of KI as a protective measure for the general public supplements other options for public officials responsible for protective action decisions. A few States have indeed included KI as a protective action for the general public. The FRPCC does not want to usurp the State prerogative to incorporate the use of KI as a protective measure for the general public. Therefore, to ensure that States have the option to use KI if they so elect, the Federal government is prepared to provide funding for the purchase of a supply of KI. Any State (or in some cases, local government) which selects the use of KI as a protective measure for the general public may so notify FEMA, and may request funding for the purpose of purchasing a supply of KI.

In addition, the Federal government is also required to prepare for a wider range of radiological emergencies[2]. To that end, and as an added assurance, for radiological emergencies in which the location and timing of an emergency are unpredictable and for which, unlike licensed nuclear power plants, there is little planning possible, a stockpile of KI is being established by the Federal government. This Federal stockpile will be available to any State for any type of radiological emergency, at any time.

The bases for these recommendations are given below.

---

[2]In response to new threats, the Federal government broadened the scope of emergency response preparedness to include terrorism, involving nuclear, biological, and chemical agents. As a result, and in support of State and local governments, new resources were identified to be needed in response to such events. About two dozen Metropolitan Medical Strike Teams (MMST) are being established for response to such events. Medical supplies, including KI, are being stockpiled nationally for the use by MMSTs in three locations: East coast, Central, and West coast. The quantity of supplies stockpiled uses a planning basis of 100,000 people for a period of two days.

The NRC and FEMA issued guidance to State and local authorities as well as licensees of operating commercial nuclear power plants in NUREG-0654/FEMA-REP-1, Revision 1, in 1980. This guidance recommends the stockpiling and distribution of KI during emergencies to emergency workers and to institutionalized individuals. Thyroid blocking for emergency workers and institutionalized individuals was recommended because these individuals are more likely to be exposed to radioiodine in an airborne radioactive release than other members of the public. In addition, the number of emergency workers and institutionalized individuals potentially affected at any site is relatively small and requires a limited supply of KI that can be readily distributed.

For the general public, in the event of a radiological emergency at a commercial nuclear facility, evacuation and in-place sheltering are considered adequate and effective protective actions. It is well-recognized that the inclusion of KI as a protective measure, in addition to evacuation and sheltering, is beneficial only in very remote circumstances. The use of KI is not without controversy. On the one hand, KI has been shown to be an effective drug for protecting the thyroid from thyroid nodules or cancer caused by the uptake of radioiodine, especially in children fifteen years of age or younger. On the other hand, there are logistical difficulties, and potential medical side effects associated with the drug, in distributing the drug to the general public in a radiological emergency. Also, KI effectively reduces the radiation exposure of only the thyroid gland from ingested or inhaled radioiodines. While this in an important contribution to the health and safety of the individual, it is not as effective as measures which protect the total body. Both in-place sheltering and precautionary evacuations can reduce the exposure to the thyroid and the total body. It is very important to remember that the use of KI is not an effective means

by itself for protecting individuals from the radioactivity in an airborne release resulting from a nuclear power plant accident and, therefore, should only be considered in conjunction with sheltering, evacuation, or other protective methods. Therefore, while the use of KI can provide additional protection in certain circumstances, the assessment of the effectiveness of KI and other protective actions and their implementation indicates that the decision to use KI (and/or other protective actions) should be made by the States and, if appropriate, local authorities on a site-specific, accident-specific basis.

Those States or local governments which opt to include KI for the general population will be responsible for the maintenance, distribution, and any subsequent costs associated with this program.

The incorporation of a program for KI stockpiling, distribution and use by any State or local government into the emergency plans will not be subject to Federal evaluation. This is based on the recognition that the use of KI by the State for the general public is a supplemental protective measure, and on the Federal government's determination that the existing emergency planning and preparedness guidance for nuclear power plants is effective and adequate to protect the public health and safety.

The FDA has evaluated the medical and radiological risks of administering KI for emergency conditions and has concluded that it is safe and effective and has approved over-the-counter sale of the drug for this purpose. FDA guidance states that risks from the short term use of relatively low doses of KI for thyroidal blocking in a radiological emergency are outweighed by the risks of radioiodine induced thyroid nodules or cancer at a projected

dose to the thyroid gland of 25 rem or greater. Since FDA has authorized the nonprescription sale of KI, it is available to individuals who, based on their own personal analysis, choose to have the drug immediately available.

Attached is a list of ten references intended to assist State and local authorities in decisions related to the use of KI.

Conclusion

The FRPCC did not find any new information that would require a change in the basis of the existing Federal policy concerning the stockpile or pre-distribution of KI for the general public in the event of a radiological emergency at a commercial nuclear plant. The policy is that KI should be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies, but leaves the decision for the stockpiling, distribution, and use of KI for the general public to the discretion of State, and in some cases, local governments. Any State or local government that selects the use of KI as a protective measure for the general public may so notify FEMA and may request funding for the purpose of purchasing an adequate supply.

The incorporation of a program for KI stockpiling, distribution and use by any State or local government into the emergency plans will not be subject to Federal evaluation. This is based on the recognition that the use of KI by the State for the general public is a supplemental protective measure, and on the Federal government's determination that the

existing emergency planning and preparedness guidance for nuclear power plants is effective and adequate to protect the public health and safety.

Those States or local governments which opt to include KI for the general population will be responsible for the maintenance, distribution, and any subsequent costs or legal liabilities associated with this program.

As an added assurance, for a broader range of radiological emergencies in which the location and timing of an emergency are unpredictable and for which, unlike licensed nuclear power plants, there is little planning possible, a stockpile of KI will be established by the Federal government. Such a stockpile would consist of individual KI caches at VA hospitals in major metropolitan centers across the country. This supply would be available to any State or local government for any type of radiological emergency.

References

1. National Council on Radiation Protection and Measures (NCRP), "Protection of the Thyroid Gland in the Event of Releases of Radioiodine," NCRP Report No. 55, August 1, 1977.

2. Food and Drug Administration (HHS), Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency, 43 FR 58798, December 15, 1978.

3. Halperin, J. A., B. Shleien, S. E. Kahans, and J. M. Bilstad; "Background Material for the Development of the Food and Drug Administration's Recommendations on Thyroid Blocking with Potassium Iodide," FDA 81-8158, U.S. Department of Health and Human Services (March 1981).

4. Food and Drug Administration; Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Final Recommendations on Use (Notice of Availability) 47 FR 28158, June 29, 1982).

5. Food and Drug Administration; Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Recommendations on Use. (April 1992). Prepared by the Bureau of Radiological Health and Bureau of Drugs, Food and Drug Administration, Department of Health and Human Services.

6. Nuclear Regulatory Commission; Examination of the Use of Potassium Iodide (KI) as an Emergency Protective Measure for Nuclear Reactor Accidents (NUREG/CR-1433, March 1990). Prepared by Sandia National Laboratories for the NRC.

7. Nuclear Regulatory Commission; An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident (NUREG/CR-6310, February 1995). Prepared by S. Cohen and Associates, Inc. and Scientech, Inc. for the NRC.

8. Nuclear Regulatory Commission; Re-Evaluation of Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant (SECY-93-318, November 23, 1993).

9. Nuclear Regulatory Commission; Addendum to SECY-93-318, Re-Evaluation of Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant (SECY-94-087, March 29, 1994).

Signed:

_____

O. Megs Hepler, III
Chair
Federal Radiological Preparedness Coordinating Committee

Estimation of the Cost to Purchase KI for the States in Using Three Scenarios

The option 2 proposed Federal policy contains an offer by the Federal government (most likely the NRC) to fund the purchase of a supply of KI for any State that chooses to add KI to its options of protective actions in response to an emergency at a NRC licensed nuclear power plant. Currently, resources are not budgeted for the purchase of KI and funds would have to be reprogrammed should a State (or States) request funding through FEMA.

To fulfill this proposed obligation, staff's estimate of the range of NRC costs is given below:

	No. of Sites Added Each Year	No. of Years	Cost in k$/yr Year 1-3	Cost in k$/yr Year 4-5	Cost in k$ Year 8	Cost k$/yr Year 9-10	Cost in k$/yr Year 11-12
Scenario 1[3]	3	3	48		48	48	
Scenario 2	10	5	160	160	160	160	160
Scenario 3	70	1	1,120		1,120		

Table: Cost of KI purchase in $1000 for three scenarios

The cost estimate does not include the administrative costs associated with the KI purchase. Although the cost/benefit ratio to purchase KI for the population in the 10-mile Emergency Planning Zone (EPZ) may be excessive for most sites, the NRC staff used the 10-mile EPZ population as the basis for cost estimation. The cost range is from $48,000/year for the first three years and repurchased every seven years, to a maximum of $1,280,000 the first year and repurchased every seven years. The higher estimate assumes all sites would request funding for the purchase of KI in the first year, which staff believes is highly unlikely. The more likely scenario is that several sites may request funding each year for a few years. In that case, the estimate is about $50,000 each year for a period of three years and repeated every seven years, thereafter.

Three scenarios were used to estimate the cost to purchase KI for the States who request such funding. The first is based on the assumption that one State per year (with three sites) requests funding for a period of three years. The second scenario assumes three States per year (with a total of 10 sites) request funding for a period of five years. The third scenario assumes every State with a nuclear power plant requests funding the first year.

ATTACHMENT 2

[3]The three scenarios are described in Attachment 2.

The staff assumed the entire 10-mile EPZ population in the cost estimation. Although the KI package contains an insert instructing the user to take one tablet a day for 10 days unless directed otherwise by State or local public health officials, the cost estimation was based on a two-day supply.

Our estimate of the range of costs are as follows:

Scenario 1

One State (with three sites) per year requests funding for a period of three years.

Number of sites added per year, S: 3
Average number of people per site (within 10-mile EPZ), P: 80,000
Average number of KI tablets/person, T: 2
Average cost/KI tablet, c: $0.10
Average shelf life of KI, L: 7 years

The start-up cost would be: C = S*P*T*c = 3*80,000*2*0.1 = $48,000/year, or $146,000 over three years.

Scenario 1	1998	1999	2000
No. of Sites Added	3	3	3
Cost ($1000)	48	48	48

The replacement cost would be the same plus inflation, every seven years.

Scenario 2

Three States per year (containing a total of 10 sites) request funding for a period of five years.

Number of sites added per year, S: 10
Average number of people per site (within 10-mile EPZ), P: 80,000
Average number of KI tablets/person, T: 2
Average cost/KI tablet, c: $0.10
Average shelf life of KI, L: 7 years

The start-up cost would be: C = S*P*T*c = 10*80,000*2*0.1 = $160,000/year, or $800,000 for five years.

Scenario 2	1998	1999	2000	2001	2002
No. of Sites Added	10	10	10	10	10
Cost ($1000)	160	160	160	160	160

The replacement cost would be the same plus inflation, every seven years.

Scenario 3

Number of sites, S: 70
Average number of people per site (within 10-mile EPZ), P: 80,000
Average number of KI tablets/person, T: 2
Average cost/KI tablet, c: $0.10
Average shelf life of KI, L: 7 years

If every State with a nuclear power plant site requested funding in the first year, the start-up cost would be: C = S*P*T*c = 70*80,000*2*0.1 = $1,120,000

Scenario 3	1998
No. of Sites	70
Cost ($1000)	1,120

The replacement cost would be $1,120,000, plus inflation, every seven years.

'Population Data within the Nuclear Power Plant Emergency Planning Zones

SITE	'PERMANENT 0-2 MILES	0-5 MILES	0-10 MILE	TRANSIEN 0-10 MILE	'Total 0-10 miles	
KANSAS	853	7,320	25,394	6,000	31,394	1
BEAVER VALLEY	3,676	16,658	142,268	3,400	145,668	2
BELLEFONTE	309	4,696	25,050	2,437	27,487	3
BIG ROCK POINT	269	4,368	9,274		9,274	4
BRAIDWOOD	3,545	11,490	26,015	8,105	34,120	5
BROWNS FERRY	148	2,414	27,678	19,600	47,278	6
BRUNSWICK	711	4,373	10,583	21,000	31,583	7
BYRON	371	7,140	21,393	43,762	65,155	8
CALLAWAY	82	632	5,759	4,545	10,304	9
CALVERT CLIFFS	241	3,501	19,972	1,150	21,122	10
CATAWBA	340	1,058	81,423	46,879	128,302	11
CLINTON	48	918	12,666	28,472	41,138	12
COMANCHE PEAK	29	2,684	10,731	8,918	19,649	13
COOPER STATION	40	830	5,417	3,000	8,417	14
CRYSTAL RIVER	0	825	13,595	1,010	14,605	15
DC COOK	723	12,364	53,755	16,089	69,844	16
DAVIS BESSE	1,030	2,572	16,427		16,427	17
DIABLO CANYON	10	57	18,099	53,700	71,799	18
DRESDEN	613	7,498	39,289	5,900	45,189	19
DUANE ARNOLD	235	3,821	79,323		79,323	20
FARLEY	27	1,577	10,681	1,420	12,101	21
FERMI	3,004	13,460	71,517		71,517	22
FITZPATRICK	242	3,909	35,155	20,790	55,945	23
FORT CALHOUN	207	7,666	15,254	871	16,125	24
GINNA	930	9,979	39,162	5,863	45,025	25
GRAND GULF	180	2,025	7,255	2,873	10,128	26
HADDAM NECK	2,345	12,129	74,080	29,415	103,495	27
HARRIS	110	1,545	15,795	11,000	26,795	28
HATCH	107	894	5,312	150	5,462	29
HOPE CREEK	0	1,209	22,556	5,539	28,095	30
INDIAN POINT	15,165	74,755	240,455	92,852	333,307	31
KEWAUNEE	163	1,600	11,086		11,086	32
LASALLE	130	1,145	13,913	3,130	17,043	33
LIMERICK	4,349	100,364	164,870	23,165	188,035	34
MAINE YANKEE	372	2,001	28,730	42,338	71,068	35
MCGUIRE	420	4,189	46,233	31,178	77,411	36
MILLSTONE	5,176	48,648	110,166	83,129	193,295	37
MONTICELLO	279	7,611	20,153		20,153	38
NINE MILE POINT	242	3,909	35,155	20,790	55,945	39
NORTH ANNA	225	1,639	8,688	1,166	9,854	40
OCONEE	401	4,670	50,841	20,000	70,841	41
OYSTER CREEK	4,700	14,950	71,440	73,676	145,116	42
PALISADES	959	5,203	32,773		32,773	43
PALO VERDE	10	205	761	4,000	4,761	44
PEACH BOTTOM	512	6,153	28,647	9,858	38,505	45
PERRY	1,882	17,238	71,902	53,271	125,173	46

PILGRIM	1,716	15,249	41,401	1,200	22,194	48
POINT BEACH	239	1,256	20,994		21,462	49
PRAIRIE ISLAND	290	4,228	21,462	12,035	48,480	50
QUAD CITIES	224	5,740	36,445	13,700	36,572	51
RIVERBEND	601	4,053	22,872	5,000	31,908	52
ROBINSON	1,164	10,435	26,908	40,000	134,854	53
ST LUCIE	210	9,417	94,854	5,539	28,095	54
SALEM	0	1,209	22,556	25,900	83,050	55
SAN ONOFRE	3,650	28,450	57,150	116,988	217,708	56
SEABROOK	6,040	32,060	100,720	24,000	62,972	57
SEQUOYAH	890	7,503	38,972	4,622	7,172	58
SOUTH TEXAS	4	268	2,550	2,000	10,869	59
SUMMER	220	1,883	8,869	63,755	137,166	60
SURRY	49	1,399	73,411	3,720	54,952	61
SUSQUEHANNA	1,177	13,317	51,232	6,335	167,844	62
THREE MILE ISLAND	2,331	27,466	161,509	4,500	97,164	63
TURKEY POINT	0	30	92,664	3,544	35,453	64
VERMONT YANKEE	2,086	9,231	31,909	200	2,869	65
VOGTLE	517	1,133	2,669	7,000	67,009	66
WATERFORD	914	13,756	60,009	8,000	21,916	67
WATTS BAR	209	2,696	13,916	1,100	6,620	68
WOLF CREEK	24	3,698	5,520	11,824	13,162	69
WNP-2	0	80	1,338	65,750	310,756	70
ZION	12,981	59,247	245,006			
SUM	90,946	697,696	3,111,627	1,320,238	4,431,865	

These are estimates of 1982 population which were developed by NRC staff
Transient population estimates were based on information obtained from FSARs, E Plans, NUREG/CR -1856 (1981) and on licensee estimates. Transient population data are considered to include a large degree of 'uncertainty

Average population per site	63,312
Ave pop/site assuming 20% increas	75,975

ENCLOSURE 4a

POLICY ISSUE
(Notation Vote)

November 10, 1998

SECY-98-264

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: PROPOSED AMENDMENTS TO 10 CFR 50.47; GRANTING OF PETITIONS FOR RULEMAKING (PRM 50-63 AND 50-63A) RELATING TO A REEVALUATION OF POLICY ON THE USE OF POTASSIUM IODIDE (KI) AFTER A SEVERE ACCIDENT AT A NUCLEAR POWER PLANT

PURPOSE:

To obtain Commission approval to publish a proposed rule in the Federal Register for a 90-day public comment period, that would grant petitions for rulemaking (PRM 50-63 and 50-63A). These petitions requested changing the NRC policy on the use of potassium iodide (KI) as a radioprotective agent for the general public in the event of a severe reactor accident.

BACKGROUND:

On September 9, 1995, a petition for rulemaking (PRM 50-63) was filed with the NRC by Mr. Peter Crane. The petitioner requested that the NRC amend its emergency planning regulations to require that emergency plans specify a range of protective actions to include sheltering, evacuation, and the prophylactic use of KI.

In SECY-97-245, dated October 23, 1997, the staff presented three options to the Commission for resolving PRM 50-63.

CONTACT:
Mike Jamgochian, NRR/DRPM/PGEB
(301) 415-3224

On November 5, 1997, the Commission was briefed by the NRC staff, the Federal Emergency Management Agency (FEMA), and the petitioner regarding the options available for resolving the petition for rulemaking. During the meeting, the Commission invited the petitioner to submit a modification to his petition in order to address the views he discussed during the meeting.

On November 11, 1997, the petitioner submitted a revision to his petition, PRM 50-63A (Enclosure 1). The petitioner made two requests:

> A statement be made clearly recommending stockpiling of KI as a "reasonable and prudent" measure, and
>
> A proposed rule change to 10 CFR 50.47(b)(10), which would be accomplished by inserting the following sentence after the first sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate."

The petitioner also provided a marked-up version of the proposed Federal Radiological Preparedness Coordinating Committee (FRPCC) Federal Register notice concerning a revision to the Federal policy relating to the use of KI for the general public.

On June 26, 1998, the Commission directed the staff in SRM 98-061 (Enclosure 2) to grant the petition for rulemaking PRM 50-63A by revising 10 CFR 50.47(b)(10).

PUBLIC COMMENT ON THE AMENDED PETITION:

On November 27, 1995 (60 FR 58256), a Notice of Receipt of the Petition for Rulemaking was published in the Federal Register requesting public comment. A total of 63 comment letters were received, of which 20 utilities, 9 State governmental agencies, 2 utility interest organizations, 1 letter signed by 12 health physicists, 2 State universities and 1 member of the public were against the granting of the petition for rulemaking. Those letters in favor of granting the petition came from 5 environmental groups, 22 members of the public (including 1 from the petitioner), and the American Thyroid Association.

On December 17, 1997 (62 FR 66038), the Commission published a request for public comment on the amended petition in the Federal Register. In response to several requests, the comment period was extended until February 17, 1998, by a Federal Register notice published on January 21, 1998 (63 FR 3052). A total of 82 comment letters were received, of which 13 utilities, 3 State government agencies, 1 utility interest association, and 1 member of the public were against granting the petition for rulemaking. The letters in favor of granting the petition came from 8 public interest groups, 46 members of the public (including 1 from the petitioner), 3 physicians, 2 U.S. Senators, and 1 State Representative. A detailed analysis of the issues raised by the public comments along with the Commission response to those issues is in the proposed Federal Register Notice (Enclosure 3).

DISCUSSION:

In the revised petition (PRM 50-63A) dated November 11, 1997 the petitioner requested that consideration be given to including KI as a protective measure for the general public. This is a change from the original petition in which the petitioner requested that the regulations be amended to require emergency plans to include KI as a protective measure. In both the original and the amended petitions, the proposed rule language lists sheltering and evacuation as protective measures along with KI. The planning standard (10 CFR 50.47(b)(10)) currently does not identify any specific protective actions, but indicates that a range of protective actions should be developed for the plume exposure pathways zone (EPZ) for emergency workers and the public, and included in emergency response plans. Additionally, the petitioner requested that a statement be made clearly recommending stockpiling of KI as a reasonable and prudent protective measure.

On June 26, 1998, the Commission voted 3 to 1 to grant the petition for rulemaking. Accordingly, the staff was directed to proceed with rulemaking to change 10 CFR 50.47(b)(10) by inserting the following sentence, or similar words, after the first sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and, as a supplement to these, the prophylactic use of potassium iodide (KI), as appropriate." In addition, the statement of considerations for the proposed rule should include a statement to the effect that State and local decision makers, provided with proper information, may find that the use of KI as a protective supplement is reasonable and prudent for specific local conditions. The Commission also noted that, consistent with the Commission's decision on June 30, 1997, the Federal government (most likely NRC) is prepared to fund the purchase of a stockpile of KI for the States, upon request. The NRC staff also was directed to work with other relevant agencies to ensure that there are established procedures to enable the national stockpile, for response to terrorism, to be effectively and timely used by States that have not established local stockpiles and wish to make use of the national stockpiles in the event of a severe nuclear power plant accident.

The attached Federal Register notice implements the Commission's decision by publishing the proposed amendment to 10 CFR 50.47(b)(10) for a 90-day public comment period.

RESOURCES:

Approximately one FTE is budgeted to resolve this petition by conducting a rulemaking in accordance with the Commission direction. The cost of purchasing KI was discussed in SECY 97-124 (Enclosure 4) with the estimates ranging from $48K to $1.3M. The staff has recently found these estimates to be overly conservative by approximately a factor of 2.5 due to the increased costs of purchasing the KI tablets. Therefore, the revised estimate range is $117K to $3.25M depending on the number of States that request funding. These resources are not currently budgeted and would have to be reprogrammed from existing agency programs or carryover. A more detailed cost and funding analysis will be provided prior to the final rulemaking. Additionally, prior to FEMA going forward with the issuance of the FRPCC Federal KI policy, a letter from the NRC committing the above funds will be necessary.

COORDINATION:

The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections. The CRGR has reviewed this Commission paper but does not agree with the staff's no backfit analysis (see Enclosure 6). The Office of the Chief Information Officer has reviewed this Commission paper for information technology impacts and compliance with the Paperwork Reduction Act and concurs in it. The Office of the General Counsel has no legal objection.

RECOMMENDATION:

That the Commission:

1. Approve publication of the proposed rule in the Federal Register.

2. Note:

   a. The proposed rule change would be published in the Federal Register for a 90-day public comment period.

   b. Appropriate Congressional committees will be notified.

   c. The Office of Public Affairs draft public announcement is attached (Enclosure 5).

   d. The evaluation of a need for a backfit analysis was prepared by OGC. The EDO accepts OGC's position that this rule change does not constitute a backfit under 10 CFR 50.109; therefore, a backfit analysis is not required.

   e. FEMA has been provided with an advance copy of this rulemaking package.

William D. Travers
Executive Director
for Operations

Attachments:

1. Revised Petition for Rulemaking (PRM 50-63A)
2. SRM 98-061, dated June 26, 1998
3. Proposed Federal Register Notice
4. SECY 97-124
5. Draft Public Announcement
6. CRGR comment letter dtd. October 23, 1998

Commissioners' completed vote sheets/comments should be provided directly to the Office of the Secretary by COB Friday, November 27, 1998.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT November 19, 1998, with an information copy to the Office of the secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

DISTRIBUTION:
Commissioners
OGC
OCAA
OIG
OPA
OCA
CIO
CFO
EDO
REGIONS
SECY

Peter G. Crane / 4809 Drummond Avenue / Chevy Chase, MD 20815 / 301-656-3998

November 11, 1997

Mr. John C. Hoyle, Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Amendment to Petition for rulemaking (PRM-50-63)

Dear Mr. Hoyle:

At the Commission meeting on potassium iodide held on November 5, 1997, Chairman Jackson asked me whether I could submit, within the week, language reflecting the modified position that I outlined during the meeting. Attached to this letter is a draft of a proposed rule change, accompanied by a statement of considerations explaining the change.

Under the approach I outlined in the meeting, the NRC would "require that consideration of potassium iodide be given in the formulation of emergency plans," but "would not ram potassium iodide down the throat of a state that emphatically rejected it." I made clear that I was asking for two things: a statement clearly recommending stockpiling of KI as a "reasonable and prudent" measure, and a rule change identifying what is meant by a "range of protective actions" (i.e., evacuation, sheltering, and KI) and requiring their consideration.

In the meeting, I sometimes referred to the "reasonable and prudent" statement as a "statement of policy," while elsewhere I talked about "clarification which could readily be done in the statement of considerations for such a rule." (At one point, Commissioner Diaz observed, and I agreed, that I was proposing that the Commission, in a "public statement or a rule," express the belief that stockpiling was a prudent measure.) In short, there may have been ambiguity as to whether I was seeking two separate documents -- a rule change and a policy statement explaining it -- or just one, a rule change with policy stated and explained in the statement of considerations. Plainly, the latter makes more sense (in any event, to propose a rule change, the NRC would have to offer its reasons for doing so) and seems most consistent with the Commission's interest in resolving the KI issue in an efficient and timely way.

In the attached proposal, which represents an amendment to my petition, the Commission's expression of policy therefore would take place in the context of the rule change, i.e., in the statement of considerations. I trust that no one will view this as any deviation from what I was proposing in the meeting.

I realize that it is an ancient negotiating ploy to press for more than you think you can possibly get, as a prelude to bargaining. The fact that this proposal does not do that, but instead is squarely in line with what I described

ENCL 1

on November 5, is an indication that I take this amendment of my petition very seriously, without game-playing. I would like as much as anyone to see this protracted process brought to closure, with broad consensus acceptance. Accordingly, I have tried to produce a solution that satisfies the NRC's obligations to protect and inform the public, that does not encroach unnecessarily on state prerogatives, and that enables the Commission to put a difficult and divisive issue behind it.

I have also tried in this draft Statement of Considerations to present the KI issue in such a way that no one can accuse the Commission, if it adopts this approach, of being alarmist, or of failing to put safety issues in their proper perspective. Moreover, although I have often, in past submissions, discussed troubling past events, such as those I referred to in the November 5 meeting, I have omitted these historical matters from the proposed Statement of Considerations that I am offering today. This reflects a conscious decision to look forward, not to the past, in the recognition that for a health and safety agency, the central question must always be: What makes sense <u>today</u>, in light of what we know <u>now</u>?

I believe that if the approach I am proposing is accepted, it would be viewed as so patently reasonable that if challenged legally, it would be sustained by any reviewing court, whether the challenge came from those who thought it went too far or from those who thought it did not go far enough. In the memorable words of the late Judge Harold Leventhal of the U.S. Court of Appeals for the D.C. Circuit, "When agencies make good sense, courts are loth to find that it is not good law." On issues of litigation risk, however, the Commission should of course rely on the General Counsel and the Solicitor for advice.

A rulemaking of this kind need not consume significant resources. Though it was suggested at the November 5 Commission meeting that a rulemaking would take two additional years (i.e., for a total of more than four years since the filing of the petition), this seems exaggerated. It is a matter of public record, for example, that the Commission's last major emergency planning rulemaking, the "realism" rule of 1987, did not require any two years, though it involved many extremely complicated issues and elicited more than 38,000 comments (including many duplicates), all of which had to be read. In that case, a 66-page memorandum to the Commission was prepared in which the issues and comments were analyzed and discussed in detail, with the arguments on both sides fairly presented. A Commission briefing was also held at which the merits of the competing arguments were discussed at length. In the end, the analysis and the final rule were sufficiently airtight, both as policy and as law, that none of those dissatisfied with the rule -- and there were many -- decided to seek judicial review. The entire process, from proposed rule to final rule, took 9 months.

A KI rulemaking along the lines I am proposing would be a minor, not a major rulemaking. It would involve fewer issues and, to judge from the 60 or so comments filed on the petition, would probably elicit comments numbered in the dozens, not in the tens of thousands. If the staff turns to the KI rulemaking with a will, and it is given a firm deadline for turning it around, there is no reason why it could not be completed in significantly less time than the nine months that the "realism" rule required.

I was also asked to provide for the record the citation to an Environmental Protection Agency document that I referred to. The document is the Manual of Protective Action Guides and Protective Actions for Nuclear Incidents, EPA-400-R-92-001, published by EPA in May, 1992. On November 11, 1995, I wrote to you, as Secretary of the Commission, that at the time I filed my rulemaking petition two months earlier, I had been unaware of this document. I therefore wished "to draw the Commission's attention to this document and to ask that this letter and its attachment [a detailed discussion of the EPA Manual and its implications for the KI issue] be considered as a comment supplementing my petition." This letter and its attachment are in the rulemaking docket as comment no. 5, docketed November 13, 1995.

Finally, I was asked to provide a suggested markup of the draft Federal Register notice proposed to the Commission in SECY-97-124. First, I would like to put the notice in context. SECY-97-124 asked for Commission approval of an approach, not of the appended Federal Register notice.[1] Neither the SRM nor the vote sheets of Chairman Jackson or Commissioner Dicus, who voted for Option 2, referred specifically to the draft Federal Register notice in Attachment 1. Nor did the Commission's Staff Requirements Memorandum of June 30, 1997. Thus I do not think that the Commission's vote for Option 2 should be regarded as a vote for the Federal Register notice as drafted by the NRC staff, and my criticisms of the notice are directed at the NRC staff, not at the Commission.

The NRC staff has already acknowledged, at the November 5 Commission meeting, that SECY-97-124 misinformed the Commission as to one element of the procedural history of the KI issue: it was the NRC, not FEMA, whose opposition to stockpiling helped produce -- almost -- the reaffirmation of the 1985 policy in 1995. The same lack of perspective (to use the mildest term possible) that was responsible for that misstatement can be seen in the staff's

---

[1] All that SECY-97-124 had to say about the draft notice was the following, at p. 10: "Attachment 1 contains a proposed Federal policy on KI that reflects the key elements of this option. It incorporates changes recommended by the FRPCC's Subcommittee on Potassium Iodide, acknowledges the developments in the area of NBC events regarding KI but does not alter the current emergency planning requirements."

draft Federal Register notice, both in the selection of the facts it chooses to report and in its overall tone, which is heavily slanted against KI.

I would therefore be remiss if I did not candidly advise the Commission that the draft Federal Register notice, if issued in its present form, is likely to bring nothing but opprobrium to the NRC and to FEMA. In large measure, the notice's failings speak for themselves. What is one to say about a notice that does not get around until page 8 to mentioning that the prevention of cancer is the primary purpose of using KI? What is one to say about a purported history of the KI issue that describes how the FRPCC almost reaffirmed the 1985 KI policy two years ago, but does not mention Chernobyl, even though that accident has produced an extraordinary wealth of new data both on radiation-caused thyroid cancer and on the safety and efficacy of KI?

Can the NRC staff really mean to suggest that it is important that the public learn all about petty bureaucratic maneuverings that occurred in 1994 and 1995, but nothing about the upsurge of childhood thyroid cancer taking place now in the former Soviet Union? This is the way to court not merely criticism, but also ridicule and contempt.

I have tried, therefore, to offer suggestions to make the notice more informative to the reader, more balanced in substance and tone, and less susceptible to being quoted out of context.

For example, I think it is unwise for the NRC and FEMA to embrace too vigorously the line, "no new information that seriously challenges the bases for the 1985 recommendations." It is worth asking the staff to explain exactly what that line means. The ordinary reader is likely to interpret it to mean that there is no new information bearing significantly on the KI issue. That, however, would be demonstrably untrue. Rather, the sentence seems to mean that the 1985 policy was based on a cost-benefit analysis which showed that KI was not cost-beneficial, and the Government has not received any new information suggesting otherwise.[2] But of course, the discussion of KI in the last several years, including the Government's decision to stockpile the drug for NBC terrorist events, has all been based on prudency, not on cost-benefit considerations.

If the Commissioners or the EDO were sometime called upon to explain this sentence, and it turned out to mean what I suggest it seems to mean, would

---

[2] It would not even be correct to say that there is no new information challenging the cost-benefit analysis that was the basis of the 1985 "not worthwhile" policy. The reanalysis of costs and benefits in 1992 showed the ratio of costs and benefits to be almost equal for close-in populations, whereas the cost-benefit analysis that underlay the 1985 policy showed an extremely high ratio of costs to benefits.

they feel comfortable that the notice had done a good job of informing the public? Or would the sentence seem, on examination, to be a cleverly worded way of disguising the fact that an enormous amount of new information bearing on the value of KI has emerged since 1985? I believe that Government agencies should be careful to speak so clearly and forthrightly on issues like these that they never leave themselves open to the charge, just or unjust, of having used words artfully to create a misleading impression.

At one point, I have included the words "reasonable and prudent," on the assumption that the Commission would not be proposing to offer KI to states and localities, and the Government would not be stockpiling KI now, if stockpiling of KI were not regarded as a reasonable and prudent measure. I highlight this only because I do not want to give anyone the excuse to accuse me of trying to slip something into the notice without the Commission's being aware of it.

Finally, I have also suggested some additions to, and one deletion from, the list of references.

Please note that this submission is, as in the past, submitted in my capacity as a member of the public, not in my official capacity as Counsel for Special Projects in the NRC's Office of the General Counsel. It was written on my own time, at home, using my own computer and materials, and relying on information available to the public in the NRC's Public Document Room.

Sincerely,

Peter Crane

Peter G. Crane

Attachments: Draft rule change with Statement of Considerations
Markup of draft Federal Register notice from SECY-97-124

cc: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Executive Director for Operations
General Counsel
Director, Federal Emergency Management Agency

PROPOSED RULE CHANGE

For the reasons set forth in the Statement of Considerations, the NRC is proposing to change the planning standard in 10 CFR §50.47(b)(10) by adding one sentence, as indicated by underlining:

> (10) A range of protective actions have been developed for the plume exposure EPZ for emergency workers and the public. In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate. Guidelines for the choice of protective actions during an emergency, consistent with Federal guidelines are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed.

STATEMENT OF CONSIDERATIONS

The Nuclear Regulatory Commission is proposing to amend its emergency planning rules, codified at 10 CFR §50.47(b)(10), to clarify the requirement that emergency plans must demonstrate that "a range of protective actions has been developed" for protecting the public in the unlikely event of a radiological emergency.

As amended, the regulation will spell out that in developing emergency plans, states must consider the following: evacuation, sheltering, and the use of radioprotective drugs (i.e., potassium iodide, or KI).

Potassium iodide, if taken in time, can protect against radiation-caused thyroid cancer, as well as hypothyroidism and benign thyroid nodules. Children's thyroid glands are particularly sensitive to these effects. Since the efficacy of KI in protecting the thyroid depends on timing (i.e., administering it either before or within a few hours after the exposure to radioactive iodine), the NRC believes that stockpiling of KI in the vicinity of nuclear power plants is a reasonable and prudent measure.

This proposed rule change should not be taken to imply that the NRC believes that the present generation of nuclear power plants is any less safe than previously thought. On the contrary, present indications are that nuclear power plant safety has improved since the current emergency planning requirements were put in place after the Three Mile Island accident. Rather, the rule change primarily reflects lessons learned from the Chernobyl disaster of 1986, both about the consequences of an accident and about the safety and efficacy of KI.

The Chernobyl accident demonstrated that thyroid cancer can indeed be a major result of a large reactor accident. Moreover, although the Food and Drug

Administration declared KI "safe and effective" as long ago as 1973, the drug had never been deployed on a large scale until Chernobyl. The experience of Polish health authorities during the accident has provided confirmation that large scale deployment of KI is indeed safe. Further reassurance about the safety of KI comes from a U.S. study of potential adverse reactions to KI, which is an ingredient in many cough and cold medicines. This study showed 38 million equivalent doses without a single adverse reaction being reported. According to the World Health Organization, children are even less likely than adults to experience allergic reactions to KI.

The NRC therefore recommends that states make KI stockpiling one of their tools to prepare for the unlikely event of a major nuclear accident with offsite releases of radioactivity. While NRC strongly encourages the stockpiling of KI by the states, it does not mandate it under this rule change. The rule change requires only that states consider KI stockpiling in developing the "range of protective actions" mandated by the NRC's emergency planning rules.

The NRC has previously decided (on June 30, 1997) to support a change in federal policy by which supplies of KI will be made available, paid for by the Federal Government, to states that request it. The rule change proposed in this notice is consistent with that change in policy, and clarifies the effect of the policy change on the NRC's emergency planning rules.

The use of potassium iodide is intended to complement, not to replace, other protective measures. This rule change thus represents no alteration in the NRC's view that the primary and most desirable protective action in a radiological emergency is evacuation of the population before any exposure to radiation occurs, when that is feasible. (Evacuation protects the whole body, whereas potassium iodide protects only a single gland, the thyroid.) Depending on the circumstances, KI may offer additional protection if used in

conjunction with evacuation and/or sheltering.

The approach taken in this rule change is consistent with International Basic Safety Standards issued by the International Atomic Energy Agency, et al.; with the Federal Radiological Emergency Response Plan, issued by the Federal Emergency Management Agency in 1996; and with recommendations of the President's Commission on the Accident at Three Mile Island, the World Health Organization, and the American Thyroid Association, which represents physicians specializing in thyroid disease. Stockpiling of the drug is currently the practice in numerous European countries, as well as Japan, Canada, and three U.S. states: Alabama, Tennessee, and Maine.

In the event that a state, having considered the NRC's recommendation to stockpile KI, nevertheless decides not to include KI stockpiling in its emergency plan, it would still have access, in the event of a radiological emergency, to the various stockpiles of the drug that have been created by the Federal Government as part of readiness for acts of "NBC" (nuclear, biological, and chemical) terrorism. These stockpiles will be available on an ad hoc basis for radiological emergencies of all kinds. However, because experience shows that pre-planning is more effective than ad hoc responses to emergencies, and because pre-positioning of KI is likely to mean quicker access to supplies of the drug in an emergency, the NRC believes that it is reasonable and prudent to maintain stockpiles in the vicinity of nuclear reactors and to include provisions for their distribution in emergency plans.

The NRC recognizes that the decision to stockpile KI presents issues of how best to position and distribute the medicine, to ensure, e.g., that optimal distribution takes place in an emergency, with first priority given to protecting children; that persons with known allergies to iodine not take it; that members of the public understand that KI is not a substitute for measures that protect

the whole body; etc. To date, these issues have been addressed in different ways in the numerous countries that currently stockpile KI. The NRC intends to work with states and localities to develop guidance on these and other points relating to the use of KI. The NRC believes that these implementation issues are soluble, given the level of expertise in the relevant federal and state agencies.

It is expected that FEMA or the FRPCC will provide guidance to states to assist their consideration of the issue of KI stockpiling, and that it will offer technical assistance to help those states which decide in favor of stockpiling to incorporate it into their emergency plans. It is expected that states will inform FEMA and the NRC of the results of their consideration of whether or not to opt for stockpiling. This will enable the Federal Government to provide KI as expeditiously as possible to states which desire it, as well as to provide any further assistance that may be called for, and it will also allow the Government to engage in better contingency planning for states that decide against stockpiling KI.

Billing Code 6718-06-P

April 16, 1997

FEDERAL EMERGENCY MANAGEMENT AGENCY

DRAFT

Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent

AGENCY: Federal Emergency Management Agency.

ACTION: Issuance of Revised Federal Policy on Potassium Iodide for Thyroid Protection in Radiological Emergencies.

SUMMARY: The Federal Radiological Preparedness Coordinating Committee (FRPCC) is issuing this revised Federal policy concerning the purchase, stockpiling, and use of the drug potassium iodide (KI) as a prophylaxis to protect the thyroid gland in the unlikely event of a major radiological emergency at a commercial nuclear power plant. Taken in time, KI blocks the thyroid's uptake of airborne radioactive iodine, and thus could help prevent thyroid cancer and other reduce thyroid diseases especially in children caused by such exposure. It can therefore complement other protective actions, i.e., evacuation and in-place sheltering, used to protect the general public in a radiological emergency. Believing that KI stockpiling is a reasonable and prudent measure, the Federal Government will purchase supplies of KI for those states (or in some cases, local governments) that elect to make KI part of their emergency plans.

Current [The] Federal policy already provides that KI should be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies. In developing the range of [public] protective actions for the general public for severe accidents at commercial nuclear facilities, the available [best] technical information indicates that evacuation and in-place sheltering provide the best [adequate] protection for the general public, because they protect the whole body. However, the State (or in some cases, the local government) is ultimately responsible for the protection of its citizens. Therefore, the decision for local stockpiling and use of KI as a protective measure for the general public is left to the discretion of State (or, in some cases, local government.) KI provides additional protection for one radiation-sensitive organ, the thyroid, when used in conjunction with evacuation and/or sheltering.

ATTACHMENT 1

by the Federal Government.

It is recognized that the State (or in some cases, the local government), within the limits of its authority, can take measures beyond those recommended or required. The availability of KI as a protective measure for the general public supplements other options for public officials responsible for protective action decisions. A few States have indeed included KI as a protective action for the general public. The FRPCC does not want to usurp the State prerogative to incorporate the use of KI as a protective measure for the general public. Therefore, to ensure that States have the option to use KI if they so elect, the Federal government is prepared to provide funding for the purchase of a supply of KI. Any State (or in some cases, local government) which selects the use of KI as a protective measure for the general public may so notify FEMA, and may request funding for the purpose of purchasing a supply of KI.

In addition, the Federal government is also required to prepare for a wider range of radiological emergencies[1]. To that end, and as an added assurance for radiological emergencies in which the location and timing of an emergency are unpredictable and for which, unlike licensed nuclear power plants, there is little planning possible, a limited stockpile of KI is being established by the Federal government at a number of sites around the U.S. These ~~This~~ Federal stockpiles will be available to any State for any type of radiological emergency, at any time.

---

[1]In response to new threats, the Federal government broadened the scope of emergency response preparedness to include terrorism involving nuclear, biological, and chemical agents. As a result, and in support of State and local governments, new resources were identified to be needed in response to such events. About two dozen Metropolitan Medical Strike Teams (MMST) are being established for response to such events. Medical supplies, including KI, are being stockpiled nationally for the use by MMSTs in three locations: East coast, Central, and West coast. The quantity of supplies stockpiled uses a planning basis of 100,000 people for a period of two days.

The policy herein incorporates changes recommended by the FRPCC's Subcommittee on Potassium Iodide, and supersedes the 1985 Federal policy (50 FR 30258). The principal difference between this revised policy and the 1985 version are the addition of the offer of the Federal Government to purchase a supply of KI for States at a State's request, and the establishment of a Federal stockpile. The Federal Emergency Management Agency (FEMA) chairs the FRPCC, thereby assuming the responsibility for this publication.

For Further Information Contact: William F. McNutt, Senior Policy Advisor, Room 834, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-2857; facsimile (202 646-4183.

and the explicit recognition by the Federal Government, reflected in the offer to purchase KI, that this medicine can complement other protective measures and thereby enhance protection of the public

Background

This policy on use of KI as a thyroidal blocking agent is the result of a Federal interagency effort coordinated by FEMA for the FRPCC. On March 11, 1982, FEMA issued a final regulation in the Federal Register (47 FR 10758), which delineated agency roles and responsibilities for radiological incident emergency response planning (44 CFR 351). One of the responsibilities assigned to the Department of Health and Human Services (HHS) and in turn delegated to the Food and Drug Administration (FDA) was providing guidance to State and local governments on the use of radioprotective substances and prophylactic use of drugs (e.g., KI) to reduce radiation doses to specific organs including dosage and projected radiation exposures at which such drugs should be used.

In the June 29, 1982 Federal Register (47 FR 28158), FDA published recommendations for State and local agencies regarding the projected radiation dose to the thyroid gland at which State and local health officials should consider the use of KI. The Federal policy on stockpiling and distribution of KI was published in the July 24, 1985 Federal Register (50 FR 30258). On September 11, 1989, the American Thyroid Association requested FEMA, as Chair of the FRPCC, to reexamine the 1985 policy and to revisit the issue of stockpiling and distribution of KI for use by the general public. In response, the FRPCC established an Ad Hoc Subcommittee on Potassium Iodide. [On December 5, 1994, the FRPCC adopted the report and recommendations of the Ad Hoc Subcommittee on Potassium Iodide, which reaffirmed the Federal position as expressed in the 1985 policy.]

COMMENT: IT IS A STRANGE APPROACH TO HISTORY THAT FINDS THE FRPCC VOTE WORTH MENTIONING TO THE PUBLIC BUT NOT CHERNOBYL. THE FRPCC DETERMINATION WAS NOT PUBLISHED BECAUSE FEMA REALIZED THAT IT HAD BEEN BASED ON INCOMPLETE INFORMATION. THUS THIS SENTENCE MAY LEAD THE READER ASTRAY.

THE PHRASE "WITHOUT CHANGING ... FEDERAL POL. ?" CAN EASILY LEAD TO CONFUSION.

On April 3, 1996, in connection with a September 9, 1995 Petition for Rulemaking submitted to the Nuclear Regulatory Commission (NRC) on this issue, the FRPCC established a new Subcommittee on Potassium Iodide to review current information. The Subcommittee conducted a public meeting on June 27, 1996. Based on the information collected, the Subcommittee concluded that there was no new information that seriously challenges the bases for the 1985 recommendations concerning public use of KI for radiological emergencies at nuclear power plants. However, several recommendations were made to the FRPCC. The Subcommittee's three recommendations were: 1) without changing the Federal policy [that it is] by interceding in the State's prerogative to make its own decisions on whether or not to use KI, the Federal government (NRC, or through FEMA) should fund the purchase of a stockpile for any State that, hereinafter, decides to incorporate KI as protective measure for the general public; 2) The Subcommittee believes the language in the 1985 policy should be softened to be more flexible and balanced. For example, the problem many intervenors observe in the Federal policy is in the italicized statement "The Federal position with...potassium iodide for use by the general public is that it should not be required." It would not be as negative if the last phrase were reworded to state "it [potassium iodide for use by the general public] is not required, but may be selected as a protective measure at the option of the State or, in some cases, local governments." and 3) The subcommittee recommends that local jurisdictions who wish to incorporate KI as a protective action for the general public should consult with the State to determine if such arrangements are appropriate. If local governments have the authority or secure the approval to incorporate KI as a protective measure for the general public, they would need to include such a measure in their emergency plans.

NOTE: I RECOGNIZE THAT THIS IS WHAT THE SUBCOMMITTEE SAID. THE PROBLEM IS THAT THE KEY PHRASE IS "THE BASES FOR THE 1985 RECOMMENDATIONS" -- I.E., COST-BENEFIT THE PHRASE "NO NEW INFORMATION" IS EASILY TAKEN OUT OF CONTEXT. IT LAYS THE GOVERNMENT OPEN TO THE QUESTION, "SO NO NEW INFORMATION CAME OUT OF CHERNOBYL?"

The full FRPCC endorsed the subcommittee's recommendations with some modifications.

Policy on Distribution of KI Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent

The purpose of this document is to provide Federal policy and guidance with regard to distribution of KI, and its usage as a thyroid blocking agent, around operating nuclear power generating facilities. The issue has been addressed in terms of two components of the population that might require or desire KI use: (1) Emergency workers and institutionalized individuals close to the nuclear power plant site, and (2) the nearby general population. This guidance is for those State and local governments who, within the limits of their authority, need to consider these recommendations in the development of emergency plans and in determining appropriate actions to protect the general public.

Current already provides
~~The~~ Federal policy ~~is~~ that KI should be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies. In developing the range of ~~public~~ for the general public protective actions for severe accidents at commercial nuclear facilities, the ~~best~~ available technical information indicates that evacuation and in-place sheltering provide ~~adequate~~ the best protection for the general public, ~~However~~, the State (or in some cases, the local government) is ultimately responsible for the protection of its citizens. Therefore, the decision for local stockpiling and use of KI as a protective measure for the general public is left to the discretion of State (or, in some cases, local government.)

because they protect the whole body. KI provides additional protection for one radiation-sensitive organ, the thyroid, when used in conjunction with evacuation and/or sheltering.

It is recognized that the State (or in some cases, the local government), within the limits of its authority, can take measures beyond those recommended or required by the Federal ... The availability of KI as a protective measure for the general public supplements other options for public officials responsible for protective action decisions. A few States have indeed included KI as a protective action for the general public. The FRPCC does not want to usurp the State prerogative to incorporate the use of KI as a protective measure for the general public. Therefore, to ensure that States have the option to use KI if they so elect, the Federal government is prepared to provide funding for the purchase of a supply of KI. Any State (or in some cases, local government) which selects the use of KI as a protective measure for the general public may so notify FEMA, and may request funding for the purpose of purchasing a supply of KI.

In addition, the Federal government is also required to prepare for a wider range of radiological emergencies[2]. To that end, and as an added assurance, for radiological emergencies in which the location and timing of an emergency are unpredictable and for which, unlike licensed nuclear power plants, there is little planning possible, limited stockpiles of KI are being established by the Federal government at a number of sites around the U.S. These Federal stockpiles will be available to any State for any type of radiological emergency, at any time.

The bases for these recommendations are given below.

---

[2] In response to new threats, the Federal government broadened the scope of emergency response preparedness to include terrorism, involving nuclear, biological, and chemical agents. As a result, and in support of State and local governments, new resources were identified to be needed in response to such events. About two dozen Metropolitan Medical Strike Teams (MMST) are being established for response to such events. Medical supplies, including KI, are being stockpiled nationally for the use by MMSTs in three locations: East coast, Central, and West coast. The quantity of supplies stockpiled uses a planning basis of 100,000 people for a period of two days.

The NRC and FEMA issued guidance to State and local authorities as well as licensees of operating commercial nuclear power plants in NUREG-0654/FEMA-REP-1, Revision 1, in 1980. This guidance recommends the stockpiling and distribution of KI during emergencies to emergency workers and to institutionalized individuals. Thyroid blocking for emergency workers and institutionalized individuals was recommended because these individuals are more likely to be exposed to radioiodine in an airborne radioactive release than other members of the public. In addition, the number of emergency workers and institutionalized individuals potentially affected at any site is relatively small and requires a limited supply of KI that can be readily distributed.

For the general public, in the event of a radiological emergency at a commercial nuclear facility, evacuation and in-place sheltering are considered adequate and effective protective actions. It is well-recognized that the inclusion of KI as a protective measure, in addition to evacuation and sheltering, is beneficial only in very remote circumstances. The use of KI is not without controversy. On the one hand, KI has been shown to be an effective drug for protecting the thyroid from thyroid nodules, ~~or cancer~~ caicer, and hypothyroidism caused by the uptake of radioiodine, especially in children fifteen years of age or younger. On the other hand, there are logistical difficulties, and potential medical side effects associated with the drug, in distributing the drug to the general public in a radiological emergency. Also, KI effectively reduces the radiation exposure of only the thyroid gland from ingested or inhaled radioiodines. While this in an important contribution to the health and safety of the individual, it is not as effective as measures which protect the total body. Both in-place sheltering and precautionary evacuations can reduce the exposure to the thyroid and the total body. It is very important to remember that the use of KI is not an effective means

OMMENT: ZUE OF ALL E.P.

OMMENT: O RAISE HE SPECTRE OF SIDE FFECTS ITHOUT MENTIONING DA "SAFE EFFECTIVE" OR THE HERNOBYL DATA EAVES THE OUT. OPEN TO CHARGE OF EMPHASIZING THE NEGATIVES AND WITHHOLDING THE POSITIVES. THE FDA IS MENTIONED SEVERAL PARAGRAPHS LATER, TO BE SURE, BUT THIS PARAGRAPH, IF QUOTED BY ITSELF, CAN ONLY BE SEEN AS STRONGLY DISCOURAGING STOCKPILING.

by itself for protecting individuals from the radioactivity in an airborne release resulting from a nuclear power plant accident and, therefore, should only be considered in conjunction with sheltering, evacuation, or other protective methods. Therefore, while the use of KI can provide additional protection in certain circumstances, the assessment of the effectiveness of KI and other protective actions and their implementation indicates that the decision to use KI (and/or other protective actions) should be made by the States and, if appropriate, local authorities on a site-specific, accident-specific basis.

Those States or local governments which opt to include KI for the general population will be responsible for the maintenance, distribution, and any subsequent costs associated with this program.

The incorporation of a program for KI stockpiling, distribution and use by any State or local government into the emergency plans will not be subject to Federal evaluation. This is based on the recognition that the use of KI by the State for the general public is a supplemental protective measure, and on the Federal government's determination that the existing emergency planning and preparedness guidance for nuclear power plants is effective and adequate to protect the public health and safety.

← THIS CAN'T BE CORRECT; SEE DISCUSSION IN NOUS MEETING.

The FDA has evaluated the medical and radiological risks of administering KI for emergency conditions and has concluded that it is safe and effective and has approved over-the-counter sale of the drug for this purpose. FDA guidance states that risks from the short term use of relatively low doses of KI for thyroidal blocking in a radiological emergency are outweighed by the risks of radioiodine induced thyroid nodules or cancer at a projected

dose to the thyroid gland of 25 rem or greater. Since FDA has authorized the nonprescription sale of KI, it is also available to individuals who, based on their own personal analysis, choose to have the drug immediately available.

Attached is a list of ten references intended to assist State and local authorities in decisions related to the use of KI.

Conclusion

The FRPCC did not find any new information that would require a change in the basis of the existing Federal policy concerning the stockpile or pre-distribution of KI for the general public in the event of a radiological emergency at a commercial nuclear plant. The policy is that KI should be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies, but leaves the decision for the stockpiling, distribution, and use of KI for the general public to the discretion of State, and in some cases, local governments. Any State or local government that selects the use of KI as a protective measure for the general public may so notify FEMA and may request funding for the purpose of purchasing an adequate supply.

The incorporation of a program for KI stockpiling, distribution and use by any State or local government into the emergency plans will not be subject to Federal evaluation. This is based on the recognition that the use of KI by the State for the general public is a supplemental protective measure, and on the Federal government's determination that the

AGAIN, STRONG POTENTIAL FOR CRITICS TO ASK IF THE FEDERAL GOVT. IS UNAWARE OF THE NEW DATA FROM CHERNOBYL, WHICH IS NOT MENTIONED IN THIS NOTICE

OLD

LETE

ENGLISH

← SEE COMMENT ABOVE

existing emergency planning and preparedness guidance for nuclear power plants is effective and adequate to protect the public health and safety.]

Those States or local governments which opt to include KI for the general population will be responsible for the maintenance, distribution, and any subsequent costs or legal liabilities associated with this program.

As an added assurance, for a broader range of radiological emergencies in which the location and timing of an emergency are unpredictable and for which, unlike licensed nuclear power plants, there is little planning possible, a stockpile of KI will be established by the Federal government. Such a stockpile would consist of individual KI caches at VA hospitals in major metropolitan centers across the country. This supply would be available to any State or local government for any type of radiological emergency.

References

1. National Council on Radiation Protection and Measures (NCRP), "Protection of the Thyroid Gland in the Event of Releases of Radioiodine," NCRP Report No. 55, August 1, 1977.

2. Food and Drug Administration (HHS), Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency, 43 FR 58798, December 15, 1978.

3. Halperin, J. A., B. Shleien, S. E. Kahans, and J. M. Bilstad; "Background Material for the Development of the Food and Drug Administration's Recommendations on Thyroid Blocking with Potassium Iodide," FDA 81-8158, U.S. Department of Health and Human Services (March 1981).

4. Food and Drug Administration; Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Final Recommendations on Use (Notice of Availability) 47 FR 28158, June 29, 1982).

5. Food and Drug Administration; Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Recommendations on Use. (April 1992). Prepared by the Bureau of Radiological Health and Bureau of Drugs, Food and Drug Administration, Department of Health and Human Services.

6. Nuclear Regulatory Commission; Examination of the Use of Potassium Iodide (KI) as an Emergency Protective Measure for Nuclear Reactor Accidents (NUREG/CR-1433, March 1990). Prepared by Sandia National Laboratories for the NRC.

7. Nuclear Regulatory Commission; An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident (NUREG/CR-6310, February 1995). Prepared by S. Cohen and Associates, Inc. and Scientech, Inc. for the NRC.

BY NOW, THIS SHOULD BE REGARDED AS DISCREDITED. AT THE VERY LEAST, IT HAS BEEN SUPERSEDED BY THE REANALYSIS IN NUREG/CR-6310 (ITEM 7).

8. Nuclear Regulatory Commission; Re-Evaluation of Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant (SECY-93-318, November 23, 1993).

9. Nuclear Regulatory Commission; Addendum to SECY-93-318, Re-Evaluation of Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant (SECY-94-087, March 29, 1994).

Signed:

O. Megs Hepler, III
Chair
Federal Radiological Preparedness Coordinating Committee

I WOULD SUGGEST ADDING THE FOLLOWING REFERENCES

-- EPA-400-R-92-001, MANUAL OF PROTECTIVE ACTION GUIDES AND PROTECTIVE ACTIONS FOR NUCLEAR INCIDENTS (MAY, 1992)

-- WHO GUIDANCE (QUOTED IN NUREG ICR 6310, BUT DESERVES SEPARATE LISTING).

-- INTERNATIONAL BASIC SAFETY STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION AND FOR THE SAFETY OF RADIATION SOURCES (INTERIM EDITION), IAEA (VIENNA, 1994).

-- NAUMAN, J., and WOLFF, J., "IODIDE PROPHYLAXIS IN POLAND AFTER THE CHERNOBYL REACTOR ACCIDENT: BENEFITS AND RISKS," AMERICAN JOURNAL OF MEDICINE, VOL. 94, p. 524 (MAY, 1993).

-- REPORT OF THE PRESIDENT'S COMMISSION ON THE ACCIDENT AT THREE MILE ISLAND (1979)

-- HALPERIN, J., "POTASSIUM IODIDE AS A THYROID BLOCKER -- THREE MILE ISLAND TO TODAY," DICP, THE ANNALS OF PHARMACOTHERAPY, VOL 23 (MAY 1989).

November 12, 1997

Mr. John C. Hoyle, Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Amendment to Petition for rulemaking (PRM-50-63)

Dear Mr. Hoyle:

On rereading my filing of earlier today (dated November 11), I find a minor editing error (two references instead of one to the Commission's SRM of June 30, 1997) in the third paragraph of the third page. Would you be so kind as to replace the third page with the attached correction? Otherwise the document is unchanged.

Thank you.

Sincerely,

Peter Crane

Peter G. Crane

Attachment: corrected page 3

IN RESPONSE, PLEASE
REFER TO M971105A

November 25, 1997

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: John C. Hoyle /s/

SUBJECT: BRIEFING ON PROPOSED RESOLUTION TO A PETITION FOR RULEMAKING RELATING TO USE OF POTASSIUM IODIDE (KI) FOLLOWING SEVERE ACCIDENT AT A NUCLEAR POWER PLANT, 9:35 A.M. WEDNESDAY, NOVEMBER 5, 1997, COMMISSIONERS CONFERENCE ROOM, ROCKVILLE, MARYLAND (OPEN TO PUBLIC ATTENDANCE)

The Commission was briefed by representatives of the Federal Emergency Management Agency; by Mr. Peter Crane, author of a petition for rulemaking (PRM-50-63) on the use of potassium iodide (KI); and by the NRC staff regarding issues associated with a proposed change to the Federal policy on the use of KI as a protective measure for the general public following severe accidents.

The Commission indicated that it would temporarily defer action with respect to resolution of PRM 50-63 (SECY 97-245) and the draft Federal Register Notice on Federal KI Policy (COMSECY-97-028 pending submission by the petitioner of a revision to his petition reflecting the petitioner's comments at the meeting and the staff's subsequent evaluation of the impact of the revised petition on its recommendations as reflected in SECY 97-245.

(EDO) (SECY Suspense: 12/12/97)

cc: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
OGC
CIO
CFO
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (by E-Mail)
PDR
DCS

Action: Collins, NRR/Martin, AE

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

OFFICE OF THE SECRETARY

Cys: Callan
Thompson
Thadani
Norry
Blaha
Bangart, SP
Knapp, NMSS
Morris, RES
Meyer, ADM
Shelton, CIO
Jamgochian, NI
Congel, AEOD
Trottier, RES

June 26, 1998

WITS 9700193

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: John C. Hoyle, Secretary

SUBJECT: STAFF REQUIREMENTS - SECY-97-245 and SECY-98-061 - STAFF OPTIONS FOR RESOLVING A PETITION FOR RULEMAKING (PRM-50-63 AND 50-63A) RELATING TO A RE-EVALUATION OF THE POLICY REGARDING THE USE OF POTASSIUM IODIDE (KI) BY THE GENERAL PUBLIC AFTER A SEVERE ACCIDENT AT A NUCLEAR POWER PLANT
and
COMSECY-97-028 - FEDERAL REGISTER NOTICE ON POTASSIUM IODIDE

The Commission has disapproved the staff's recommendation to deny the petition for rulemaking and approved Option 1. As such, the staff should proceed with rulemaking to change 10 CFR 50.47(b)(10) by inserting the following sentence, or similar words, after the first sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and, as a supplement to these, the prophylactic use of potassium iodide (KI), as appropriate." In addition, the Federal Register notice and the statements of considerations for the proposed and final rules should be modified to include a statement to the effect that State and local decision makers, provided with proper information, may find that the use of KI as a protective supplement is reasonable and prudent for specific local conditions. The Federal Register notice should be reviewed by the Commission before the notice is given to the other relevant agencies for their review. The Commission notes that, consistent with the Commission's decision on the June 30,1997, SRM, the Federal government (most likely NRC) is prepared to fund the purchase of a stockpile of KI for the States upon request. The NRC staff should work with other relevant agencies to ensure that there are established procedures to enable the national stockpile to be effectively and timely used by states that have not established local stockpiles and wish to make use of the national stockpiles in the event of a severe nuclear power plant accident.

To assist the State and local decision makers, the staff should submit its paper, "Assessment of

SECY NOTE: This SRM, SECY 98-061, SECY 97-245, COMSECY-97-028, and the Commission Voting Record for SECY 98-061 containing the vote sheets of all Commissioners will be made publicly available 5 working days from the date of this SRM.

ENCL 2

the Use of Potassium Iodide (KI) as a Public Protective Action During Severe Reactor Accidents," for public comment. Staff is encouraged to submit the assessment in whole, or in part, to peer reviewed journals for publication.

Following receipt and evaluation of the public comments, the staff should revise the paper, as appropriate, subject to Commission review. Using this as a basis, the staff should complete and issue a user-friendly information brochure containing the essential data and analyses in the technical assessment attached to SECY 98-61 to assist State and local planners in reaching an informed decision as to whether KI is an appropriate protective supplement.

~~(EDO)~~ (SECY Suspense:	Draft Federal Register Notice	~~7/15/98~~	7/8/98	9700193
(NRR/AEOD)	Notice of proposed rulemaking	10/29/98	10/22/98	"
	Issuance of final assessment report	10/29/98	10/22/98	"
	Issuance of brochure	no later than final rule)		"

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

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN: 3150-AG11

Consideration of Potassium Iodide in

Emergency Plans

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing an amendment to its emergency planning regulations governing the domestic licensing of production and utilization facilities. The proposed rule would amend the current regulations to indicate that consideration shall be given to including potassium iodide (KI), along with sheltering and evacuation, as a supplemental protective measure for the general public. The proposed rule responds to petitions for rulemaking submitted by Mr. Peter G. Crane concerning the use of KI in emergency plans.

EFFECTIVE DATES: The comment period expires 90 days after publication in the Federal Register. Comments received after this date will be considered if practical to do so, but only those comments received on or before this date can be assured of consideration.

ENCLOSURE 3

ADDRESSES: Comments may be sent to the Secretary of the Commission, Attention: Rulemaking and Adjudications Staff, U.S. Nuclear Regulatory Commission, Washington, DC 20555, or may be hand-delivered to One White Flint North, 11555 Rockville Pike, Rockville, MD 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays. Copies of comments received may be examined at the Commission's Public Document Room at 2120 L Street NW (Lower Level), Washington, DC.

You may also provide comment via the NRC's interactive rulemaking web site on the NRC home page (http://www.nrc.gov). This site provides the availability to upload comments as files in any format that the NRC web browser supports. For information about the interactive rulemaking site, contact Ms. Carol Gallagher, (301) 415-6215; e-mail CAG@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Michael T. Jamgochian, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Telephone: (301) 415-3224. Internet: MTJ1@NRC.GOV.

SUPPLEMENTARY INFORMATION:

By undertaking this rulemaking, the Commission is proposing to grant two petitions for rulemaking (PRM-50-63 and 50-63A) from Mr. Peter Crane submitted on September 9, 1995, and November 11, 1997.

Considering all public comments received, the information available in the literature, 20 years of experience gained in evaluating licensee emergency preparedness plans, and the arguments presented by the petitioner, the Commission has decided to grant the petition for rulemaking and to proceed with rulemaking to amend 10 CFR 50.47(b)(10) by inserting the following sentence, after the first sentence: "In developing this range of actions, consideration

has been given to evacuation, sheltering, and, as a supplement to these, the prophylactic use of potassium iodide (KI), as appropriate." In addition, the preamble for this proposed rule includes a statement to the effect that State and local decision makers, provided with proper information, may find that the use of KI as a protective supplement is reasonable and prudent for specific local conditions. The Commission also noted that, consistent with the Commission's decision on June 30, 1997, the Federal government (most likely the NRC) is prepared to fund the purchase of a stockpile of KI for the States, upon request. The NRC staff will work to ensure that the process for States to obtain funding for KI is established. The NRC staff will also work with other relevant agencies to ensure that there are established procedures to enable the national stockpile of KI, for terrorist activities, to be effectively and timely used by states that have not established local stockpiles and wish to make use of the national stockpiles in the event of a severe nuclear power plant accident.

On November 27, 1995 (60 FR 58256), the Nuclear Regulatory Commission (NRC) published a Notice of Receipt of a petition for rulemaking (PRM-50-63) filed by Mr. Peter G. Crane on his own behalf. The petitioner requested that the NRC amend its regulations concerning emergency planning to include a requirement that emergency planning protective actions include the prophylactic use of potassium iodide (KI), which the petitioner notes prevents thyroid cancer after nuclear accidents.

On November 11, 1997, the petitioner submitted a revision to his original petition (PRM-50-63A). The NRC published a Notice of Receipt of the amended petition on December 17, 1997 (62 FR 66038). In the amended petition, the petitioner requested that:

> A statement [be made] clearly recommending stockpiling of KI as a "reasonable and prudent' measure, and;
>
> A proposed rule change to 10 CFR 50.47(b)(10) which would be accomplished by inserting the following sentence after the

first sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate."

The petitioner also provided a marked-up version of the proposed Federal Radiological Preparedness Coordinating Committee (FRPCC) Federal Register notice concerning Federal policy relating to the use of KI for the general public.

On June 26, 1998 (SRM 98-061), the Commission decided to grant the petition for rulemaking PRM-50-63A by directing the requested amendment to 10 CFR 50.47(b)(10). The Commission also directed that the preamble for the proposed rule include a statement to the effect that State and local decision makers, provided with proper information, may find that the use of KI as a protective supplement is reasonable and prudent for specific local conditions.

Petitioner's Basis for Requesting Potassium Iodide

The petitioner stated that potassium iodide (KI) protects the thyroid gland, which is highly sensitive to radiation from the radioactive iodine that would be released in extremely serious nuclear accidents. By saturating the gland with iodine in a harmless form, KI prevents any inhaled or ingested radioactive iodine from lodging in the thyroid gland, where it could lead to thyroid cancer or other illnesses. The petitioner stated that the drug itself has a long shelf-life, at least 5 years, and causes negligible side effects.

The petitioner further stated that, in addition to preventing deaths from thyroid cancer, KI prevents radiation-caused illnesses. The petitioner notes that thyroid cancer generally means surgery, radiation treatment, and a lifetime of medication and monitoring. The petitioner asserted that the changes in medication that go with periodic scans put many patients on a physiological and psychological roller coaster. The petitioner stated that hypothyroidism can

cause permanent retardation in children and, if undiagnosed, can condemn adults to a lifetime of fatigue, weakness, and chills.

The Petitioner's Discussion of the Three Mile Island Accident (TMI)

The petitioner noted that in December 1978, the Food and Drug Administration (FDA) announced that it had determined that KI was safe and effective for thyroid protection in nuclear accidents. The petitioner stated that the issue attracted little attention, that the NRC and the Federal Government as a whole took no public position on the drug, and that three months after the FDA announcement, on March 28, 1979, the TMI accident began to unfold. The petitioner stated that Federal and State officials, searching for supplies of KI in case it should be needed, discovered that none was to be had and that a supply had to be manufactured, literally overnight. The petitioner indicated that at 3:00 a.m. on Saturday, March 31, 1979, an FDA official arranged with the Mallinckrodt Chemical Company for the immediate production of 250,000 doses of KI.

The petitioner also discussed the Report of the President's Commission on the Accident at Three Mile Island (the Kemeny Commission report), issued in October 1979, and stated that the report was strongly critical of the failure to stockpile KI. The petitioner noted that among the Kemeny Commission's major recommendations was that an adequate supply of the radiation protective agent, KI for human use, should be available regionally for distribution to the general population and workers affected by a radiological emergency.

The Petitioner's Discussion of the Potassium Iodide Policy

The petitioner stated that in NUREG-0632, "NRC Views and Analysis of the Recommendations of the President's Commission on the Accident at TMI," issued in November 1979, the NRC agreed with the findings of the Kemeny Commission and planned to require nuclear power plant licensees to have adequate supplies of KI available for nuclear power plant workers and the general public as part of State emergency response plans.

According to the petitioner, the three agencies most concerned, the FDA, the NRC, and the Federal Emergency Management Agency (FEMA), favored the stockpiling of KI for the next several years. The petitioner stated that the Atomic Industrial Forum, a nuclear industry trade association, declared itself against the stockpiling of KI in May 1982.

The petitioner indicated that the NRC staff was strongly in favor of KI stockpiling as late as September 27, 1982, when the NRC staff submitted a memorandum to the Commissioners proposing that the Commission agree with a draft interagency policy statement supporting KI stockpiling. The petitioner further stated that on October 15, 1982, less than 3 weeks after sending the draft policy statement to the Commission for approval, the NRC staff sent a supplementary memorandum withdrawing the memorandum of September 27. The later memorandum informed the Commissioners that NRC's Office of Nuclear Regulatory Research (RES) could, by January 1, 1983, produce a paper showing that KI was significantly less cost - beneficial than previously assumed. The NRC staff proposed sending this document to the FDA and FEMA with the recommendation not to stockpile and distribute KI. The petitioner indicated that the NRC staff briefed the Commission in November 1983 on the NRC staff's proposal to take a strong position against KI. A policy statement was later issued that disposed of the Kemeny Commission's recommendation in favor of stockpiling KI. According to the

petitioner, only a year later, the Chernobyl accident would give tangible proof of the value of the drug in radiological emergencies.

The Petitioner's Discussion of the Effects of Chernobyl

The petitioner stated that during the Chernobyl accident of 1986, the damaged reactor spewed radioactive iodine over a wide area of what was then the Soviet Union and Poland. The petitioner further stated that in Russia, the Ukraine, and Belarus, where the distribution of KI was inadequate and untimely, the population in these countries is now experiencing extraordinarily high levels of childhood thyroid cancer. However, in Poland, where KI was administered to 97 percent of the nation's children, there has been no similar increase in thyroid cancer. The petitioner noted that Poland is a proof-positive example of the benefits of a well-prepared KI program.

The petitioner stated that the U.S. Government is spending money to study radiation-caused thyroid cancer in the Ukraine and Belarus, and the Department of Energy (DOE) announced a $15 million, 15-year program that will follow 70,000 children in the Ukraine, to understand the thyroid cancer risk of exposure to radioiodine. The petitioner further stated that the U.S. Government has spent generously to bring Ukrainian doctors to the United States for training in thyroid surgery because mishandled operations can result in damaged nerves and larynxes, rendering patients permanently mute.

The petitioner discussed post-Chernobyl developments on KI policy. He stated that the Chernobyl accident demonstrated that KI worked and that countries that failed to stockpile and distribute it are experiencing serious public health problems.

The Petitioner's Discussion of the NRC's Reconsideration of Potassium Iodide

The petitioner notes that in June 1989, the NRC reconsidered the KI issue after the petitioner filed a differing professional opinion urging a change in policy. On November 27, 1989, the American Thyroid Association wrote to the NRC urging KI stockpiling on a nationwide basis and, in 1990, the NRC announced that it was reconsidering the existing Federal policy. In April 1992, a contractor under the sponsorship of the NRC Office of Nuclear Regulatory Research issued a report that included a revised cost-benefit analysis of the use of KI. The petitioner described the report as concluding that stockpiling KI continued to be not cost-effective, but that the difference between costs and benefits was narrower than had been calculated by the NRC staff in the early 1980s. The petitioner further indicated that, in December 1993, an industry trade group, the Nuclear Utility Management and Resources Council, sent a report entitled "Review of Federal Policy on Use of Potassium Iodide," to the Commission arguing against any change in current KI policy.

The petitioner noted that, in March 1994, the NRC staff declared its support for KI stockpiling. However, the NRC staff proposal for a change in policy was not adopted, the Commissioners having voted 2 to 2 on the staff's proposal in May 1994. (Under Commission procedures, a tie vote means that a proposal fails.)

The Petitioner's Discussion of Additional Support for Granting the Petition for Rulemaking

The petitioner described a September 1994, FEMA publication proposing a "Federal Radiological Emergency Response Plan" that envisioned the use of KI during radiological emergencies. Under the plan, the NRC would be the lead Federal agency during emergencies at nuclear power plants and would advise State and local governments whether or not to

distribute KI (based on advice received from an interagency panel). The States and localities would then administer the KI, if necessary.

The petitioner also indicated that the Board of Governors of the International Atomic Energy Agency, with U.S. Government support, adopted new International Basic Safety Standards in 1994. The petitioner stated that these standards represented the consensus of the world's experts on radiation safety and the standards provide, among other things, that intervention levels of immediate protective actions, including sheltering, evacuation, and iodine prophylaxis, shall be specified in emergency plans. Thus, the petitioner stated, the international radiation protection community, like the Kemeny Commission in 1979 and the short-lived draft Federal policy statement of 1982, recognized that effective preparedness for radiological emergencies means having three actions to consider [evacuation, sheltering and iodine prophylaxis].

The Petitioner's Discussion of the Merits of the Petition for Rulemaking

The petitioner believes the NRC should implement the recommendation of the Kemeny Commission and that the United States should maintain the option of using the drug KI for public thyroid protection during nuclear accidents. The petitioner requested that the Commission definitively review and decide on the issue rather than simply having the NRC staff decide not to propose it to the Commission.

The petitioner stated that evacuation is not necessarily the protective measure of choice in every emergency, and even when it is the preferred option, it is not always feasible. The Kemeny Commission report explained that different types of accidents, and the particular circumstances presented, may call for different protective measures. The petitioner notes that

maintaining a KI option ensures that responsible authorities have the option of additional protection at their disposal.

The petitioner indicated that NRC has made it clear that a finding of adequate emergency planning does not translate into a guarantee that the entire affected public can be evacuated, but that evacuation is generally feasible.

The petitioner believes that sometimes, either by choice or necessity, authorities may decide to shelter people or tell them to remain indoors rather than evacuate them. The petitioner points out that it may be desirable to administer KI any time people are sheltered or told to stay indoors, when evacuation routes would take people through areas of radiological contamination, and when there has been a large airborne release of radioactive iodine to the atmosphere.

The petitioner believes that the decision on stockpiling KI should turn on whether, given the enormous consequences of being without it in a major accident, the drug is a prudent measure; not on whether it will necessarily pay for itself over time. The petitioner further believes that KI represents a kind of catastrophic-coverage insurance policy offering protection for events which, while they occur only rarely, have such enormous consequences that it is sensible to take special precautions.

The petitioner stated that the estimates of KI's cost-effectiveness depend on estimates that are no more than informed guesses about the probability of severe accidents and that the NRC's cost-benefit analysis of the early 1980s was based on the assumption that a severe accident with a major release of radioactivity could occur in this country only once every 1 or 2 thousand years.

The petitioner believes that if it were really true that serious accidents with a release of radioactivity were so unlikely, there would be good reason not only to reject stockpiling of KI but also to dispense with all emergency planning. The petitioner also stated that if KI is not

cost-effective, then the rest of nuclear emergency planning is probably not cost-effective either.

The petitioner believes that cost-benefit analysis is a technique that should be applied with good sense, especially where public health measures are concerned. According to the petitioner, the cost-benefit analysis of KI proceeded from the assumption that there was no difference in desirability between prevention of radiation-caused thyroid disease and cure. Thus, the only factor to be considered in evaluating KI was the cost. The petitioner also believes that the U.S. Government determined that instead of spending money to prevent radiation-caused thyroid disease, society should spend its money treating the disease if and when it occurs.

The petitioner believes that the existing policy on KI was defective from the start because it was based, in part, on inaccurate information provided to the NRC Commissioners. He stated that the information provided to the NRC Commissioners seriously understated the significance of radiation-caused thyroid disease and thereby understated to an equal degree the value of KI.

The petitioner also believes that it was not clear that the Commission had any idea of the real nature of post-accident thyroid disease at the time it adopted an anti-KI position.

The petitioner stated that existing policy left the judgment on stockpiling KI to the States. The petitioner asserts that this policy also ensures that the States do not have an adequate basis for making informed decisions. He believes that the Federal Government, and NRC in particular, has failed to provide the States with sound technical advice on the subject. The petitioner also believes that without accurate and current information on KI--including the Chernobyl experience and the consensus of international experts--States cannot make an informed judgment.

The petitioner believes that no State or local official or member of the public could imagine that in a real emergency, there would be no KI to administer. The petitioner raised the

question: If KI stockpiling is not worthwhile, why is the administration of the drug one of the protective measures identified in the 1994 Federal Emergency Response Plan? He also asked why, if KI is worthwhile, as the plan implies, something is not being done to make sure that it is available.

The petitioner believes that the Federal Government should either change the 1985 policy and make the use of KI a viable option in a real emergency, or it should explain why the United States has decided that KI will not be an option.

The Petitioner's Proposed Amendment to the NRC Regulations

In the original petition (PRM-50-63) that was submitted on September 9, 1995, the petitioner requested that 10 CFR Part 50 be amended to include language taken from FEMA's Federal Radiological Emergency Response Plan of September 1994, and recommended the following revision to the regulations.

The petitioner proposed that Section 50.47(b)(10) be amended to read as follows:

> (10) A range of protective actions <u>including sheltering, evacuation and prophylactic use of iodine</u> have been developed for the plume exposure pathway EPZ [emergency planning zone] for emergency workers and the public. Guidelines for the choice of protective actions during an

emergency, consistent with Federal guidelines, are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed.

In the revised petition (PRM-50-63A) that was submitted on November 11, 1997, the petitioner requested that 10 CFR 50.47(b) be revised to read:

> (10) A range of protective action have been developed for the plume exposure EPZ for emergency workers and the public. In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate. Guidelines for the choice of protective actions during an emergency, consistent with Federal guidelines, are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed.

The petitioner believes that if this revised change is adopted, the plan will become an accurate description of emergency preparedness for radiological emergencies; the recommendation of the Kemeny Commission will at last be implemented; and the United States will be in compliance with the International Basic Safety Standards.

The petitioner suggested that the NRC, either on its own or jointly with other agencies, issue a policy statement declaring that KI stockpiling is a reasonable and prudent measure that is necessary to ensure that the drug will be available in the event of a major accident. The

petitioner believes that this statement would clarify that KI can be used in conjunction with evacuation and sheltering to maximize protection to the public.

The petitioner also believes that the policy statement would show the willingness of the NRC to provide a stockpile of the drug to States and localities upon request, and would support the Kemeny Commission's recommendation to create regional stockpiles of the drug as a backup for emergencies.

Discussion

Stockpile of Medicinal Supplies for Nuclear, Biological, and Chemical Agents (1995)

In June 1995, the President issued Presidential Decision Directive 39 (PDD-39) on U.S. Policy on Counter Terrorism. The PDD-39 directed Federal agencies to take a number of measures to reduce vulnerability to terrorism, to deter and respond to such acts, and to strengthen capabilities to prevent and manage the consequences of terrorist use of nuclear, biological, and chemical (NBC) weapons, including weapons of mass destruction. The PDD-39 assigned to FEMA the task of ensuring that the Federal Response Plan (FRP) was adequate to respond to the consequences of terrorism.

FEMA, in coordination with the Catastrophic Disaster Response Group (CDRG)[1], developed a draft report to the President entitled, "An Assessment of Federal Consequence Management Capabilities for Response to Nuclear, Biological or Chemical (NBC) Terrorism," dated June 12, 1996. The report recommended, among other things, that the Federal Government purchase and stockpile thyroid blocking agents (KI) for the general public that

[1]The CDRG is the headquarters senior-level coordinating group which addressees policy issues regarding the Federal Response Plan (FRP). The CDRG is chaired by FEMA and comprises representatives of Federal departments and agencies with responsibilities under the FRP. The NRC is represented by the Incident Response Division Director, AEOD.

could be used in the event of a nuclear terrorist event. The NRC was a member of the Core Group which generated the recommendations and was instrumental in adding KI to the list of medical supplies to be stockpiled nationally.

The Core Group concluded that as the result of recent events, significant threats over the past few years, and the increased availability and proliferation of NBC materials, there is an increasing concern for the potential of terrorist incidents. NBC events, the report continued, may occur as a local event with potentially profound national implications. In responding to these events, the first responders must be able to provide critical resources to the victims. These include, but are not limited to, chemical nerve antidotes, vaccines for anthrax, and antibiotics. The Core Group identified the need to purchase and preposition stockpiles of adequate medical supplies at the Federal, State, and local level. While KI was not considered as vital as chemical nerve antidotes and vaccines, the NRC staff was successful in getting KI included with other medical supplies for NBC events because of the unusual characteristics of these events.

Because of the special characteristics of NBC events, the Core Group recommended a broader range of protective actions. The NRC concurred in the findings of the report in a letter dated September 25, 1996, from the Director of NRC's Office of Analysis and Evaluation of Operational Data to FEMA's Director. The report was subsequently presented to the President in February 1997, and approved for distribution in May 1997.

FRPCC Subcommittee on KI (1996).

Along with petitioning the NRC, Mr. Crane also requested that FEMA review his petition and reconsider the Federal policy. In early 1996, the FRPCC convened an Ad-Hoc Subcommittee on Potassium Iodide to request and review new information on this matter from

interested parties. The subcommittee conducted a public meeting on June 27, 1996. The subcommittee evaluated all comments from the June 27 public meeting and made the following recommendation regarding the Federal KI policy:

1. Without changing the Federal policy by interceding in the State's prerogative to make its own decisions on whether to use KI, the Federal Government (NRC, or through FEMA) should fund the purchase of a stockpile for a State that decides to incorporate KI as a protective measure for the general public;

2. The Subcommittee believes the language in the 1985 policy should be softened to be more flexible and balanced. For example, the problem many intervenors observe with the Federal policy is the italicized statement "The Federal position with...potassium iodide for use by the general public is that it should not be required." It would not be as negative if the last phrase were reworded to state "it [potassium iodide for use by the general public] is not required, but may be selected as a protective measure at the option of the State or, in some cases, local governments."

3. The subcommittee recommends that local jurisdictions that wish to incorporate KI as a protective action for the

general public should consult with the State to determine if these arrangements are appropriate. If local governments have the authority or secure the approval to incorporate KI as a protective measure for the general public, they would need to include this measure in their emergency plans.

Analysis of Issues Raised by Public Comments

On November 27, 1995 (60 FR 58256), a Notice of Receipt of the Petition for Rulemaking was published in the Federal Register requesting public comment. A total of 63 comment letters were received, of which 20 utilities, 9 State governmental agencies, 2 utility interest organizations, 1 letter signed by 12 health physicists, 2 State universities and 1 member of the public were against the granting of the petition for rulemaking. Those letters in favor of granting the petition came from 5 environmental groups, 22 members of the public (including 1 from the petitioner), and the American Thyroid Association.

On December 17, 1997 (62 FR 66038), the Commission published a request for public comment on the revised petition in the Federal Register. In response to several requests, the comment period was extended until February 17, 1998, by a Federal Register notice published on January 21, 1998 (63 FR 3052). A total of 82 comment letters were received, of which 13 utilities, 3 State governmental agencies, 1 utility interest association, and 1 member of the public were against granting the petition for rulemaking. The letters in favor of granting the petition came from 8 public interest groups, 46 members of the public (including 1 from the petitioner), 3 physicians, 2 U.S. Senators, and 1 State Representative. The following issues were raised by the public commenters with an accompanying Commission response:

Issue 1

Nearly all nations with nuclear power protect their citizens by having KI readily available and the logistics of distribution do not seem to pose any significant problems. Would implementing a policy of using KI for the general public be so difficult?

Commission Response

At the November 5, 1997, Commission meeting, senior NRC staff members told the Commission: "We recognize that there are difficulties in distribution, but they are not insurmountable. If a decision is made by the State to do it [stockpile and/or predistribute KI] we can figure out a way to do it." It is the Commission's perception that if the State decides to include KI as a supplemental protective measure for the general public, one possible method of implementation could be that the State could make KI readily available where other over-the-counter drugs can be purchased. The public could be informed of the drug's availability through the yearly emergency preparedness information brochure that is mailed out to all residents throughout the 10 mile EPZ. It would then be up to individual members of the public to obtain and store this supply of KI, which should then be available for use in the event of an emergency. The administration of the KI could be at the direction of the State Medical Officer.

Issue 2

It is "factual that the 1986 Chernobyl accident clearly demonstrated the benefit of having KI readily available. In Poland, where authorities expediently administered 18 million

doses of KI, 97 percent of all Polish children were protected from thyroid disease. In contrast, there are soaring rates of childhood thyroid cancer, 200 times pre-Chernobyl levels, in the former Soviet republics of Russia, Belarus, and the Ukraine because very little KI was administered, too long after exposure."

Commission Response

The Chernobyl reactor (a RBMK-1000 design) is located in the Ukraine close to Belarus. The accident occurred at 01:23 on Saturday, 26 April 1986, when explosions destroyed the reactor core and reactor building. The explosions sent debris from the core flying into the air and exposed the reactor core to the atmosphere. The heavier debris from the plume was deposited close to the site. In general, the initial release is thought to have risen to over 1 km in altitude, thereby resulting in much lower doses close to the site than those expected from a ground level release. The major release lasted 10 days, during which most of the noble gases and more than 40 percent of the iodines are estimated to have been released. The varying meteorological conditions, release rates, and release heights resulted in very complex dose and ground deposition patterns.

It is often assumed that ingestion was the major source of thyroid dose early in the accident. However, the contribution of inhalation cannot be assessed because air sampling was not effectively conducted early in the accident. As of 1996, except for thyroid cancer, there has been no confirmed increase in the rates of other cancers,

including leukemia, among the first responders, liquidators,[2] or the public, that have been attributed to release from the accident.

Belarus Experience. With the Chernobyl plant located only 4 miles (7 km) away, Belarus was heavily impacted by the accident. This impact was heightened by the fact that protective actions were not implemented in Belarus during the first six days after the accident. Several authors have stated that KI was distributed to the population in Belarus during the first week following the accident.[3] However, there is no confirmed published data on the dosage, coverage, or other details concerning the implementation of the thyroid blocking in Belarus.[4] In addition, cows typically grazed in Belarus at the time of year when the accident occurred, and yet no efforts were taken to restrict the consumption of contaminated milk for the first 10 days following the accident.

On May 2 (day 7 following the accident) the decision was made to evacuate the areas of Belarus and Ukraine within 18 miles (30 km) of the plant (30 km zone). The evacuation was completed on May 5, 1986.

Since 1990, a rapid increase has been observed in the incidence in thyroid cancer among Belarus children who were 0 to 14 years old at the time of the accident. Before the accident, the rate of thyroid cancer among this cohort was about 0.4 per 100,000; by 1996, this

---

[2]Liquidators are a large number (about 200,000) of workers and military personnel who performed cleanup, construction of the sarcophagus, and other operations in the contaminated zones following the accident.

[3]Personal communication, E. Buglova M.D., Head Laboratory of Radiation Hygiene and Risk Analysis, Ministry of Health, Republic of Belarus, December 1997.

[4]"Thyroid Cancer in Children Living Near Chernobyl, Expert Panel Report on the Consequences of the Chernobyl Accident" - Williams D. et al., K.H. ECSL-EAEC, Report EUR 15248 EN, Brussels-Luxembourg, 1993, p. 108.

rate had risen to 3.9 per 100,000.[5,6] This included approximately 3,000 children, 0 to 18 years old, that were evacuated from the 30-km zone within Belarus. Among this group, four thyroid cancer cases have been detected since the accident. All of these cases were registered after the end of the latent period for radiation-induced thyroid cancer. Taking into account the spontaneous rate of this disease in this age group and the number of evacuated persons, all of these cases are considered accident-induced.

The total number of excess cancers in Belarus children is currently about 750, and is estimated to reach a maximum of more than 3500 over the lifetime of this cohort.[3,4,6] The vast majority of the thyroid cancers were diagnosed among those living more than 50 km (31 miles) from the site.

The increase in the rate of thyroid cancers in Belarus is concentrated among those who were youngest at the time of the accident. Fortunately, these cancers respond favorably to early treatment; to date, two or three of the Belarus children diagnosed with thyroid cancer have died as a result of that disease.[6]

Poland Experience. Poland detected increased levels of airborne radioactive contamination on the night of April 27, 1986 (day 2). Although there was no official notification of the accident by the USSR, it was assumed, on the basis of Tass News Agency reports, that the increase were attributable to the accident at Chernobyl. On April 28 (day 3), the country formed a governmental commission to recommend protective actions. Among these actions,

---

[5]E. Buglova et al., "Thyroid Cancer in Belarus After the Chernobyl Accident; Incidence, Prognosis, Risk Assessment." Low Doses of Ionizing Radiation: Biological Effects and Regulator Control, Spain, November 1997, Contributed Paper, pp. 280-284.

[6]"Thyroid Cancer Incidence Rate in the Republic of Belarus." Okeanov A. et al., Radiation and Risk Bulletin of National Radio-Epidemiological Registry, Obninsk., 1995, Issue 6, pp. 236, 239.

the commission recommended intervention levels for taking protective actions on the morning of April 29 (day 4).[7]

On April 29, Poland's Minister of Health gave orders to prepare and distribute KI to the 11 provinces most affected. KI was to be made available through hospitals, public health centers, schools, and kindergartens. The country used its mass media to announce the protective action and to appeal for volunteers to assist in the nationwide distribution.

The Commission then instituted the following additional protective meases:[8]

- Feeding of cows on pastures or with fresh fodder was banned countrywide until May 15, 1986.
- Fresh milk with radioactivity concentration above 1,000 Bq/L was banned for consumption by children and pregnant or lactating women.
- All children under the age of 4 were given powdered milk through numerous distribution centers.
- Children and pregnant or lactating women were advised to eat a minimum of fresh leafy vegetables (until May 16, 1986).

The distribution of KI was initiated on April 29 (day 4) and was virtually completed by May 2 (day 7). This included the distribution of KI to more than 90 percent of the children under the age of 16 and about a quarter of the adults. A total of 10.5 million doses of KI were given to children and 7 million doses were given to adults. Multiple doses, although not recommended, were taken in a number of cases. Because of diminishing air contamination, the KI prophylaxis was not repeated. In the second phase of the response, powdered milk was made available to all children less than 4 years of age. This program effectively started on May 3 (day 8).

It is estimated that approximately a 40-45 percent reduction in thyroid burden was achieved by thyroid blocking and milk restrictions in the 11 provinces treated.[7] Had the Russian authorities given prompt warning, the 24- or 48-hour gain in time might have improved the effectiveness of their response.

There were no reported serious adverse reactions except for two adults with known iodide sensitivity. About 36,000 medically significant reactions were also reported (mostly nausea). Because of the low iodine concentrations in Poland it is doubtful that epidemiological studies could detect excess cancers resulting from intake of radioiodine.[8]

International Practices - During this assessment, the NRC staff examined the current policies and practices regarding the use of thyroid blocking during Nuclear Power Plant accidents for a number of countries. The NRC staff accomplished this task primarily through personal communication with colleagues in each country. In general, the countries either are following or intend to implement systems that are consistent with the guidance promulgated by the World Health Organization (WHO). Specifically, the WHO recommends predistribution of stable iodine close to the site and stockpiles further from the site. These stocks should be strategically stored at points such as schools, hospitals, pharmacies, fire stations, or police stations, thereby allowing prompt distribution. A further description of the WHO guidance is provided below, followed by a discussion of the guidance promulgated by IAEA and a comparison between U.S. and international practice.

---

[7]The Implementation of Short-term Countermeasures After a Nuclear Accident, Proceeding of an NEA Workshop Stockholm," Sweden, 1-3 June 1994, OECD 1995.

[8]Manual on Public Health Actions in Radiation Emergencies, WHO, European Center of Environmental and Health, Rome Division, 1995.

World Health Organization (WHO) Guidance. The main points of the WHO Guidelines[9,10] regarding the use of stable iodine are as follows:

- Near field: Stable iodine should be available for immediate distribution to all groups if the predicted thyroid dose is likely to exceed national reference levels. Close to nuclear installations iodine tablets should be stored or predistributed to facilitate prompt utilization.
- Far field: Stable iodine should be available for distribution to pregnant women, neonates, infants, and children if the predicted dose is likely to exceed reference levels.

Conclusion from Polish Experience. (1) Small amounts of radioactive iodine were deposited in Poland as a result of the Chernobyl accident, (2) no protective actions were taken for the first 2 days of the accident, and (3) protective actions (except sheltering or evacuation) were taken after the first 2 days of the accident. Because of the low iodine concentrations in Poland and the protective actions implemented, Poland has not detected excess cancers resulting from intake of radioiodines.

Overall Chernobyl Conclusion. The World Health Organization, almost every industrial country in the world with nuclear power plants, and the American Thyroid Association, believe that the low iodine concentrations, the banning of the consumption of fresh milk and the distribution and administration of 90 million doses of KI contributed to the observed lack of

---

[9]International Basic Safety Standards for Protection Against Ionizing Radiation and for Safety of Radiation Sources, Safety Series No. 115, IAEA, 1996.

[10]"Method for the Development of Emergency Response Preparedness for Nuclear or Radiological Accident," Tecdoc-953, IAEA, July 1997.

increase of childhood thyroid cancers in Poland. Most industrial nations with nuclear power plants have decided to stockpile KI around nuclear power for use by the general public.

In the event of an accident in the United States, our emergency planning calls for protective actions, (sheltering, evacuation, and removal of contaminated food from consumption) that would significantly reduce the risk to the public. Making KI available to the public for use during evacuation could, under certain conditions, reduce the risk further.

One public commenter articulated the conclusion of the Chernobyl experience by stating:

> "Early arguments against the stockpiling of KI for use in such an event have focused on the issues of possible toxicity from widespread use of potassium iodide, the difficult logistics of early distribution of KI and the question of cost/benefit ratio. Although all of those arguments have some cogency, the recent Chernobyl experience has nullified their pertinence. To date, over 1200 children in the Chernobyl area have developed papillary thyroid cancer requiring major medical intervention. Although the certainty of the fallout initiation of these cancers cannot be fully confirmed until current dose assessment studies are completed, the remarkable coincidence and extraordinarily high incidence of this rare tumor in the Chernobyl area is convincing enough to require some action."
>
> "The concern about significant toxicity from potassium iodide in emergency blocking doses has been made moot by the extensive Polish experience where 18 million individuals received prophylactic potassium iodide with overall toxicity of .2 percent (mostly nausea) but with only a fraction of 1 percent having serious side-effects. Current packaging of KI in Europe has appeared to resolve the problems about shelf life and the blister packing that is used in Sweden is certainly effective and inexpensive. There are admittedly problems in effective and complete rapid early distribution and certainly in predistribution. However, should a reactor accident occur in the U.S. requiring KI and it not be available because of an overly heavy emphasis on perceived difficulties, the resultant medical and political/sociological impact will be disastrous."
>
> "One cannot minimize the significance of a cluster of 1200 children with this serious and fortunately rare cancer. Although with modern intensive therapy results are good, such treatments often have very serious disrupting effect upon the life of the individual and such effect cannot be minimized."
>
> "The simplicity of having available a simple, inexpensive agent that can greatly lower the likelihood of this disease occurring is a fact that cannot be overlooked. Indeed, KI will not decrease whole body radiation and evacuation clearly is an optimal initial response to an accident, but it is not always possible and supplementation of evacuation with potassium iodide is undoubtedly useful. The Polish study showed that potassium iodide administration decreased the potential thyroid radiation dose by as much as 40 percent

and this was given as late as 3 to 5 days after the initial exposure to fallout from the continuing fire at the Chernobyl plant."

Issue 3

"Stockpiling or predistribution of potassium iodide (KI) as a protective action would not add any significant public health and safety benefit to the current level of protection provided by existing emergency plans for commercial nuclear power plants. Our emergency plans focus on evacuation as the key protective action to prevent exposure since it protects against exposure to all radionuclides, not just iodine. In addition, the potential for misadministration of KI is present when predistributed to the general public, and incidents of misadministration have been informally reported at industry meetings by states which predistributed KI to the public."

Commission Response

The Commission agrees that it is the State's prerogative to decide to include stockpiling or predistribution of KI as a protective action for the general public. The FDA concluded that risks from short term use of relatively low doses of KI are out weighed by the radiologically induced thyroid modules or cancers at a projected dose to the thyroid gland of 25 rem or greater. In so doing, the FDA approved KI as an over-the-counter drug. The American Thyroid Association fully endorses the use of KI and, as previously discussed, there were only 2 significant adverse reactions and 36,000 medically significant reactions (nausea) in 90 million doses of KI after the Chernobyl accident. The taking of KI should require precautions similar to those associated with any other over-the counter drug, and, of course, the packaging instructions should be followed.

Issue 4

"Evacuation is more feasible and practicable. Stockpiling of KI has logistical problems which we feel renders this idea impracticable and unmanageable."

Commission Response:

The Commission agrees that evacuation is usually "feasible and practicable" and is most effective protective action. If the State decides to include KI as a supplemental protective measure for the general public, one possible method of implementation could be that the State could make KI readily available where other over-the-counter drugs can be purchased. The public could be informed of the drug's availability through the yearly emergency preparedness information brochure that is mailed out to all residents throughout the 10 mile EPZ. Individual members of the public would be responsible for obtaining and storing this supply of KI, which could then be available for use in the event of an emergency. Other approaches to predistribution could include stockpiling at reception centers for distribution during an evacuation. Other countries have found ways to effectively distribute KI when needed and the distribution issue is certainly not unsurmountable. The administration of the KI should be at the direction of the State Medical Officer.

Issue 5

The Three Mile Island experience has shown us that it is not easy to obtain an adequate supply of KI in an emergency.

Commission Response:

The commenter is correct, in that it was difficult to obtain KI after the Three Island accident. However, with the limited Federal stockpile of KI for terrorist events and the willingness of the Federal Government to provide a stockpile of KI for any State that decides to use it as a supplemental protective measure for the general public, the Commission believes that an adequate supply of KI could be obtained.

Issue 6

Even though KI administration before any exposure is ideal, the Chernobyl experience also has shown that the exposure can continue for days. Is the institution of KI blockade at any time in this period beneficial?

Commission Response

The administration of KI is most effective if done before or immediately after (within 2 to 4 hours) a release. Nonetheless, during a chronic exposure of several days, the administration of KI any time during the exposure period may block some uptake of radioactive iodine. However, the benefit diminishes quickly over time and may be very small if administered late. If a release is expected to continue for several days, the NRC anticipates that the public would be evacuated or other protective action would be taken, depending on the level of release. KI could nevertheless serve as a useful supplemental and complement to these primary protective actions.

Issue 7

KI is an effective thyroid blocking agent only when administered immediately before or after an exposure to radioactive iodine (that is, within one to two hours). Distribution of KI in a timely fashion to the general public following an accident could further complicate and decrease the effectiveness of implementing evacuation or residential sheltering.

Commission Response

The Commission disagrees with this position. If a State chooses to include KI as an additional protective measure, it is anticipated that the State could make KI readily available to the public where other over-the-counter medicines are available or by other distribution means and that the public be made aware of its (the KI) availability, not at the time of an emergency, but KI could be made available year round.

Issue 8

One of the major impediments to distribution of KI to school children is coordination and administration of the program, e.g., the actual decision making process to administer KI or evacuate, parental approval and recordkeeping, identification and documenting allergic reactions, and the availability of a qualified medical professional to administer the potassium iodide.

Commission Response

The Commission disagrees. Upon declaration of a general emergency there should be NO decision "to administer KI or evacuate." The preferred protective action for the close-in population should be evacuation. The administration of KI should be treated in the same fashion as any other over-the-counter medication that might be given to children while away from home, after observing the instructions provided with the KI packaging. Prior parental approval to administer KI in the event of an emergency can and should be addressed in the planning process for any State that decides to use KI. The individual State may provide the appropriate guidance and establish a system for obtaining parental approval before the taking of other protective actions that are currently being followed in the EPZ around nuclear power plants.

Issue 9

Does the post-Chernobyl Polish experience show that large-scale deployment of KI is safe?

Commission Response

Approximately 18 million doses of KI were distributed primarily, but not exclusively, to children. The bulk of the distribution took about three days. There were no reported serious adverse reactions except for two adults with known iodide sensitivity. The rate of serious side effects (10^{-7}) is consistent with the frequency seen during routine use of KI for medical treatment of respiratory disease. The incidence of medically significant,

but not serious, reactions to this single dose of KI was also very low (0.2 percent). In addition, no detectable long-term disturbance in children's thyroid function was detected as of 1989. Additionally, the FDA has approved KI for over-the-counter distribution. The Commission, therefore, agrees that the post-Chernobyl experience has shown that large-scale deployment of KI is relatively safe.

Issue 10

Several comments raised the question of liability: "Is the NRC prepared to address the number of legal implications should a member of the general public be given KI at their directive or recommendation and the individual have an extreme allergic reaction, possibly death?; " "The Federal Register Notice does not address legal issues for states who decide to adopt KI and states who do not decide to adopt or administer KI to the public."; "The issue of legal liability should not be dismissed lightly. If the NRC decides to require stockpiling of KI for the general public, has NRC considered what liability may arise from any adverse health effects? No initiative such as this should be undertaken without resolution of this issue."; "Who would assume liability if the KI was used prior to the Governor ordering its use?"

Commission Response:

The comments focus principally on concerns that State and local governments involved in distribution and administration of KI may be liable in tort if an individual receiving the KI has a significant adverse medical reaction to the KI. To the extent that commenters are raising the potential for federal government liability for the promulgation of this

proposed rule, the NRC believes that whether the Commission may be subject to tort liability through the implementation of a KI program depends upon a number of factors. However, it would appear that a Commission decision to require State and local emergency planning officials to consider stockpiling KI for public distribution should be subject to the "discretionary function" exception to the Federal Tort Claims Act, 28 USC 2671, et seq.,[11] which protects the Federal Government from liability. The question of whether a State of locality might be liable for involvement with administration of KI to the general public can only be answered by reference to the laws and precedents of particular States. The NRC presumes that this would be part of the "consideration" that States and localities will undertake if this rule is promulgated. The NRC has not undertaken this analysis.

Issue 11

Does the NRC staff consider stockpiling and using KI as a reasonable and prudent protective measure for the general public?

---

[11]This exception from waiver of sovereign immunity provides that:

Any claims based upon an act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.

28 USC 2680(a). United States v. Varig Airlines, 467 U.S. 797, 808 (1984); Berkovitz v. United States, 486 U.S. 531 (1988).

Commission Response

The Commission considers that State and local decision makers, provided with proper information, may find that the use of KI as a protective supplement to evacuation and sheltering is reasonable and prudent for specific local conditions.

The 1998 proposed Federal Policy on use of KI as an emergency preparedness measure for commercial nuclear power plant accidents is being developed by the FRPCC. FEMA plans to publish this policy in the Federal Register in early 1999, nonetheless, it currently is proposed to state that:

> The revised Federal policy is that KI should be stockpiled and distributed to emergency workers and institutionalized persons for radiological emergencies, but leaves the decision on whether to stockpile, distribute and use KI for the general public to the discretion of State and, in some cases, local governments. Any State or local government that selects the use of KI as a protective measure for the general public may so notify the appropriate FEMA Regional Director, and may request funding for the purpose of purchasing a supply. The Federal offer to fund purchases of KI for the States represents an explicit recognition that this medicine can, under certain conditions, supplement other protection measures and thereby enhance protection of the public. State and local governments that opt to include KI as a protective measure for the general public will be responsible for preparing guidelines for its stockpiling, maintenance, distribution and use. State and local governments may also contact FEMA when the shelf life of the drug has expired and the supply needs to be replenished. It should also be noted that medical supplies, including KI, will be stockpiled in 27 metropolitan areas and in three national stockpiles across the country in support of State and local government response to emergencies caused by acts of terrorism involving nuclear, chemical and biological agents. For radiological emergencies resulting from any cause, including accidents at commercial nuclear power plants, this additional stockpile can be acquired ad hoc by State or local government officials if they determine its use would be beneficial.

Commission Decision

On June 26, 1998, the Commission decided to grant the petition for rulemaking. Accordingly, the NRC staff was directed to proceed with rulemaking to change 10 CFR

50.47(b)(10) by inserting the following sentence, after the first sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and, as a supplement to these, the prophylactic use of potassium iodide (KI), as appropriate." In addition, the preamble for the proposed rule was to include a statement to the effect that State and local decision makers, provided with proper information, may find that the use of KI as a protective supplement is reasonable and prudent for specific local conditions. The Commission also noted that, consistent with the Commission's decision on June 30, 1997, the Federal government (most likely the NRC) will fund the purchase of a stockpile of KI for the States upon request. The Commission also directed the NRC staff to work with other relevant agencies to ensure that there are established procedures to enable the national stockpiles to be effectively and timely used by States that have not established local stockpiles and wish to make use of the national stockpiles in the event of a severe nuclear power plant accident.

The Commission decision is implemented by publication of this proposed rule that would change 10 CFR 50.47(b)(10) with a 90-day public comment period. If the proposed rule is adopted in final form, the petition would be granted and NRC action would be completed on PRM 50-63 and PRM 50-63A.

Commission Conclusions or Issues Raised by the Petitioner and Public Commenters

The Commission agrees with many of the issues raised by the petitioner and the public commenters. The commission has reached the following conclusions:

A. The Commission agrees that KI, if administered in a timely fashion, could protect the thyroid gland from exposure to radioiodines inhaled or ingested following a major radiological accident. This is the basis for stockpiling it and distributing it to emergency workers and institutionalized persons during radiological emergencies. The petitioner believes that the

distribution of KI was inadequate and untimely in the Ukraine and Belarus after the Chernobyl accident in 1986 and that this accounts for the increased incidence of thyroid cancer in these areas. He also argues that distribution of KI in Poland was timely and effective and that no similar increase in the incidence of thyroid cancer was seen. The Commission considered all of the above information in deciding to grant the petitioner's requested actions.

B. The Kemeny Commission criticized the failure to stockpile KI and recommended that regional stockpiles be established. The Kemeny Commission's report recognized that evacuation was not invariably the preferred response to an emergency and that even when evacuation was desirable, it might not be feasible. The Commission believes that prompt evacuation and/or sheltering are the generally preferred protective measures for severe reactor accidents. In developing the range of public protective actions for severe accidents at commercial nuclear power plants, evacuation and in-place sheltering provide adequate protection for the general public. The Commission believes that KI for the general public should not replace evacuation and sheltering, but supplement them.

C. The Federal Radiological Emergency Response Plan (FRERP) is the plan that would be used by the Federal Government to support State and local officials in responding to any peacetime radiological emergency. Such emergencies range from transportation accidents involving radioactive materials to terrorist events involving nuclear materials. The FRERP includes a range of protective actions commensurate with the risks associated with the range of emergencies for the general public and emergency workers. These protective actions include evacuation, sheltering, and the prophylactic use of stable iodine. With respect to protective actions for nuclear power plants, the NRC and FEMA have issued Draft Supplement 3 to NUREG-0654/FEMA-REP-1, Rev. 1, to provide updated guidance for the development of protective action recommendations for severe reactor accidents. This

document emphasizes that prompt evacuation is the preferred protective action for actual or projected severe core damage accidents.

D. The Commission recognizes that in 1994 the Board of Governors of the IAEA adopted new International Basic Safety Standards. With respect to emergency planning, these standards provide, among other things, "intervention levels for immediate protective action, including sheltering, evacuation, and iodine prophylaxis." It is important to note that each country bases its response plans on local and regional characteristics. For example, Italy and France, using the same international standards and guidelines, implement them differently.

E. The Commission agrees with the NRC staff estimate that the purchase of KI tablets is inexpensive. KI-related costs increase when the cost of maintenance, distribution, and public education are considered.

F. The Commission believes that NBC medicinal stockpiles should provide assurance to States and local governments that a limited Federal stockpile of KI is available, if needed.

Commission approval to fund KI:

On June 30, 1997, the Commission voted to approve the NRC staff recommendation to endorse the FRPCC recommendations for the Federal Government to fund the purchase of potassium iodide (KI) for States at their request and endorsed the FRPCC recognition of the availability of the Federal stockpile of KI to State and local governments for purposes of mitigating the consequences of terrorist use of nuclear, biological, or chemical (NBC) weapons. Under this endorsement, the Federal Government would fund the purchase of KI, and State and local governments would be responsible for maintenance, distribution, and subsequent costs. As part of their emergency response planning, NRC licensees should discuss this matter with State and local governments that make decisions on protective measures in planning for responses to emergencies.

Findings

Metric Policy

On October 7, 1992, the Commission published its final Policy Statement on Metrication. According to that policy, after January 7, 1993, all new regulations and major amendments to existing regulations were to be presented in dual units. The amendment to the regulations contains no units.

ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT FOR GRANTING THE PETITION FOR RULEMAKING RELATING TO THE USE OF POTASSIUM IODIDE (KI)

I. Introduction

On September 9, 1995, a petition for rulemaking (PRM 50-63) was filed with the NRC by Mr. Peter Crane. The petitioner requested that the NRC amend its emergency planning regulations to require that emergency plans specify a range of protective actions to include sheltering, evacuation, and the prophylactic use of KI.

In SECY 97-245, dated October 23, 1997, the staff provided three options for the Commission's consideration in order to resolve PRM 50-63.

On November 5, 1997, the Commission was briefed by the NRC staff, the Federal Emergency Management Agency (FEMA), and the petitioner regarding the options available for resolving the petition for rulemaking. During the meeting, the Commission invited the

petitioners to submit a modification to his petition in order to address views he discussed during the meeting.

On November 11, 1997, the petitioner submitted a revision to his petition PRM 50-63A, which requested two things:

1. A statement clearly recommending stockpiling of KI as a "reasonable and prudent" measure, and

2. A proposed rule change to 10 CFR 50.47(b)(10) which would be accomplished by inserting the following sentence after the first sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate."

On June 26, 1998, the Commission directed the staff in SRM 98-061 to grant the petition for rulemaking PRM 50-63A by revising 10 CFR Part 50.47 (b)(10). This proposed rulemaking is in response to this directive.

Alternatives were essentially considered in previous documents. In SECY-97-124 (June 16, 1997), on the "Proposed Federal Policy Regarding Use of Potassium Iodide after a Severe Accident at a Nuclear Power Plant." The staff identified three options, one of which contained three sub-options, concerning a proposed change in the Federal policy regarding the use of potassium iodide (KI) as a protective measure for the general public during severe reactor accidents. Next, in an SRM dated June 30, 1997, the Commission approved an option that endorsed the Federal offer to fund the purchase of KI for States at their request and endorsed Federal Radiological Preparedness Coordinating Committee (FRPCC) recognition of the availability to State and local governments of the Federal stockpiling of KI.

II. Need for Action

In SECY-97-245, the staff proposed options for resolving the referenced petition for rulemaking. In SRM 98-06, the Commission directed the staff to proceed with the rulemaking.

III. Environmental Impact of the Proposed Action

The environmental impacts of the proposed action and its alternative are considered negligible by the NRC staff. Given the proposed action would only add the sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate." The staff is not aware of any environmental impact as a result of this proposed action.

IV. Alternative to the Proposed Action

The alternative to the proposed action at this time is to deny the petition and require no action with respect to the use of KI by the public. Should this no-action alternative be pursued, the staff is not aware of any resulting environmental impact.

V. Agencies and Persons Consulted

Cognizant personnel from the Federal Emergency Management Agency were consulted, as was the petitioner, as part of this rulemaking activity.

VI. Finding of No Significant Impact:: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that the amendments are not a major Federal action significantly affecting the quality of human environment, and therefore, an environmental impact statement is not required. This amendment will require that emergency plans specify a range of protective actions to include sheltering, evacuation, and the prophylactic use of KI. This action will not have a significant impact upon the environment.

Paperwork Reduction Act Statement

This proposal rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C 3501 et seq.). Existing requirements were approved by the Office of Management and Budget (OBM) approval numbers 3150-0009 and 3150-0011.

Public Protection Notification

If an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Regulatory Analysis of the Proposed Rulemaking Granting Petitions for Rulemaking (PRM 50-63 AND 50-63A) Relating to the Use of Potassium Iodide (KI)

On September 9, 1995, a petition for rulemaking (PRM 50-63) was filed with the NRC by Mr. Peter Crane. The petitioner requested that the NRC amend its emergency planning regulations to require that emergency plans specify a range of protective actions to include sheltering, evacuation, and the prophylactic use of KI.

In SECY 97-245, dated October 23, 1997, the staff provided three options for the Commission's consideration in order to resolve PRM 50-63.

On November 5, 1997, the Commission was briefed by the NRC staff, the Federal Emergency Management Agency (FEMA), and the petitioner regarding the options available for resolving the petition for rulemaking. During the meeting, the Commission invited the petitioners to submit a modification to his petition in order to address views he discussed during the meeting.

On November 11, 1997, the petitioner submitted a revision to his petition PRM 50-63A, which requested two things:

A statement clearly recommending stockpiling of KI as a "reasonable and prudent" measure, and

A proposed rule change to 10 CFR 50.47(b)(10) which would be accomplished by inserting the following sentence after the first sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic us of potassium iodide (KI), as appropriate."

On June 26, 1998, the Commission directed the staff in SRM 98-061 to grant the petition for rulemaking PRM 50-63A by revising 10 CFR Part 50.47 (b)(10). This proposed rulemaking is in response to this directive.

Alternatives were essentially considered in previous documents. In SECY-97-124 (June 16, 1997), on the "Proposed Federal Policy Regarding Use of Potassium Iodide after a Severe Accident at a Nuclear Power Plant." The staff identified three options, one of which contained

three sub-options, concerning a proposed change in the Federal policy regarding the use of potassium iodide (KI) as a protective measure for the general public during severe reactor accidents. Next, in an SRM dated June 30, 1997, the Commission approved an option that endorsed the Federal offer to fund the purchase of KI for States at their request and endorsed Federal Radiological Preparedness Coordinating Committee (FRPCC) recognition of the availability to State and local governments of the Federal stockpiling of KI.

In SECY-97-245, the staff proposed options for resolving the referenced petition for rulemaking. In SRM 98-06, the Commission directed the staff to proceed with the rulemaking.

Given the Commission considered the options and directed the staff to grant the petition, the only alternatives considered here are the Commission approved option and the baseline, no-action alternative.

The proposed rulemaking does not "require" anything of licensees, but States are to have shown "consideration" of the use of KI along with evacuation and sheltering as protective actions. It is estimated that 30 States will need to make this consideration. Further, the staff estimates that the labor needed by the States could range from a staff-week, to a half staff-year. The latter being the case if a State decided to hold hearings on the issue.

If one assumes an average hourly salary of $70 (this estimate includes benefits, pro-rated secretarial and managerial assistance, but not overhead), the range of estimates would be from $2800 to $63,000. Again using a base of 30 States, the range is from $84,000 to $1.9 million.

It is difficult to estimate the benefit of a State's consideration to stockpile KI. However, we believe the benefit of such an action by the States is summed up by the petitioner who stated that the decision to stockpile KI should turn on whether, given the enormous consequences of being without KI in a major accident, the drug is a prudent measure; not on whether it will necessarily pay for itself over time. As the petitioner further noted, KI represents

a kind of catastrophic-coverage insurance policy offering protection for events which, while they occur only rarely, can have such enormous consequences that it is sensible to take special precautions, especially where, as here, the cost of such additional precautions is relatively low.

As stated above, this analysis focuses on the rule being proposed as the result of a petition. Also, since the Commission has directed the staff to pursue the FRPCC results with respect to KI and has directed the staff to pursue the rulemaking, the regulatory analysis presented here is for the edification of the decision makers so they can make an informed decision on the proposed rule.

The above constitutes the regulatory analysis for this action.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule, if adopted, will not have a significant economic impact on a substantial number of small entities. This proposed rule would affect only the licensees of nuclear power plants. These licensees, do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act. 5 U.S.C. 601, or the size standards adopted by the NRC (10 CFR 2.810).

Backfit Analysis

The definition of backfit, as set forth in 10 CFR 50.109(a)(1), is clearly directed at obligations imposed upon licensees (and applicants) and their facilities and procedures. Section 50.109(a)(1) defines a backfit as:

. . . the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility, any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position . . . .

Section 50.109 is replete with references to "facilities" and "licensees," which in their totality make clear that the rule is intended to apply to actions taken with respect to nuclear power plant licensees and the facilities they operate. See Section 50.109(a)(7), "If there are two or more ways to achieve compliance with a license or the rules or orders of the Commission, or with written licensee commitments . . . then ordinarily the applicant or licensee is free to choose the way that best suits its purposes [emphasis added]." This focus on licensees and their facilities is further confirmed by the Statement of Considerations accompanying the backfit rule, 53 FR 20603 (June 6, 1988), where the Commission stated that backfitting "means measures which are intended to improve the safety of nuclear power reactors . . . ." 53 FR at 20604. The nine factors to be considered under 10 CFR 50.109(c) further make clear that the rule is aimed at requirements on licensees and facilities. These include: "(2) General description of the activity that would be required by the licensee or applicant in order to complete the backfit; . . . (5) Installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay; [and] (6) The potential safety impact of changes in plant or operational complexity. . . . [emphasis added]"

The proposed rule imposes no new requirements on licensees, nor does it alter procedures at nuclear facilities. Rather, it is directed to *States* or local governments -- the entities with the authority to determine the appropriateness of the use of KI for their citizens --

calling upon the governments to "consider" KI as one of the elements of their offsite emergency planning. Even as to states or local governments, it imposes no binding requirement to alter plans and procedures. Furthermore, the basic standard that emergency planning must include consideration of a range of protective actions, is already set forth in the existing wording of section 50.47(b)(10). On this basis, the proposed rule in reality does not impose new requirements on anyone. On a consideration of all of the above factors, no backfit is involved and no backfit analysis is required.

Commission precedent also makes clear that the proposed rule change does not constitute a backfit. The Commission's position was stated explicitly in 1987, when the last major change took place in emergency planning regulations. 52 FR 42078 (Nov. 3, 1987). The Commission's final notice of rulemaking on this rule involving the "Evaluation of the Adequacy of Off-Site Emergency Planning for Nuclear Power Plants at the Operating License Review Stage Where State and Local Governments Decline to Participate in Off-Site Emergency Planning" stated that the emergency planning rule change in question "does not impose any new requirements on production or utilization facilities; it only provides an alternative method to meet the Commission's emergency planning regulations. The amendment therefore is not a backfit under 10 CFR 50.109 and a backfit analysis is not required." 52 FR at 42084. Likewise, when the Commission altered its emergency planning requirements in 1987 to change the timing requirements for full participation emergency exercises (a change that, as a practical matter, could be expected to result in licensees' modifying emergency preparedness-related procedures to accommodate exercise frequency changes), it stated: "The final rule does not modify or add to systems, structures, components or design of a facility; the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct, or operate a facility. Accordingly, no backfit analysis pursuant to 10 CFR 50.109 is

required for this final rule." 52 FR 16828 (May 6, 1987). The instant proposed emergency planning rule change is of a similar nature and similarly does not involve a backfit.

It has been argued by at least one commenter on the petition for rulemaking that, although licensees are not directly burdened by the proposed rule, they would be indirectly burdened because they would feel called upon to explain the new policy to their customers. By this logic, almost any Commission action that led an NRC licensee to issue a press release could be considered a backfit. Such a position would represent unsound law and policy. Here, the burden of public information on licensees or applicants, if any, appears *de minimis*. It plainly does not rise to the level of the type of concrete burden contemplated by the Commission when it enacted the backfit rule. It might also be argued that, if a State or local government were to decide to stockpile and use KI for the general public, it would undertake interactions with the affected licensee to coordinate offsite emergency planning. Although this could result in some voluntary action by the licensee to coordinate its planning, the proposed rule itself does not impose any requirement or burden on the licensee. Accordingly, the Commission concludes that the proposed rule, if adopted, would not impose any backfits as defined in 10 CFR 50.109.

List of Subjects

10 CFR Part 50

Antitrust, Classified Information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act for 1954, as amended, the Energy Reorganization Act of 1974, as amended, the National

Environmental Policy Act of 1969, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendment to 10 CFR Part 50.

PART 50--DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for 10 CFR Part 50 continues to read as follows:

Authority: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2239, 2282); secs. 201, as amended, 202, 206, 88 State. 1242, as amended 1244, 1246, (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951, as amended by Pub. L. 102 - 486, sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851). Sections 50.10 also issued under secs. 101, 185, 68 State. 936, 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L. 91 - 190, 83 Stat. 853 (42 U.S.C. 4332). Section 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80, 50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. In § 50.47, paragraph (b)(10) is revised to read as follows:

§ 50.47 Emergency plans.

* * * * *

(b) * * * * *

(10) A range of protective actions have been developed for the plume exposure pathway EPZ for emergency workers and the public. In developing this range of actions, consideration has been given to evacuation, sheltering, and, as a supplement to these, the prophylactic use of potassium iodide (KI), as appropriate. Guidelines for the choice of protective actions during an emergency, consistent with Federal guidance, are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed.

* * * * *

Dated at Rockville, Maryland, this _____ day of _____, 1998.

For the Nuclear Regulatory Commission.

_____
John C. Hoyle
Secretary of the Commission

COORDINATION:

The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections. The CRGR has reviewed this Commission paper but does not agree with the staff's no backfit analysis (see Enclosure 6). The Office of the Chief Information Officer has reviewed this Commission paper for information technology impacts and compliance with the Paperwork Reduction Act and concurs in it. The Office of the General Counsel has no legal objection.

RECOMMENDATION:

That the Commission:

1. Approve publication of the proposed rule in the Federal Register.

2. Note:

   a. The proposed rule change would be published in the Federal Register for a 90-day public comment period.
   b. Appropriate Congressional committees will be notified.
   c. The Office of Public Affairs draft public announcement is attached (Enclosure 5).

   d. The evaluation of a need for a backfit analysis was prepared by OGC. The EDO accepts OGC's position that this rule change does not constitute a backfit under 10 CFR 50.109; therefore, a backfit analysis is not required.

   e. FEMA has been provided with an advance copy of this rulemaking package.

William D. Travers
Executive Director
for Operations

Attachments:
1. Revised Petition for Rulemaking (PRM 50-63A)
2. SRM 98-061, dated June 26, 1998
3. Proposed Federal Register Notice
4. SECY 97-124
5. Draft Public Announcement
6. CRGR comment letter dtd. October 23, 1998

cc w/atts:
SECY, OIP, OCA, OGC, CFO, CIO

DOCUMENT NAME:O:\JAMGOCHNODIDE\CPAPER.WPD *See previous concurrence

OFC	*DRPM:PGEB		*DRPM:PGEB		*TECH ED		*DRPM:PGEB	
NAME	MJamgochian:ayw		RAuluck				TEssig	
DATE	10/10/98		/ /98		10/20/98		10/21/98	

OFC	*DRPM:EPRP		*AD:DRPM		*D:NMSS		*OGC	
NAME	CMiller		JRoe		CPaperiello		JGray	
DATE	10/10/98		10/121/98		10/20/98		10/21/98	

OFC	*CFO		*CIO		*D:NRR		DEDE	
NAME	JFunches		BShelton		SCollins		RThompson	
DATE	10/23/98		10/20/98		10 /23 /98		11 /98	

OFC	*AEOD		OEDO	
NAME	TTMartin		WDTravers	
DATE	10/20/98		11 /98	

98-225

ENCLOSURE 5

From: Harvey Brugger <HBRUGGER@GW.ODH.State.OH.US>
To: GATED.nrcsmtp("pgcrane@erols.com")
Date: Thu, Dec 17, 1998 3:26 PM
Subject: KI supplier in Sweden -Reply -Forwarded

Peter,

In response to Ms. Hiatt's request, I am forwarding information to you regarding our contacts with the Swedish company that provides KI. Two letters are appended to this message directly. (They should also appear as Wordperfect 6.1attachments in the mail forwarded to Ms. Hiatt, which is also attached.)

Harvey

ATTACHMENT 1
##########

From: <allan.skolfman@recip.se>
To: ODH_OMIS.DPM1(COSTROVE)
Date: 11/3/98 10:04am
Subject: Potassium Iodide -your e-mail dated october 30, 1998

Dear Ms.Ostrove,

Thank you very much for your above message which we duly have taken care of. We would like to give you the following information:

1. Our product is registered in Europe.

2. All formal export rights from Sweden can be obtained.

3. In many countries registration is not a necessity as the authorities have the responsibility for the storage and the distribution of the tablets.

4. Potassium Iodide tablets are generally not to be found at pharmacies demanding a regular registration procedure.

5. Does the product have to be registered in the United States as the state of Ohio is having the responsibility for the handling of the product? If so is the case we will arrange for any authorisation needed, including the FDA. This may, however, take a considerable time to accomplish and also be associated with costs.

6. The availability of the product is totally dependent upon the volumes to be shipped. Consequently we would like to have your input in order to present the most adequate answer to you.

7. Pricing. This is also totally dependent upon volumes. However below please find our general price list.

100,000 packs (blister of 10 tablets) -USD 1.15 per pack

500,000 " " - " 0.90 " "
1,000,000 " " - " 0.70 " " 700 K
5,000,000 " " - " 0.60 " " = 3 M

8. Shipping costs. Generally we are selling at Ex Works (Incoterms 1990). However we are always open for discussion. in order to facilitate your ordering procedure.

9. Payment conditions. Generally Irrevocable Letter of Credit. For US customers we may consider Cash on Delivery or Stand by Letter of Credit.

10. Ordering address:
RECIP AB
Branningevagen 12
120 54 ARSTA
Sweden

11. We have, as you may know, furnished not only Sweden with our product but also other European countries as well as Latvia and Belarus. A number of countries are just about to change from the old 200mg product to the new one of 65mg. A positive interest has been shown from international organisations.

12. As can be seen from our pamphlet our product does follow the WHO recommendations. We can also guarantee a shelf-life of up to 10 years. (Some of our batches have been tested even up to 12-14 years).

We hope that the above information will be of assistance to you.

If there are additional questions to be answered by us, please do not hesitate to contact us whenever you want.

Telephone number: Switchboard +46 8 6025200 direct +46 8 6025329
Telefax number: " +46 8 818703 " +46 8 6025302

We look forward to hearing from you.

With kind regards,

Allan Skolfman
Export Manager

CC: ODH_REMOTE.SMTP("hans-henrik.bark@recip.se","thoma...

ATTACHMENT 2

##########

M E M O R A N D U M

TO: Harvey B. Brugger, Supervisor

FROM: Dwain C. Baer, Health Physicist III

SUBJECT: Potassium Iodide [KI] Manufacturers

DATE: October 30, 1998

****

Based on the research conducted by Connie Ostrove and myself, the only company which manufactures and distributes tablet KI specifically for use as a thyroid protection product is Carter-Wallace Laboratories, located on Half Acre Road in Cranbury, New Jersey 08512. Current cost per case of 100 bottles [fourteen tablets per bottle] is $250.00 [17.8 cents per tablet]. This cost has increased over 80% from last year, based on the anticipated increase of sales.

Roxane Laboratories, located at 1809 Wilson Road in Columbus, Ohio 43228-8601, produces a liquid solution labeled for use as an expectorant. However, the Food and Drug Administration [FDA] has approved this product for use as a thyroid protection method during a nuclear power plant radiological release. Roxane has never produced tablet KI for use as an expectorant, or for use as a thyroid protective method.

Several other companies within the United States were researched for thyroid blocking KI. However, all of the companies researched market KI for expectorants of various bronchitis problems only, and have not been approved by the FDA for thyroid blocking usage.

A company in Sweden called Recip AB, Branningevagen, has provided a cost estimate via e-mail. A pack of ten KI tablets can cost as much as $1.15 per pack [11.5 cents per tablet] plus the cost of shipping to the United States, and the cost of any authorization which may be required.

cc: Connie Ostrove, Librarian
R.A.S./KI File

Date: Mon, 14 Dec 1998 13:00:09 -0500
From: Harvey Brugger <HBRUGGER@GW.ODH.STATE.OH.US>
To: susan.hiatt@hamradio.org
Cc: dbaer@GW.ODH.STATE.OH.US,rsuppes@GW.ODH.STATE.OH.US,
shelmer@GW.ODH.STATE.OH.US
Subject: KI supplier in Sweden -Reply

Susan,

I am attaching two Wordperfect 6.1 documents. Since their preparation, one additional contact with the Swedish supplier, Recip AB, indicates their disinclination to provide Ki tablets at any different dosage that they currently manufacture. However, this is not necessarily an impediment. In fact, for purposes of public distribution, the Export Manager, Mr. Allan Skolfman, indicated that the 65 mg size may be more useful. Their tablet can be divided at score lines in order to comply with World Health Organization recommendations for dosages to children.

On a cost basis, comparing the Swedish Product with the Carter-Wallace product follows:

Carter Wallace Product
130 mg tablets packaged in a bottle of 14 tablets with a shelf life of 5 years cost $2.50 per bottle.

Recip AB (Swedish) Product
65 mg tablets packaged in a blister pack of 10 tablets with a shelf life of 10 years cost $1.15 per package in the quantities contemplated.

If one were not contemplating the subdivision of a bottle or packet, then it would be cheaper using the Swedish product to dispense one product per person.

Emergency workers and institutionalized are given a ten day supply plus extra tablets equivalent of a 14 day supply. If a five day supply without extra tablets would suffice, then they could be given one blister packet. Even if they were given two packets, in order for them to take two 65 mg tablets per day for 10 days, it would still be cheaper to use the Swedish product.

On strictly a comparison of cost/mg/year, the Swedish product is also cheaper: $1.77 E-4 versus $2.75 E-4

Harvey

Harvey

CC: GATED.nrcsmtp("susan.hiatt@hamradio.org")

ENCLOSURE 6

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 3, 2000

Mr. Peter G. Crane
4809 Drummond Avenue
Chevy Chase, MD 20815

Dear Mr. Crane:

This is in response to your letter dated October 15, 1999, in which you raised issues regarding the interactions between the Federal Emergency Management Agency (FEMA) and the U.S. Nuclear Regulatory Commission (NRC). In addition, you asked several questions concerning the NRC's efforts in dealing with potassium iodide (KI) policy making.

First, I do not agree that the NRC misrepresented FEMA's position on regional KI stockpiles. In a letter from FEMA Director James L. Witt, dated April 29, 1999 (Enclosure 1), to former NRC Chairman Shirley Jackson, Commissioner Dicus, Commissioner Diaz, Commissioner McGaffigan, and Commissioner Merrifield, Director Witt stated, among other concerns, that FEMA did not support establishment of regional KI stockpiles. Chairman Jackson's reply (Enclosure 2), dated June 15, 1999, included a statement that she was confident that the NRC and FEMA staffs will be successful in resolving the KI issue. The NRC's responses to the post-hearing questions reflected that NRC and FEMA were undertaking this effort and NRC's belief that the agencies would reach a successful outcome. The NRC never stated nor intended to imply that FEMA had indicated any change in its position. As a result of Chairman Jackson's letter to Mr. Witt and Commission direction to the staff, the NRC and FEMA staffs have been meeting to identify options for stockpiling KI, consistent with the views of each agency.

On January 12, 2000, the NRC received a letter from FEMA, signed by Ms. Kay Goss, Associate Director for Preparedness, Training, and Exercises. The letter reiterates the concerns expressed by Mr. Witt in his letter of April 29, 1999. The letter also provided comments on a predecisional final rulemaking package not available to the public, and we cannot be more specific regarding its contents until these documents become publicly available. We will place a copy of the FEMA letter and NRC response on the NRC website after they are publicly available.

You also stated that the Commission withdrew draft "NUREG-1633, in the face of withering criticism from the health departments of New York State and Ohio, and from me." In the staff requirements memorandum (SRM) dated June 26, 1998, the Commission stated, in part, "To assist the State and local decision makers, the staff should submit its paper, 'Assessment of the Use of Potassium Iodide (KI) as a Public Protective Action During Severe Reactor Accidents,' for public comment. Staff is encouraged to submit the assessment in whole, or in part, to peer reviewed journals for publication. Following receipt and evaluation of the public comments, the staff should revise the paper, as appropriate subject to Commission review." In conformance with this directive (COMSECY 98-016, dated July 13, 1998), the staff announced the availability of NUREG-1633 in the Federal Register and solicited public comments.

By the end of September 1998, the staff received about 80 comment letters from individuals, organizations and States. All comments received on draft NUREG-1633 are attached for your information and review (Enclosure 3). In an SRM dated September 30, 1998, the Commission directed the staff to withdraw draft NUREG-1633, and "in light of the many useful public comments on draft NUREG-1633, a substantially revised document that takes those comments into account will be issued in its place, and that the draft NUREG is therefore being withdrawn." The staff is currently developing an updated NUREG-1633 that conforms to the direction of the SRM.

You also raise the issue of a staff apology at the Commission meeting held on November 5, 1997, regarding the accuracy of the information upon which the Commission's policies on KI are based. The meeting transcript pages addressing this issue (Enclosure 4) show that, in response to a specific question, the staff requested that the record reflect correction of an error in one statement in a Commission paper, dated June 16,1997 -- SECY-97-124, "Proposed Federal Policy Regarding the Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant" (Enclosure 5). The statement mistakenly implied that FEMA [where correctly it was the NRC] was the primary Federal regulatory agency [on KI] that did not support the purchase and stockpiling of KI by the Federal government.

Another issue you raised concerned the cost of KI. The basis for the cost figures presented in our Congressional response is described in Attachment 2 to SECY-97-124 (see Enclosure 5) and updated in SECY-98-264, dated November 10, 1998 (Enclosure 5a). At this time, the U.S. Food and Drug Administration (FDA) is reevaluating its 1978/1982 KI guidance. If FDA proposes KI dosages other than the current ones (130 mg per day for adults and children over 1 year old), the cost for KI could change. It is not practical or possible at this time to provide an exact total cost of KI. You also raised a question regarding the staff's representation of these costs. All costs presented refer to the annual costs for purchasing KI. In the situation where it was assumed that all of the potential purchases of KI occurred in one year, that total cost was attributed to one year, consistent with budget implementation. Even if the cost did not recur for 10 years, the cost per year is still the total amount for the first year, zero cost for the next nine years, with the total cost occurring again in the tenth year.

Notwithstanding these limitations, the cost of KI tablets when purchased in large quantities (greater than about 500,000 tablets) was estimated. As you stated, a Swedish firm offers KI in bulk at 6 cents per pill, with a stated 10 year shelf life. The Swedish company, RECIP AB, provided costs that ranged from 11.5 cents per tablet for 1,000,000 tablets to 6 cents per tablet for 50,000,000 tablets. It should be noted that these costs are for 65 mg tablets whereas the current recommended FDA KI dosage for adults and children over 1-year old is 130 mg KI per day. The cost per 130 mg dose is twice the cost per tablet stated above and would therefore range from 23 cents to 12 cents per 130 mg dose. Additionally, this cost does not include shipping nor any costs associated with RECIP AB obtaining FDA approval of this KI product. In the United States, we have located two companies advertising KI tablets on the internet for purchase by the general public that have received FDA approval. ANBEX charges $10 per package of 14 KI tablets (130 mg dose) plus $4.00 for shipping up to 10 packages. The shelf-life is stated by ANBEX to be "indefinite." Based on the staff's informal inquiry to the company, it was indicated that the cost could be reduced to about $2.50 - $2.60 per package of 14 tablets in quantities of about 1,000,000 tablets, resulting in a cost of about 18 cents to 19 cents per tablet. Carter-Wallace Laboratories sells Thyro-Block Tablets, a 130 mg KI tablet. The tablets

are sold in a 98-day supply (98 130 mg tablets) for individuals at a cost of $42.95 or in a case of 100 bottles of 14 130 mg KI tablets per bottle for $560. This is about 40 cents to 43 cents per tablet. It is estimated that purchasing a million or more tablets at a time could get the price down to about 20 cents per tablet.

You also requested that NRC provide an accurate account of the actual expended costs of studying the KI issue. In our answer to the hearing question, we estimated that our spending to study the KI issue exceeded $2.6 million in period from October 1989 to August 11, 1999. The precise sum for the individual items listed came to $2.64 million. The response to the hearing question 16(B) represents the staff's best estimate of costs associated with the KI issue over the last 10 years (1989 - 1999). On the basis of the records available from our internal work tracking system, the staff was able to determine the cost of preparing the cost-benefit study entitled, "An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident" (NUREG/CR-6310) and the number of NRC full-time equivalent (FTE) positions associated with its publication. In addition, the cost associated with the KI rulemaking was determined with the aid of the internal tracking system. The cost to the NRC for providing travel funds to State members of the group preparing and reviewing the document, "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents", draft NUREG-1633, in December, 1998, and March, 1999, totaled about $9,100. Other KI activities involving offices and regions were not captured here because they did not necessarily have a specific tracking number referencing KI efforts over the 10-year period being evaluated. Furthermore, all Commissioner and management involvement is considered "overhead" with no specific reference to projects. Therefore, on the basis of a review of the records to the extent possible and discussions with principal staff members, the staff estimated that approximately 5 FTEs of lead technical staff time (through 1999) and 3 FTEs of lead coordinator time were expended. The other 12 FTEs represent the sum of the following estimates: (1) the management overhead cost at 0.2 FTE per year, subtotal — 2 FTE; (2) direct staff (other than lead staff), for example, development of the staff's technical reports on KI (for example, various versions of draft NUREG-1633), and Commission correspondence, at 0.8 FTE per year, subtotal — 8 FTEs; (3) technical staff assistance with reviews of reports, meetings with the Federal Radiological Preparedness Coordinating Committee and FEMA, and correspondence review at 0.2 FTE per year, subtotal — 2 FTE. These estimates result in the total of approximately 20 FTEs, which was provided in the response to question 16(B). It should be noted that the management overhead cost estimate is somewhat uncertain and could be higher than 0.2 FTE per year but the staff does not have a basis to make a better estimate.

In addition to NRC staff and its contractors, it is important to note that other Federal agencies have also expended FTEs and incurred other costs associated with KI, together with the efforts expended by States and local governments. None of these costs for work on the KI issue by government entities outside the NRC have been included in the staff's estimates noted above (with the exception of the state travel cost reimbursement stated above).

You also asked, "Who must consider KI under the proposed rule?" The proposed rule is directed principally to States and local governments, the entities with the important role to determine the appropriateness of the use of KI for their citizens, calling on these governments to 'consider' KI as one of the elements of their offsite emergency planning.

I hope this addresses your concerns.

Sincerely,

William D. Travers
Executive Director
for Operations

Enclosures:
1. Letter to NRC Commission fm J. L. Witt, FEMA dtd April 29, 1999
2. Letter to J. L. Witt, FEMA fm Chairman S. Jackson, NRC dtd June 15, 1999
3. Comments on draft NUREG-1633
4. November 5, 1997 Meeting Transcript Pages
5. NRC SECY-97-124, dtd June 16, 1997 - Proposed Federal Policy Use of Potassium Iodide after a Severe Accident at a Nuclear Power Plant

5a. NRC SECY 98-264, dtd November 10, 1998 - Proposed Amendments to 10 Cfr 50.47; Granting of Petitions for Rulemaking (Prm 50-63 and 50-63a) Relating to a Reevaluation of Policy on the Use Of Potassium Iodide (Ki) after a Severe Accident at a Nuclear Power Plant