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 'stockpile<u>s</u>'. 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:

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

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[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.

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.

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[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.

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,

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.

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[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.

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.**

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.

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.

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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

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, Rcom 634, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-2857; facsimile (202 646-4183.

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.

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.

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[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.

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

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.

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:

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

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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

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

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[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."

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

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

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 caused by such exposure, especially in children. 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 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 best available technical information indicates that evacuation and in-place sheltering provide adequate the best protection for the general public, 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. 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

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.

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

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?"

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[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.

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[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.

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

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.

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 SHEET 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).

Peter G. Crane / 4809 Hammond Avenue / Chevy Chase, M. 20815 / 301-656-3998

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

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

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

OFFICE OF THE SECRETARY

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

[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

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

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.

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.

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

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

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

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

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:

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,

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,

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[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.

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.

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[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.

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

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.

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.

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

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

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

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

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.

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

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:

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

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.

* * * * *

SECY-10-0107

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:\JAMGOCHI\ODIDE\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