

ATTACHMENT 2

SRM 98-264 DATED

APRIL 22, 1999



UNITED STATES
NUCLEAR REGULATORY COMMISSION

OFFICE OF THE
SECRETARY

April 22, 1999

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: Annette Vietti-Cook, Secretary *Annette Vietti-Cook*

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

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

(EDO)

(SECY Suspense: 5/31/99)

The staff should amend the draft Federal Register Notice on the federal KI policy provided to FEMA to conform to this SRM, particularly with respect to the Commission's decision not to fund State stockpiles.

(EDO)

(SECY Suspense: 5/31/99)

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

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

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

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

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

Attachment:
As stated

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

Changes to the Federal Register Notice

1. On page 1, paragraph 2, sentence 2 should be revised to read "The proposed rule would amend the current regulations to require ~~indicate~~ that consideration shall be given to including potassium iodide (KI) ~~along with sheltering and evacuation~~, as a supplemental protective measure for the general public: that would supplement sheltering and evacuation. KI would help prevent thyroid cancers in the unlikely event of a major release of radioactivity from a nuclear power plant.
2. The FRN currently states incorrectly that the Commission granted two petitions (PRM 50-63 and 50-63A). PRM 50-63 was replaced by PRM 50-63A which the Commission has granted. Therefore, the FRN should be revised to clarify this fact. On page 2, paragraph 1 under Supplementary Information, revise to read "By undertaking this rulemaking, the Commission, while not adopting the exact language suggested by the petitioner, is proposing to grant a petition for rulemaking (PRM 50-63A) submitted by Mr. Peter Crane on November 11, 1997. That petition is a revision of a petition (PRM 50-63) that he submitted on September 9, 1995.
3. On page 3, line 5, insert a new sentence after 'conditions' as follows: When the Commission amended its emergency planning regulations on November 3, 1980, it stated that 'any direct funding of State or local governments solely for emergency preparedness purposes by the Federal government would come through FEMA.' Begin the next sentence with 'In its decision on June 30, 1997, the Commission' In lines 5 and 6, delete 'consistent with the Commission's decision on June 30, 1997,'.
4. On page 3, line 7 and 8, replace the sentence 'The NRC staff will ... KI is established.' with 'The Commission has determined that notwithstanding the June 30, 1997 intention that "most likely the NRC" would fund the purchase of State stockpiles of KI, the NRC budget has continued to decrease and offers little margin for the Commission to divert resources to new initiatives. Historically, funding for State and local emergency response planning has been the responsibility of those governments usually working with licensees. The Commission notes that the Petitioner has not requested the Federal funding of stockpiles of KI.' Start the next sentence as follows: 'In the alternative, the NRC will' On page 3, line 9, delete 'also'. In lines 9 and 10, replace 'procedures to enable the national' with robust, pre-positioned regional' and add an 's' to 'stockpiles'. In line 10, delete 'for terrorist activities'. In line 11, replace 'national' with 'regional'.
5. On page 4, first full paragraph, sentence 1, insert 'NRC staff's' before 'proposed'.
6. On page 4, second full paragraph, line 1, insert 'portion of the' before 'petition'. In line 2, replace 'by directing' with 'regarding'.
7. On page 6, last line, replace 'in favor of' with 'which favored'.
8. On page 15, at end of second full paragraph insert: However, FEMA recently reported that the federal stockpiles of KI are few and stocked only for first responders to terrorist action. As things stand now, needs of members of the public for KI on an *ad hoc* basis would have to be supplied from other sources. As stated above, the Commission intends to work with FEMA to assure that stockpiles contain adequate supplies of KI.

9. On page 17, before the Analysis of issues raised by Public Comments insert a new paragraph as follows: On November 5, 1997, the Commission held a public meeting with its staff, FEMA representatives, and the author of the 1995 rulemaking petition to consider the petition and proposed changes to the Federal policy on the use of KI. In part as a result of the meeting, the petitioner amended his petition to ask for a rule that would require that consideration would be given in the formulation of emergency plans to the use of KI as a supplement to evacuation or sheltering, and on June 26, 1998, the Commission granted the amended petition, and directed the NRC staff to initiate the requested rulemaking. The Commissioners also decided that the FRPCC Federal Register notice on Federal KI policy should include a statement to the effect that the State and local decision makers, provided with proper information, may find that the use of KI as a protective supplement is reasonable and prudent for specific local conditions. On September 30, 1998, the Commission approved a draft Federal Register notice and directed that it be sent to the FRPCC.
10. On page 21, first full paragraph, line 1, insert 'thyroid' after 'excess'.
11. On page 22, second full paragraph, line 1, correct spelling of 'measures'.
12. On page 23, paragraph 2, add a footnote at end of second sentence, to read 'A "medically significant" reaction was one for which the person suffering the reaction consulted a physician more than once. Nauman and Wolff, "Iodide Prophylaxis in Poland After the Chernobyl Reactor Accident: Benefits and Risks," The American Journal of Medicine, Vol. 94, May 1993, p.530. About .02% of the population that received KI had "medically significant" adverse reactions to KI. Id. However, "[i]t should be pointed out that control values for these side effects in a population not receiving KI are not available." Id.' That is, it is not known what the incidence of such reactions would be in a population under similar stress, but not receiving KI, and thus it is not known to what extent these adverse reactions were the result of KI.
13. On page 24, under Conclusions from Polish Experience, line 1, insert 'In Poland' before '(1)'. In line 2, delete 'in Poland'.
14. On page 25, first full paragraph, line 1, insert 'In contrast to the Chernobyl experience,' before 'in the event'. In lines 2 and 3, remove the parentheses. In line 3 replace 'that would' with 'all of which'. In line 3, replace 'risk to' with 'risk of exposure of'. Also in line 3, insert 'to all radionuclides' after 'public'. In line 4, add 'or especially sheltering' after 'evacuation', and replace 'further' with 'resulting from exposure to one important group of radionuclides, the radioiodines.' That is why current NRC guidance discusses KI for plant personnel, emergency workers, and institutionalized persons unlikely to be evacuated promptly.
15. On page 25, delete the start of the second full paragraph (One public commenter) to the start of Issue 3 on the next page. Replace it with 'In this light, the Commission agrees that the use of KI may be determined by State and local emergency response planners to be a useful supplementary protective measure.'
16. On page 26, line 7 from the bottom, correct spelling of "nodules".

17. On page 27, under Commission Response, line 4, insert 'such as by making it available' after 'available'. In line 9, replace 'Other approaches' with 'Another approach' and replace 'could' with 'is to'.
18. On page 28, paragraph 1, replace with "The commenter is correct, in that it was difficult to obtain KI after the Three Mile Island accident. That is one reason why the Commission believes that planners should consider stockpiling KI, and why the Commission supports Federal stockpiles, so that States that have chosen not to stockpile KI could have access, albeit *ad hoc* and delayed, to an adequate supply in a radiological emergency at a nuclear power plant. As noted elsewhere in this notice, the Commission will work with other agencies to assure that there are Federal regional stockpiles that contain adequate supplies of KI. ~~However, with the limited Federal stockpile of KI for terrorist events and the willingness of the Federal Government to provide a stockpile of KI for any State that decides to use it as a supplemental protective measure for the general public;~~ Moreover, the general availability of KI is greater now than at the time of the TMI accident, partly because of the FDA's approval of KI as an over the counter drug. Some States have elected to incorporate KI into the emergency response plans and have obtained adequate supplies for this purpose. The Commission is not aware of any factors that would constrain the availability of KI for stockpiling purposes. The Commission believes that an adequate supply of KI could be obtained.
19. On page 32, line 7, replace the 'of' after 'State' with 'or'.
20. On page 32, line 2 from the bottom, replace 'NRC staff' with 'Commission'.
21. On page 33, line 1, replace 'considers' with 'believes'. Delete the second full paragraph under the Commission Response.
22. On page 33, replace the Commission Decision with the following: 'KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering for specific local conditions. Therefore, the Commission's guidance on emergency planning has long taken KI into consideration (NUREG-0654/FEMA-REP-1, Rev. 1, p. 63, items e. and f.). However, since the last revision of that guidance, there has been experience with the mass distribution of KI during a radiological emergency, and though the record on that distribution is not complete, the indications thus far are that mass distribution is effective in preventing thyroid cancer and causes remarkably few threatening side effects. Moreover, many nations in Europe and elsewhere, nations as different in their circumstances, politics, and regulatory structures as France, Canada, and Japan, have stockpiled KI and planned for its use. So have some U.S. States. The World Health Organization and the International Atomic Energy Agency recommend its use. Therefore, in order to 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., line 1, 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'.