

February 14, 2000

FOR: The Commissioners
 FROM: William D. Travers /RA/
 Executive Director for Operations
 SUBJECT: FINAL AMENDMENTS TO 10 CFR 50.47; THEREBY GRANTING IN PART TWO PETITIONS FOR RULEMAKING (50-63 AND 50-63A); RELATING TO A REEVALUATION OF POLICY ON THE USE OF POTASSIUM IODIDE (KI) FOR THE GENERAL PUBLIC AFTER A SEVERE ACCIDENT AT A NUCLEAR POWER PLANT

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PURPOSE:

To obtain Commission approval to publish a final rule in the Federal Register that would grant in part two petitions for rulemaking, (PRM 50-63 and PRM 50-63A). These petitions requested changes to the NRC policy and regulations relating to the consideration and use of potassium iodide (KI) as one of the elements in offsite emergency planning for the general public in the event of a severe reactor accident.

SUMMARY:

This final rule amends NRC's emergency planning regulations governing the domestic licensing of production and utilization facilities. The final rule would amend [10 CFR 50.47\(b\)\(10\)](#) to require that consideration be given to including the prophylactic use of potassium iodide (KI) as a 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. The final rule responds to petitions for rulemaking (PRM 50-63 and PRM 50-63A; [Attachment 1](#) ) submitted by Mr. Peter G. Crane concerning the use of KI in emergency plans.

BACKGROUND:

On September 9, 1995, Mr. Peter Crane filed a petition for rulemaking (PRM 50-63) with the NRC. 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.

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 65 comment letters were received. 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. Letters against granting the petition came from 20 utilities, 9 State governmental agencies; 2 utility interest organizations; and 1 letter signed by 12 health physicists, 2 State university medical centers and 1 member of the public. Two letters did not specifically address the petition.

In [SECY-97-245](#), "Staff Options for Resolving a Petition for Rulemaking (PRM 50-63) 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," dated October 23, 1997, the staff presented three options to the Commission for resolving PRM 50-63. These options were to (1) grant the petition; (2) deny the petition; or (3) grant the petition in part.

On November 5, 1997, the Commission was briefed by the NRC staff, the Federal Emergency Management Agency ([FEMA](#) [EXIT](#)), 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 to address the views he expressed during the meeting. On November 11, 1997, the petitioner submitted a revision to his petition, PRM 50-63A. The petitioner made two requests:

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

The petitioner also provided for the staff's use 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 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 86 comment letters were received. Letters in favor of granting the petition came from 8 public interest groups, 48 members of the public (including 3 from the petitioner), 3 physicians, 2 U.S. Senators, 1 State Representative, the American Thyroid Association, the U.S. Pharmacopeia Convention, a KI manufacturer and from FEMA. Letters from 14 utilities, 3 State government agencies, 1 utility interest association, and 2 members of the public were against granting the petition for rulemaking. A detailed analysis of the issues raised by the public comments, along with the staff's response and Commission decision on those issues was included with the proposed rule (June 14, 1999; 64 FR 31737).

On June 26, 1998, the Commission voted to grant the revised petition for rulemaking (PRM 50-63A). Accordingly, in an SRM dated June 26, 1998, the Commission directed the staff 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." The Commission also directed that 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 its June 30, 1997, SRM, "The Federal Government (most likely the NRC) is prepared to fund the purchase of a stockpile of KI for the States upon request."

On November 10, 1998, in SECY-98-264, "Proposed Amendments to 10 CFR 50.47; Granting of Petitions for Rulemaking (PRM 50-63 and PRM 50-63A) Relating to a Re-evaluation of Policy on the use of Potassium Iodide (KI) after a Severe Accident at a Nuclear Power Plant," the staff provided the Commission with a proposed rulemaking package. On April 22, 1999, the Commission directed the staff in the SRM on SECY-98-264 ([Attachment 2](#)) to publish a proposed rule change for a 90-day public comment period. The Commission also voted: (1) not to fund State stockpiles of KI; (2) to direct the NRC staff to work with FEMA to establish and maintain regional KI stockpiles; and (3) to support NRC funding of the initial purchase and resupply of the regional KI stockpiles 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 receiving money from the NRC.

The proposed rule was published in the Federal Register on June 14, 1999 (64 FR 31737). As part of the petitioner's comments on the proposed rule, the petitioner stated that his amended petition was contingent on the Commission's decision to fund State stockpiles of KI. In light of the Commission's reversal of that decision, the Commission should consider his original petition (PRM 50-63) to be incorporated by reference and resubmitted. He also requested the Commission to grant the petition as originally submitted.

DISCUSSION:

After evaluating public comments on the original petition, the revised petition and on the proposed rule change, the NRC staff developed the attached final rulemaking package. Publication of the attached final rule would implement the Commission's decision by amending 10 CFR 50.47(b)(10) to require that consideration be given to including the prophylactic use of potassium iodide (KI) as a protective measure for the general public that would supplement sheltering and evacuation. As explained in detail later, the final rule would grant in part and deny in part, both the original petition (PRM 50-63) and the revised petition (PRM 50-63A), although it does not adopt the exact language suggested by the petitioner.

Public Comment Evaluation

On June 14, 1999 (64 FR 31737), the Commission published a Federal Register notice of proposed rulemaking and requested public comment by September 14, 1999. A total of 77 comment letters were received. The letters in favor of the proposed rulemaking and the revised petition for rulemaking originated from one United States Senator; a member of the United States House of Representatives; 3 State agencies; 4 public interest groups; 10 members of the public (including two from the petitioner); and one letter with 529 signatures. Letters that opposed the proposed rulemaking came from 14 utilities; 13 State or local government agencies; 1 utility interest association, one letter from the Conference of Radiation Control Program Directors Standards committee representing 5 committee members; a letter from the National Emergency Management Association representing emergency management directors in 50 states; a law firm representing 15 utilities; and a former assistant Secretary of Nuclear Energy at DOE. A letter from the Director of FEMA did not state a position with respect to the rule, but provided comments concerning the stockpile issue. Another 24 letters requested the Commission to grant the original petition (PRM 50-63) by requiring the use of KI rather than the consideration of KI. These letters originated from members of the public as well as public interest groups. As previously noted, the petitioner's comment letter dated August 17, 1999, on the proposed rule incorporated by reference his original petition (PRM 50-63 which was noticed in the Federal Register on November 27, 1995).

FEMA Position on Stockpiles

In a letter dated April 29, 1999, ([Attachment 3](#) ) to the Commission, Mr. James Witt, the Director of the Federal Emergency Management Agency (FEMA), stated FEMA's concerns on the issue of funding of stockpiles of potassium iodide for States. The letter objected to the Commission's "unilateral" decision on funding and stated "FEMA has always opposed the notion that

Federal regional stockpiles of KI would be effective [and believes that] regional stockpiles of KI would complicate, not strengthen radiological emergency preparedness."

Then-Chairman Jackson responded to Mr. Witt's letter in a letter of June 15, 1999 ([Attachment 4](#) ). This letter noted the Commission decision not to fund State stockpiles of KI as well as the reasons underlying that decision. It also referred to the Commission's direction to "the NRC staff to work with FEMA staff to establish and maintain regional KI stockpiles to be used in the event that local stockpiles prove to be insufficient, or when a State without a stockpile elects to use KI on an ad hoc basis in the case of a nuclear emergency." The letter expressed confidence that the FEMA and NRC staffs would be successful in resolving the KI issue.

In accordance with a Memorandum of Understanding between NRC and FEMA, the NRC staff sent draft versions of the final rule Federal Register notice to FEMA for its review and comment in November 1999 and on January 10, 2000. On January 12, 2000, FEMA sent a letter with comments on the NRC's draft final rule package sent in November 1999. That letter, signed by Ms. Kay Goss, Associate Director for Preparedness, Training, and Exercises, reiterated Director Witt's concerns noted in his April 29, 1999, letter with regard to the Commission decision not to fund State stockpiles of KI and urged the NRC to reconsider its decision on this matter. FEMA also reiterated that it continues to maintain that Federal regional stockpiles 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. The letter notes that the development of regional stockpiles of KI has not progressed. This confirms the staff's view that there is uncertainty over the establishment of regional stockpiles or any Federally-funded supply of KI for the general public. Therefore, emergency planners should not rely on the existence of a Federally-funded supply of KI in their planning. Specific comments made by FEMA on the draft FR notice were considered by the staff and as appropriate incorporated into the final rule package.

In light of FEMA's opposition to regional stockpiles, the Commission presumption that there will be regional stockpiles may be premature because the NRC staff has been unable to reach agreement with FEMA on the establishment of regional stockpiles of KI. The NRC and FEMA staffs have explored a proposal to make KI available by means of a Center for Disease Control and Prevention (CDC) "pipeline" approach, which is an evolving U.S. infrastructure to respond to terrorist efforts. This concept, more fully described in a separate paper, "Status of Potassium Iodide Activities," could be considered by the Commission as a possible alternative approach to State and/or regional KI stockpiles. It should be noted, however, that this "pipeline" concept as it pertains to KI has not been approved by either FEMA or the NRC (see for instance the discussion in the January 12, 2000, FEMA letter). Resolution of the Commission's policy on funding of KI stockpiles is not needed to support the rule as written. The Statements of Consideration (SOC) portion of the FRN for the final rule including responses to comments, reflects the status of funding of stockpiles of KI, as described above and the ongoing attempts of the NRC staff to resolve differing NRC and FEMA positions on the funding issue.

Final Rule

This final rulemaking would grant in part and deny in part both petitions. The action by the Commission to approve this final rule would grant a portion of the original petition (PRM 50-63), by including in this Federal Register notice for the final rule, a statement that "KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering for specific local conditions." Although the statements in the FRN do not use the petitioner's exact language, the Commission's statement is responsive to the petitioner's request. However, the final rulemaking would deny those parts of the original petition requesting that the Commission: 1) amend 10 CFR 50.47(b)(10) to require that the range of protective actions developed for the "plume exposure pathway EPZ include sheltering, evacuation, and the prophylactic use of iodine," and 2) declare, as a matter of policy, that the NRC is willing to provide a stockpile of the drug or arrangements for supplies of KI at the time of an emergency to States and localities.

The Commission's action in completing the final rulemaking would grant that part of the amended petition requesting amendment of 10 CFR 50.47(b)(10) to provide for consideration of KI in the range of protective actions, as a supplement to evacuation and sheltering. Inclusion in the FRN of the statement quoted above regarding KI as a reasonable, prudent and inexpensive supplement would grant another portion of the amended petition.

A change in position on funding of State stockpiles would deny the part of the amended petition that would include a statement of NRC support for State stockpiles in the Statement of Consideration for the final rule. Instead, the FRN for the final rule discusses arrangements for Federal supplies of KI as a backup for States who decide at the time of an actual emergency that they would like to distribute KI to the general public but had not created their own stockpiles or otherwise planned for such distribution. The Federal Register notices for both the proposed and final rule discuss the basis for the Commission determination to support Federal funding of regional stockpiles as opposed to Federal funding of State stockpiles.

Potential Implications in Implementation of this Final Rule

State and local governments: Under the final rulemaking, it is left to State and local emergency response planners to determine whether their emergency plans should include KI as a supplementary protective measure for the general public. The final rule does not establish a firm implementation schedule. Thus, some State and local governments may decide to defer their implementation of this rule until a final decision with respect to Federal stockpiles (regional or "pipeline") is reached.

Licensees: The final rule itself does not impose any requirement or burden on licensees. However, licensees

would have the obligation to confirm that offsite authorities have considered the use of KI as a supplemental protective action for the general public. While this ultimate responsibility could have practical implications, with some associated burdens, for licensees, the potential impact is considered minimal when viewed in the context of the overall licensee burden of complying with current emergency planning requirements.

FEMA: FEMA is the responsible Federal agency for offsite preparedness. Their regulations (44 CFR 350) parallel NRC's existing emergency planning regulations. Issuance of this new final rule would result in an inconsistency with the FEMA regulations in that FEMA's regulations do not require the consideration of KI. The impacts of this final rule upon FEMA with respect to their reviews of offsite emergency preparedness are not fully known at this time.

RESOURCES:

Approximately 1.0 FTE is budgeted to resolve this petition by conducting a rulemaking in accordance with the Commission direction. The FY 2001 budget for IRO includes a planning wedge of \$400K for the purchase of KI. However, the cost of purchasing KI in order to establish regional or Federal stockpiles or other Federally-supported supplies of KI in accordance with the SRM on SECY-98-264 dated April 22, 1999, depends on the number of doses required per supply and the number of regional stockpiles or supplies that are established.

COORDINATION:

The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections. The CRGR reviewed this rulemaking package and has no objection to issuing the rule. The ACRS received a KI briefing from the staff but did not review the proposed or final rule. The Office of the Chief Information Officer has reviewed the Commission Paper for information technology and information management implications and concurs in it. The Office of the General Counsel has no legal objection.

RECOMMENDATION:

That the Commission:

1. Approve for publication in the Federal Register the final rulemaking to 10 CFR Part 50 ([Attachment 6](#) ).
2. Certify that this rule will not have a significant economic impact on a substantial number of small entities in order to satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).
3. Note that
 - a. The final rule ([Attachment 6](#) ) will be published in the Federal Register and posted on Ruleforum;
 - b. As required by the Regulatory Flexibility Act, a regulatory flexibility analysis has been prepared and is part of the Federal Register notice. The analysis indicates the economic impact on licensees and small entities will not be significant. The analysis will be made available in the Public Document Room. A copy will be sent to the Chief Counsel for Advocacy of the Small Business Administration;
 - c. This final rule will not change the overall regulatory burden on licensees for information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rule has been reviewed by the Office of Management and Budget. The information collection requirements were approved on November 10, 1998;
 - d. A press release will be issued;
 - e. Appropriate Congressional committees will be informed;
 - f. Copies of the Federal Register notice for the final rule will be distributed to all those that commented on the proposed rule. The final rule will be sent to other interested parties upon request;
 - g. All States and power reactor licensees will be sent a copy of the Federal Register notice upon publication;
 - h. This amendment does not constitute a backfit under [10 CFR 50.109](#); and
 - i. FEMA was provided with advance copies of the Federal Register notice, and has provided comments to the NRC that were considered by the staff in preparing this notice.

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Attachments:

1. [Petitions for Rulemaking \(PRM 50-63 and PRM 50-63A\)](#) 
2. [SRM 98-264, dated April 22, 1999](#)
3. [Letter from Director of FEMA, April 29, 1999](#) 
4. [Commission letter responding to Mr. J. Witt, June 15, 1999](#) 
5. [Letter from FEMA providing comments on draft final rule FR notice, January 12, 2000](#)  [Pre-decisional document, not publicly available]
6. [Final Federal Register Notice](#) 