November 10, 1998 SECY-98-264

FOR: The Commissioners

FROM: William D. Travers /s/
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).

CONTACT:
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(301) 415-3224

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 proposed 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.

   f. The EDO accepts OGC's position that this rule change does not constitute a backfit.

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:
SEC.
OGC
OCA
OIP
CFO
CIO

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

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

OFC	*DRPM:PGEB		*DRPM:PGEB		*TECH ED		*DRPM:PGEB	
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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		HThompson	
DATE	10/23/98		10/20/98		/ /98		/ /98	

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

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.

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

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

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

SUPPLEMENTARY INFORMATION:

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

Considering all public comments received, the information available in the literature, 20 years of experience gained in evaluating licensee emergency preparedness plans, and the arguments presented by the petitioner, the Commission has decided to grant the petition for rulemaking and to proceed with rulemaking to amend 10 CFR 50.47(b)(10) by inserting the following sentence, after the first sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and, as a supplement to these, the prophylactic use of potassium iodide (KI), as appropriate." In addition, the preamble for this proposed rule includes a statement to the effect that State and local decision makers, provided with proper information, may find that the use of KI as a protective supplement is reasonable and prudent

for specific local conditions. The Commission also noted that, consistent with the Commission's decision on June 30, 1997, the Federal government (most likely the NRC) is prepared to fund the purchase of a stockpile of KI for the States, upon request. The NRC staff will work to ensure that the process for States to obtain funding for KI is established. The NRC staff will also work with other relevant agencies to ensure that there are established procedures to enable the national stockpile of KI, for terrorist activities, to be effectively and timely used by states that have not established local stockpiles and wish to make use of the national stockpiles in the event of a severe nuclear power plant accident.

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

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

A statement [be made] clearly recommending stockpiling of KI as a "reasonable and prudent' measure, and;

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

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

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

Petitioner's Basis for Requesting Potassium Iodide

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

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

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

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

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

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

The Petitioner's Discussion of the Potassium Iodide Policy

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

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

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

The Petitioner's Discussion of the Effects of Chernobyl

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

cancer. The petitioner noted that Poland is a proof-positive example of the benefits of a well-prepared KI program.

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

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

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

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

The petitioner noted that, in March 1994, the NRC staff declared its support for KI stockpiling. However, the NRC staff proposal for a change in policy was not adopted, the

Commissioners having voted 2 to 2 on the staff's proposal in May 1994. (Under Commission procedures, a tie vote means that a proposal fails.)

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

The petitioner described a September 1994, FEMA publication proposing a "Federal Radiological Emergency Response Plan" that envisioned the use of KI during radiological emergencies. Under the plan, the NRC would be the lead Federal agency during emergencies at nuclear power plants and would advise State and local governments whether or not to distribute KI (based on advice received from an interagency panel). The States and localities would then administer the KI, if necessary.

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

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

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

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

circumstances presented, may call for different protective measures. The petitioner notes that maintaining a KI option ensures that responsible authorities have the option of additional protection at their disposal.

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

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

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

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

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

The petitioner believes that cost-benefit analysis is a technique that should be applied with good sense, especially where public health measures are concerned. According to the

petitioner, the cost-benefit analysis of KI proceeded from the assumption that there was no difference in desirability between prevention of radiation-caused thyroid disease and cure. Thus, the only factor to be considered in evaluating KI was the cost. The petitioner also believes that the U.S. Government determined that instead of spending money to prevent radiation-caused thyroid disease, society should spend its money treating the disease if and when it occurs.

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

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

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

The petitioner believes that no State or local official or member of the public could imagine that in a real emergency, there would be no KI to administer. The petitioner raised the question: If KI stockpiling is not worthwhile, why is the administration of the drug one of the protective measures identified in the 1994 Federal Emergency Response Plan? He also asked why, if KI is worthwhile, as the plan implies, something is not being done to make sure that it is available.

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

The Petitioner's Proposed Amendment to the NRC Regulations

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

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

> (10) A range of protective actions <u>including sheltering</u>, <u>evacuation and prophylactic use of iodine</u> have been developed for the plume exposure pathway EPZ [emergency

planning zone] for emergency workers and the public. Guidelines for the choice of protective actions during an emergency, consistent with Federal guidelines, are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed.

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

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

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

The petitioner suggested that the NRC, either on its own or jointly with other agencies, issue a policy statement declaring that KI stockpiling is a reasonable and prudent measure that is necessary to ensure that the drug will be available in the event of a major accident. The petitioner believes that this statement would clarify that KI can be used in conjunction with evacuation and sheltering to maximize protection to the public.

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

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

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

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

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

as vital as chemical nerve antidotes and vaccines, the NRC staff was successful in getting KI included with other medical supplies for NBC events because of the unusual characteristics of these events.

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

FRPCC Subcommittee on KI (1996).

Along with petitioning the NRC, Mr. Crane also requested that FEMA review his petition and reconsider the Federal policy. In early 1996, the FRPCC convened an Ad-Hoc Subcommittee on Potassium Iodide to request and review new information on this matter from interested parties. The subcommittee conducted a public meeting on June 27, 1996. The subcommittee evaluated all comments from the June 27 public meeting and made the following recommendation regarding the Federal KI policy:

1. Without changing the Federal policy by interceding in the State's prerogative to make its own decisions on whether to use KI, the Federal Government (NRC, or through FEMA) should fund the purchase of a stockpile for a State that decides to incorporate KI as a protective measure for the general public;
2. The Subcommittee believes the language in the 1985 policy should be softened to be more flexible and balanced. For example, the problem many intervenors observe with the Federal policy is the italicized statement "The Federal position with...potassium iodide for use by the general public is that it should not be required." It would not be as negative if the last phrase were reworded to state "it [potassium iodide for use by

the general public] is not required, but may be selected as a protective measure at the option of the State or, in some cases, local governments."

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

Analysis of Issues Raised by Public Comments

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

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

3 physicians, 2 U.S. Senators, and 1 State Representative. The following issues were raised by the public commenters with an accompanying Commission response:

Issue 1

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

Commission Response:

The comments focus principally on concerns that State and local governments involved in distribution and administration of KI may be liable in tort if an individual receiving the KI has a significant adverse medical reaction to the KI. To the extent that commenters are raising the potential for federal government liability for the promulgation of this proposed rule, the NRC believes that whether the Commission may be subject to tort liability through the implementation of a KI program depends upon a number of factors. However, it would appear that a Commission decision to require State and local emergency planning officials to consider stockpiling KI for public distribution should be subject to the "discretionary function" exception to the Federal Tort Claims Act, 28 USC 2671, et seq.,[2] which protects the Federal Government from liability. The question of

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

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

whether a State of locality might be liable for involvement with administration of KI to the general public can only be answered by reference to the laws and precedents of particular States. The NRC presumes that this would be part of the "consideration" that States and localities will undertake if this rule is promulgated. The NRC has not undertaken this analysis.

Issue 2

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

Commission Response

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

Issue 3

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

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

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

Commission Response

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

It is often assumed that ingestion was the major source of thyroid dose early in the accident. However, the contribution of inhalation cannot be assessed because air sampling was not effectively conducted early in the accident. As of 1996, except for thyroid cancer, there has been no confirmed increase in the rates of other cancers, including leukemia, among the first responders, liquidators,[3] or the public, that have been attributed to release from the accident.

Belarus Experience. With the Chernobyl plant located only 4 miles (7 km) away, Belarus was heavily impacted by the accident. This impact was heightened by the fact that protective actions were not implemented in Belarus during the first six days after the accident. Several authors have stated that KI was distributed to the population in Belarus during the first

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

week following the accident.[4] However, there is no confirmed published data on the dosage, coverage, or other details concerning the implementation of the thyroid blocking in Belarus.[5] In addition, cows typically grazed in Belarus at the time of year when the accident occurred, and yet no efforts were taken to restrict the consumption of contaminated milk for the first 10 days following the accident.

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

Since 1990, a rapid increase has been observed in the incidence in thyroid cancer among Belarus children who were 0 to 14 years old at the time of the accident. Before the accident, the rate of thyroid cancer among this cohort was about 0.4 per 100,000; by 1996, this rate had risen to 3.9 per 100,000.[6,7] 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.

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

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

[6]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.

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

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

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

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

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

The distribution of KI was initiated on April 29 (day 4) and was virtually completed by May 2 (day 7). This included the distribution of KI to more than 90 percent of the children under the age of 16 and about a quarter of the adults. A total of 10.5 million doses of KI were given to children and 7 million doses were given to adults. Multiple doses, although not recommended, were taken in a number of cases. Because of diminishing air contamination, the KI prophylaxis

was not repeated. In the second phase of the response, powdered milk was made available to all children less than 4 years of age. This program effectively started on May 3 (day 8).

It is estimated that approximately a 40-45 percent reduction in thyroid burden was achieved by thyroid blocking and milk restrictions in the 11 provinces treated.[8] 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.[9]

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.

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

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

World Health Organization (WHO) Guidance. The main points of the WHO Guidelines[10,11] regarding the use of stable iodine are as follows:

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

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

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

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

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

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

> "Early arguments against the stockpiling of KI for use in such an event have focused on the issues of possible toxicity from widespread use of potassium iodide, the difficult logistics of early distribution of KI and the question of cost/benefit ratio. Although all of those arguments have some cogency, the recent Chernobyl experience has nullified their pertinence. To date, over 1200 children in the Chernobyl area have developed papillary thyroid cancer requiring major medical intervention. Although the certainty of the fallout initiation of these cancers cannot be fully confirmed until current dose assessment studies are completed, the remarkable coincidence and extraordinarily high incidence of this rare tumor in the Chernobyl area is convincing enough to require some action."
>
> "The concern about significant toxicity from potassium iodide in emergency blocking doses has been made moot by the extensive Polish experience where 18 million individuals received prophylactic potassium iodide with overall toxicity of .2 percent (mostly nausea) but with only a fraction of 1 percent having serious side-effects. Current packaging of KI in Europe has appeared to resolve the problems about shelf life and the blister packing that is used in Sweden is certainly effective and inexpensive. There are admittedly problems in effective and complete rapid early distribution and certainly in predistribution. However, should a reactor accident occur in the U.S. requiring KI and it not be available because of an overly heavy emphasis on perceived difficulties, the resultant medical and political/sociological impact will be disastrous."
>
> "One cannot minimize the significance of a cluster of 1200 children with this serious and fortunately rare cancer. Although with modern intensive therapy results are good, such treatments often have very serious disrupting effect upon the life of the individual and such effect cannot be minimized."
>
> "The simplicity of having available a simple, inexpensive agent that can greatly lower the likelihood of this disease occurring is a fact that cannot be overlooked. Indeed, KI will not decrease whole body radiation and evacuation clearly is an optimal initial response to an accident, but it is not always possible and supplementation of evacuation with potassium iodide is undoubtedly useful. The Polish study showed that potassium iodide administration decreased the potential thyroid radiation dose by as much as 40 percent and this was given as late as 3 to 5 days after the initial exposure to fallout from the continuing fire at the Chernobyl plant."

Issue 4

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

Commission Response

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

Issue 5

"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 6

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

Commission Response:

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

Issue 7

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

Commission Response

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

Issue 8

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 9

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

Commission Response

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

Issue 10

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

Commission Response

Approximately 18 million doses of KI were distributed primarily, but not exclusively, to children. The bulk of the distribution took about three days. There were no reported serious adverse reactions except for two adults with known iodide sensitivity. The rate of serious side effects (10^{-7}) is consistent with the frequency seen during routine use of KI for medical treatment of respiratory disease. The incidence of medically significant, but not serious, reactions to this single dose of KI was also very low (0.2 percent). In addition, no detectable long-term disturbance in children's thyroid function was detected as of 1989. Additionally, the FDA has approved KI for over-the-counter distribution. The Commission, therefore, agrees that the post-Chernobyl experience has shown that large-scale deployment of KI is relatively safe.

Issue 11

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

Commission Response

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

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

The revised Federal policy is that KI should be stockpiled and distributed to emergency workers and institutionalized persons for radiological emergencies, but leaves the decision on whether to stockpile, distribute and use KI for the general public to the discretion of State and, in some cases, local governments. Any State or local government that selects the use of KI as a protective measure for the general public may so notify the appropriate FEMA Regional Director, and may request funding for the purpose of purchasing a supply. The Federal offer to fund purchases of KI for the States represents an explicit recognition that this medicine can, under certain conditions, supplement other protection measures and thereby enhance protection of the public. State and local governments that opt to include KI as a protective measure for the general public will be responsible for preparing guidelines for its stockpiling,

maintenance, distribution and use. State and local governments may also contact FEMA when the shelf life of the drug has expired and the supply needs to be replenished. It should also be noted that medical supplies, including KI, will be stockpiled in 27 metropolitan areas and in three national stockpiles across the country in support of State and local government response to emergencies caused by acts of terrorism involving nuclear, chemical and biological agents. For radiological emergencies resulting from any cause, including accidents at commercial nuclear power plants, this additional stockpile can be acquired ad hoc by State or local government officials if they determine its use would be beneficial.

Commission Decision

On June 26, 1998, the Commission decided to grant the petition for rulemaking.

Accordingly, the NRC staff was directed to proceed with rulemaking to change

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

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

Commission Conclusions or Issues Raised by the Petitioner and Public Commenters

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

A. The Commission agrees that KI, if administered in a timely fashion, could protect the thyroid gland from exposure to radioiodines inhaled or ingested following a major radiological accident. This is the basis for stockpiling it and distributing it to emergency workers and institutionalized persons during radiological emergencies. The petitioner believes that the distribution of KI was inadequate and untimely in the Ukraine and Belarus after the Chernobyl accident in 1986 and that this accounts for the increased incidence of thyroid cancer in these areas. He also argues that distribution of KI in Poland was timely and effective and that no

similar increase in the incidence of thyroid cancer was seen. The Commission considered all of the above information in deciding to grant the petitioner's requested actions.

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

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

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

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

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

Commission approval to fund KI:

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

Findings

Metric Policy

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

ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT

I. Introduction

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

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

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

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

> 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 use of potassium iodide (KI), as appropriate."

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

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

II. Need for Action

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

III. Environmental Impact of the Proposed Action

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

IV. Alternative to the Proposed Action

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

V. Agencies and Persons Consulted

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

VI. Finding of No Significant Impact:: Availability

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

Paperwork Reduction Act Statement

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

It is difficult to estimate the benefit of a State's consideration to stockpile KI. However, we believe the benefit of such an action by the States is summed up by the petitioner who stated that the decision to stockpile KI should turn on whether, given the enormous

consequences of being without KI in a major accident, the drug is a prudent measure; not on whether it will necessarily pay for itself over time. As the petitioner further noted, KI represents a kind of catastrophic-coverage insurance policy offering protection for events which, while they occur only rarely, can have such enormous consequences that it is sensible to take special precautions, especially where, as here, the cost of such additional precautions is relatively low.

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

The above constitutes the regulatory analysis for this action.

Regulatory Flexibility Certification

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

Backfit Analysis

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

> . . . the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility, any of which may

result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position . . . .

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

The proposed rule imposes no new requirements on licensees, nor does it alter procedures at nuclear facilities. Rather, it is directed to *States* or local governments -- the entities with the authority to determine the appropriateness of the use of KI for their citizens -- calling upon the governments to "consider" KI as one of the elements of their offsite emergency planning. Even as to states or local governments, it imposes no binding requirement to alter plans and procedures. Furthermore, the basic standard that emergency planning must include consideration of a range of protective actions, is already set forth in the existing wording of section 50.47(b)(10). On this basis, the proposed rule in reality does not impose new requirements on anyone. On a consideration of all of the above factors, no backfit is involved and no backfit analysis is required.

Commission precedent also makes clear that the proposed rule change does not constitute a backfit. The Commission's position was stated explicitly in 1987, when the last major change took place in emergency planning regulations. 52 FR 42078 (Nov. 3, 1987). The Commission's final notice of rulemaking on this rule involving the "Evaluation of the Adequacy of Off-Site Emergency Planning for Nuclear Power Plants at the Operating License Review Stage Where State and Local Governments Decline to Participate in Off-Site Emergency Planning" stated that the emergency planning rule change in question "does not impose any new requirements on production or utilization facilities; it only provides an alternative method to meet the Commission's emergency planning regulations. The amendment therefore is not a backfit under 10 CFR 50.109 and a backfit analysis is not required." 52 FR at 42084. Likewise, when the Commission altered its emergency planning requirements in 1987 to change the timing requirements for full participation emergency exercises (a change that, as a practical matter, could be expected to result in licensees' modifying emergency preparedness-related procedures to accommodate exercise frequency changes), it stated: "The final rule does not modify or add to systems, structures, components or design of a facility; the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct, or operate a facility. Accordingly, no backfit analysis pursuant to 10 CFR 50.109 is required for this final rule." 52 FR 16828 (May 6, 1987). The instant proposed emergency planning rule change is of a similar nature and similarly does not involve a backfit.

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

could result in some voluntary action by the licensee to coordinate its planning, the proposed rule itself does not impose any requirement or burden on the licensee. Accordingly, the Commission concludes that the proposed rule, if adopted, would not impose any backfits as defined in 10 CFR 50.109.

List of Subjects

10 CFR Part 50

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

For the reasons set out in the preamble and under the authority of the Atomic Energy Act for 1954, as amended, the Energy Reorganization Act of 1974, as amended, the National Environmental Policy Act of 1969, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendment to 10 CFR Part 50.

PART 50--DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

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

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

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951, as amended by Pub. L. 102 - 486, sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851). Sections 50.10 also issued under secs. 101, 185, 68 State. 936, 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L. 91 - 190, 83 Stat. 853 (42 U.S.C. 4332). Section 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections

50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80, 50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

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

§ 50.47 Emergency plans.

* * * * *

(b) * * * * *

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

* * * * *

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

For the Nuclear Regulatory Commission.

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John C. Hoyle
Secretary of the Commission