

ATTACHMENT 1
REFERENCES SUPPLIED TO STATES

December 20, 2001

Kirksey E. Whatley, Director
Office of Radiation Control
Alabama Department of Public Health
The RSA Tower, Suite 700
P.O. Box 303017-3017
Montgomery, AL 36130-3017

Dear Mr. Whatley:

As you know, the Nuclear Regulatory Commission (NRC) has amended its emergency planning regulations to require that States consider including the prophylactic use of potassium iodide (KI) as a protective measure for the general public in the plume exposure pathway Emergency Planning Zone (EPZ) (66 FR5427, January 19, 2001). The use of KI would serve as a supplement to sheltering and evacuation. Subject to available funding, the NRC will provide an initial supply of KI for States that choose to incorporate KI for the general public in their emergency plans. The term "States" includes local governments that have been designated by the State to request such funding.

The NRC, in coordination with the Federal Emergency Management Agency (FEMA) and the Food and Drug Administration (FDA), is developing the means to provide KI to States. Within approximately 30 days, the NRC should be able to supply KI to States upon written request.

If Alabama concludes that incorporating KI for use by the general public is appropriate, you may request the NRC to provide KI by writing to Kathy Halvey Gibson, Chief, Emergency Preparedness and Health Physics Section, U.S. NRC, Washington, D.C. 20555. Your letter must provide the following information: the nuclear power plant (NPP) site(s); the population in the NPPs' 10-mile EPZ for which you are responsible; the contact person authorized to receive the KI; and the "Ship to" address for KI delivery. Upon receipt of this information, the NRC will validate the data and make arrangements for NRC's contractor to ship KI directly to your designated contact/address. The NRC will supply two KI tablets for each person in the 10-mile EPZ(s). You may also fax your request to (301) 415-2968.

We request that one request for KI be submitted for each State or Native American government. If decisions about emergency planning and the use of KI are the responsibility of local, rather than State authorities, we request that the State consolidate the local requests and forward the consolidated request covering all NPPs within the State to the NRC.

The following information is enclosed to this letter for your consideration and use: FDA guidance on use of KI (Enclosure 1); FEMA guidelines for KI program implementation (Enclosure 2); NRC Statements of Consideration published in support of the final KI rule (Enclosure 3); and NRC Disclaimer (Enclosure 4). A revision to the KI Federal policy will be issued shortly and will be provided to you when it is available. States are encouraged to begin their process for considering the use of KI as early as possible, recognizing that the NRC's resources for this purpose will be limited. NRC will provide KI to requesting States on a first come, first serve basis.

If you have questions or require assistance in this matter, please contact either Kathy Halvey Gibson, NRC, 301-415-1086 or Vanessa Quinn, FEMA, 202-646-3664.

Thank you for your consideration of this important issue.

Sincerely,

/RA/

Paul H. Lohaus, Director
Office of State and Tribal Programs

Enclosures:
As stated

Attachment 2:
FEMA Guidelines For Potassium Iodide Program Implementation
For the Use of Potassium Iodide by the General Public

CONTENTS:

FEMA Guidance on the Use of Potassium Iodide by the General Public for Commercial Nuclear Power Plant Accidents

Plan Review Requirements Regarding the Use of Potassium Iodide by the General Public

FEMA GUIDANCE ON THE
USE OF POTASSIUM IODIDE BY THE GENERAL PUBLIC
FOR COMMERCIAL NUCLEAR POWER PLANT ACCIDENTS

The Federal Emergency Management Agency (FEMA) believes that potassium iodide (KI) can be an effective supplement to sheltering and evacuation in the unlikely event of a release of radioactive iodine as a result of a commercial nuclear power plant accident.

The decision to include KI in the range of public protective actions rests with the States. FEMA is available to assist States with the decision making process and has developed a decision matrix to aid in that process. There are two basic methods of distribution: (1) pre-distribution to the public and (2) stockpiles in facilities such as reception or mass care centers. Based on the distribution method adopted by a State, the capability to implement the decision will be evaluated by FEMA as part of its "Reasonable Assurance Finding" recommendation to the NRC.

The evaluation of a State's capability to distribute KI to the general public can be achieved through the Annual Letter of Certification, when KI is pre-distributed, and/or a combination of Staff Assistance Visits and biennial exercise demonstrations, when KI is in a fixed facility.

If a State chooses to include KI in its range of public protective actions, we recommend that the State immediately prepare a procedure as to how it would disseminate the KI, if needed. The State must complete and submit revised plans and procedures, public information materials, and prescribed emergency instructions to the public by the end of the calendar year in which the State submits an application for the receipt of KI. Because States are not required to have their emergency plans revised prior to receipt of KI tablets, the tablets should be stored in convenient locations for ad hoc distribution, should that become necessary.

The capability to distribute KI tablets to the general public will be demonstrated by all

Offsite Response Organizations (ORO) during the first exercise following the submission of plans and procedures (but no sooner than 90 days); and, thereafter, OROs will demonstrate their capability as specified in the frequency of demonstration table for the evaluation areas.

ORO's will address any issues regarding the distribution of KI to the general public in their Annual Letter of Certification, including the number of KI tablets issued or reissued during the previous year. Specific plan review requirements are attached.

**PLAN REVIEW REQUIREMENTS
REGARDING THE USE OF POTASSIUM IODIDE
BY THE GENERAL PUBLIC**

The plans and procedures submitted by the States need to:

- Address legal authority
 - Identify the person with the legal authority to make the decision to recommend the ingestion of potassium iodide (KI) by the general public
- Assign responsibility for implementing the KI decision
- Specify decision criterion (projected dose, actual release data)
- Identify eligibility criteria for issuance
- Describe the distribution method (pre-distribution to resident population only, distribution at an Offsite Response Organization [ORO] facility, or distribution to a special segment of the population only)
- Specify procedure to determine the quantity of pills needed
- Specify procedure to ensure that the supply of KI is sufficient for the Emergency Planning Zone population, including the estimated transient/seasonal population, that may be advised to take KI
- Identify ORO procedures to request, store, monitor and safeguard, dispense (to include, if applicable, tracking who received the drug, when, in what quantity and maintenance of waivers from liability), and dispose of KI stocks
 - Provisions should include the availability of adequate quantities, storage, and means of the distribution of radioprotective drugs (NUREG 0654/FEMA-REP-1, Rev.1 Planning Standards E, J, and N)
 - Available supplies of KI are within the expiration date indicated on KI bottles or blister packs or there is appropriate documentation extending the shelf life
- Describe the method to alert and notify the general public of the decision to recommend that they ingest KI
 - ___ Review Alert and Notification system
 - ___ Review and approve pre-scripted Emergency Alert System message and/or news advisories
 - ___ Review and approve public education materials to include brochures, calendars, newspaper inserts, telephone book inserts

Checklist for items covered in the instructions:

_____ Groups and location of people advised to take KI

- _____ Reason for taking KI
- _____ Dosage and time period within which KI should be taken
- _____ Information on where KI can be obtained or how it will be distributed
- _____ Possible side effects (Check with your doctor before taking KI)
- _____ Other (Specify)_____

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Rules and Regulations

Federal Register

Vol. 66, No. 13

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150-AG11

Consideration of Potassium Iodide in Emergency Plans

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its emergency planning regulations governing the domestic licensing of production and utilization facilities. The final rule requires that consideration be given to including 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) submitted by Mr. Peter G. Crane concerning the use of KI in emergency plans.

EFFECTIVE DATES: April 19, 2001.

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: Section 50.47 of the Commission's regulations establishes requirements for emergency plans for nuclear power reactors to provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. Section 50.47(b) contains 16 planning standards, and in particular, § 50.47(b)(10) requires that

emergency plans include "a range of protective actions" for the plume exposure pathway emergency planning zone (EPZ) for emergency workers and the public. This provision does not identify specific protective actions that must be included in these emergency plans.

The Petitioner's Requested Amendment to the NRC Regulations

On November 27, 1995 (60 FR 58256), the NRC published a document announcing the receipt of a petition for rulemaking (PRM 50-63) filed by Mr. Peter G. Crane on his own behalf and requested public comment on the suggested action. In the original petition (PRM 50-63), 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. 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 stated prevents thyroid cancer after nuclear accidents.

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

(10) A range of protective actions *including sheltering, evacuation and prophylactic use of iodine* 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 September 9, 1995, petition (PRM 50-63), the petitioner stated that he believes that if his proposed rule change is adopted, the plan will become an accurate description of emergency preparedness for radiological emergencies; the recommendation of the Kemeny Commission to stockpile KI will at last be implemented; and the United States will be in compliance with the International Basic Safety Standards.

On November 11, 1997, the petitioner submitted a revision to his original petition (PRM 50-63A). In the revised petition, the petitioner requested that 10 CFR 50.47(b) be amended to read: (10)

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

The petitioner also provided a marked-up version of the NRC staff's proposed Federal Radiological Preparedness Coordinating Committee (FRPCC) Federal Register document concerning a revision to the Federal policy relating to the use of KI by the general public. The NRC published a document announcing the receipt of the amended petition on December 17, 1997, (62 FR 66038) and requested public comment on the amended petition.

As part of the petitioner's comments on the proposed rule, the petitioner also stated that his original petition was incorporated by reference and resubmitted because the amended petition was based in part upon the June 30, 1997, Commission decision to fund State supplies for those States that request it.

The petitioner also requested in PRM 50-63 that the NRC, either on its own or jointly with other agencies, issue a policy statement declaring that KI stockpiling is a sensible and prudent measure necessary to assure 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.

Commission Action Concerning the Petitions

By staff requirements memorandum (SRM) dated June 26, 1998, to SECY 98-061, "Staff Options for Resolving a Petition for Rulemaking (PRM 50-63 and 50-63A) Relating to 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," the Commission decided to grant the revised petition for rulemaking (PRM 50-63A). 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.

By SRM dated April 22, 1999, to SECY 98-264, "Proposed Amendments to 10 CFR 50.47; Granting of Petitions for Rulemaking (PRM 50-63 and 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 Commission voted to approve publication in the **Federal Register** of a [7590-01-P] proposed rule that would grant in part both the original petition (PRM 50-63) and the revised petition for rulemaking (PRM 50-63A). The proposed rule was published for public comment on June 14, 1999 (64 FR 31737). That notice provides greater detail concerning the basis for the petition and the NRC's rationale for the proposed rule language put forth for comment.

Other Activities Related to the Rulemaking on KI

In its decision on June 30, 1997, the Commission endorsed the Federal offer to fund the purchase of KI for States at their request. On June 26, 1998, in a decision on this rulemaking petition, the Commission again noted that the Federal government (most likely the NRC) is prepared to fund the purchase of a stockpile of KI for the States, upon request.¹ However, in its April 22, 1999, SRM, the Commission decided: (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 purchase and resupply of the regional KI stockpiles to the extent that this cannot be covered by FEMA under its initiatives. The Commission determined that notwithstanding the June 30, 1997, and June 26, 1998, intention that "most likely the NRC" would fund the purchase of State stockpiles of KI, NRC was not prepared to fund State stockpiles of KI absent Congressional funding specifically for this purpose.

The Federal Radiological Preparedness Coordinating Committee (FRPCC) is responsible to coordinate all

Federal responsibilities for assisting state and local governments in emergency planning and preparedness for peacetime radiological emergencies. Federal agencies which participate in the FRPCC include (among others): the Federal Emergency Management Agency (FEMA), NRC, the Environmental Protection Agency (EPA), and the Department of Health and Human Services (HHS). The 1985 Federal Policy recommends the stockpiling or distribution of KI during emergencies for emergency workers and institutionalized persons, but does not recommend requiring pre-distribution or stockpiling for the general public. In parallel with petitioning the NRC for rulemaking, Mr. Crane requested that the FRPCC policy be reconsidered. In early 1996, the FRPCC convened a subcommittee on Potassium Iodide. The subcommittee recommended the following to the FRPCC regarding the Federal KI policy: (1) Without changing the Federal policy that it is the State's prerogative to make its own decisions on whether to use KI, the Federal Government (NRC through FEMA), should fund the purchase of a stockpile for a State that, hereafter, decides to incorporate KI as a protective measure for the general public; (2) the language in the 1985 policy should be softened to be more flexible and balanced, as for instance, rewording it to state "it [potassium iodide for use by the general public] is not required, but may be selected as a protective measure at the option of the State or, in some cases, local governments;" and (3) local jurisdictions that wish to use KI should consult with the State to determine if the arrangements are appropriate. If local governments have the authority or secure the approval to incorporate KI as a protective measure for the general public, they would need to include such a measure in their emergency plans.

On June 16, 1997, the NRC staff forwarded to the Commission a staff version of the FRPCC-proposed Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant. In its SRM of June 30, 1997, the Commission endorsed the Federal offer to fund the purchase of KI for States. On June 26, 1998, the Commission directed that the FRPCC proposed Policy be modified to include a statement to the effect that State and local decision makers, provided with proper information, may find the use of KI as a protective supplement is reasonable and prudent for specific local conditions. As noted above, the Commission also reiterated its endorsement of the Federal offer to fund

KI stockpiles for States. Subsequently, on April 22, 1999, the Commission directed the staff to amend the draft FRN on the Federal KI Policy to conform to the Commission decision on the petitions for rulemaking, and the decision not to fund State KI stockpiles.

On April 29, 1999, the Director of FEMA, Mr. James Lee Witt, forwarded a letter to the Commission commenting on the issue of funding of stockpiles of KI for States. The letter objected to the Commission's "unilateral" decision on funding, and also noted "FEMA has always opposed the notion that Federal regional stockpiles of KI would be effective [and believes that] regional stockpiles would complicate, not strengthen radiological emergency preparedness." FEMA believes that if a State opts to use KI as a supplemental protective measure, the NRC should provide the funds for such a purchase.

The NRC responded to Mr. Witt's letter on June 15, 1999. This letter noted the Commission's decision not to fund state stockpiles of KI as well as the reasons underlying that decision. The letter 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 staffs, working together would successfully resolve the KI supply issue. The status of the stockpile and funding issues are discussed later in this notice. NRC is working closely with the other Federal agencies to determine appropriate changes to the 1985 policy. A decision regarding policy changes will be reached after the conclusion of this rulemaking.

In accordance with a Memorandum of Understanding between NRC and FEMA, NRC sent draft versions of this **Federal Register** notice to FEMA for its review and comment. FEMA responded by letter dated January 12, 2000. That letter reiterated their previous comments opposing regional stockpiles and instead favoring NRC funding of State stockpiles. The letter also noted that the development of regional stockpiles of KI had not progressed.

As discussed in the public comment evaluation, the Commission, as part of its decision to grant in full the amended rulemaking petition, has withdrawn its support for the funding of regional KI stockpiles and has reinstated its offer to provide for NRC funding of State or, in some cases, local stockpiles. The Commission agrees to fund a State's

¹ This was in contrast to previous Commission statements, such as those made when the Commission amended its emergency planning regulations (45 FR 55402) on November 3, 1980, wherein the Commission stated that any direct funding of State or local governments solely for emergency preparedness purposes by the Federal government would come through the Federal Emergency Management Agency (FEMA).

stockpile of KI, subject to various restrictions and limitations (see Staff Requirements Memorandum for the Affirmation Session on December 22, 2000). NRC intends to work closely with FEMA and the other Federal agencies in FRPCC to finalize the draft Federal Policy to replace the 1985 Federal Policy. A decision regarding changes to the draft policy will be reached after the conclusion of this rulemaking. The substance of the specific comments attached to the FEMA letter is addressed by the issues in the public comment evaluation.

On September 30, 1998, the Commission also directed the staff to withdraw its guidance document, NUREG-1633 and substantially revise it, in a number of respects, including an improved discussion on how the practical problems in KI stockpiling, distribution and use are handled by States and other nations who use KI as a supplement. To accomplish this task, the NRC formed a KI Core Group, consisting of representatives from those States that have KI as a supplemental protective action, the Conference of Radiation Control Program Directors, the National Emergency Management Association, the U.S. Food and Drug Administration (FDA), EPA and FEMA. The revised draft guidance document, NUREG-1633, "Assessment of the Use of KI as a Supplemental Protective Action During Severe Reactor Accidents", Rev. 2 is expected to be issued for comment following receipt of the FDA's draft revised position on exposure action levels and proper dosage of KI which was issued for public comment on January 4, 2001 (66 FR 801).

In addition, the NRC plans to develop a public information brochure concerning the use of KI by the general public following completion of the final NUREG.

Public Comment Evaluation

On November 27, 1995 (60 FR 58256), the NRC announced the receipt of the original petition for rulemaking (PRM 50-63), and requested public comment on the suggested rule amendment. A total of 65 comment letters were received.² 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 opposed to the petition came from 20 utilities, 9 State governmental agencies, 2 utility interest organizations,

a letter signed by 12 health physicists, 2 State university medical centers and 1 member of the public.

On December 17, 1997 (62 FR 66038), the Commission published a request for public comment on the amended petition (PRM 50-63A) 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. The 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, one State Representative, FEMA, the American Thyroid Association, a KI manufacturer, and the US Pharmacopeia Convention. Fourteen utilities, 3 State government agencies, 1 utility interest association, and 2 members of the public opposed the petition for rulemaking. A detailed analysis of the issues raised by the public comments with the response to those issues was published in the June 14, 1999, proposed rule **Federal Register** notice.

On June 14, 1999 (64 FR 31737), the Commission published a proposed rule in the **Federal Register**, based on the revised petition for rulemaking (PRM 50-63A) and requested public comment by September 14, 1999. A total of 77 comment letters were received.³ The letters in favor of the proposed rulemaking and the revised petition for rulemaking originated from a United States Senator; a member of the U.S. 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. The FEMA letter of April 29, 1999, was submitted before the rule was published and discussed KI stockpiles. 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 in emergency planning. These letters originated from members of the public as well as public interest groups. As part of the petitioner's comment letter dated August 17, 1999, on the proposed rule the petitioner stated that, in light of the Commission's decision not to fund state stockpiles of KI, 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.

The following discussion addresses the significant comments and issues raised in the three public comment periods for the original and amended petitions for rulemaking and the proposed rule.

Issue A: Should KI Be Considered as a Supplemental Protective Action to Evacuation and Sheltering

Several commenters on the proposed rule state that the rulemaking would not add significant public health and safety benefit beyond the current emergency plans, because evacuation and sheltering are the best means to protect the public in the event of a radiological emergency. According to these commenters, evacuation and sheltering are more effective at dose reduction because they reduce dose to all organs, not just to the thyroid.

Other comments express the view that the Chernobyl experience (including use of KI in Poland) shows that (1) thyroid cancer is a major result of reactor accidents, (2) the exposure can continue for days and thus the institution of KI blocking at any time is beneficial, (3) deployment of KI is safe, and (4) shelf life is extremely long. These commenters note that EPA Manual [Manual of Protective Action Guides and Protective Actions for Nuclear Incidents, EPA-400-R-92-001 (May 1992)] quotes the FDA as stating that potassium iodide "will have substantial benefit even if it is taken 3 or 4 hours after acute exposure." Thus, these commenters believe that the advantage of having a supply of KI on hand outweighs moderate cost and that KI should be a supplemental protective action. Further, these commenters note that just because there may be other radionuclides to which people are exposed is not a reason to deny them the availability of KI.

Commenters who favor the use of KI as a supplemental protective action conclude that evacuation and sheltering alone may not be sufficient safety actions in the event that evacuation is not feasible. They state that natural

² Two letters that were received in response to the notice did not address the issues in the petition and are not discussed further.

³ Three of the letters (those from FEMA, the senator and the congressional representative) were not submitted during the comment period in response to the notice, but are being treated as comment letters for purposes of this discussion.

disasters could occur that would make evacuation difficult and time consuming at best, as for instance, earthquakes, hurricanes, blizzards, and ice storms. According to these commenters, a point against strong reliance upon evacuation is the evacuation routes themselves. As an example, a commenter cites the area around the Seabrook Nuclear Plant, noting that during the summer tourist season especially, it can be predicted that evacuees will be forced to wait in traffic for great lengths of time. This commenter believes that if KI were predistributed, instances of cancer, hypothyroidism and other thyroid disorders might be avoided.

Response. The Commission recognizes evacuation to be the most effective protective measure to be taken in the event of a radiological emergency because it protects the whole body (including the thyroid and other organs) from all radionuclides and all exposure pathways. The Commission recognizes that there may be situations when evacuation is not feasible or is delayed. In-place sheltering is an effective protective action in such a situation. However, it is important to note that the issue is not evacuation or sheltering *versus* KI. Rather, it is evacuation or sheltering *with* KI versus evacuation or sheltering *without* KI. The use of KI is intended to supplement, not to replace, other protective measures. This amendment represents no change in the NRC's view that the primary and most desirable protective action in a radiological emergency is evacuation of the population before any exposure to radiation occurs. Depending on the circumstances, KI may offer additional protection for one radiation-sensitive organ, the thyroid, if used in conjunction with evacuation and sheltering. 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 but the use of KI can be a reasonable and prudent supplement. Therefore, it seems reasonable, while continuing to recognize the role of the State and local governments in matters of emergency planning, to require explicitly that emergency planners consider the use of KI.

Issue B: Is There a Need for New Regulation

Commenters in favor of the proposed rule note that a host of countries—France, Germany, Belarus, Russia, Switzerland, Austria, the Czech Republic, Japan, Great Britain, Sweden, Slovakia, and others—protect

themselves with stockpiles of KI. These commenters point to soaring rates of thyroid cancer appearing in children in the Soviet Union who were exposed to the Chernobyl nuclear accident and who received too little potassium iodide, and too late. Thus, these commenters support the view that there is new information that suggests the need for consideration by State and local governments. In addition, many of these commenters would go further than the proposed rule language and require the use of KI, not just its consideration.

In contrast to the above, letters from some state and local governments, and from utilities, say that the State and local governments have already considered the use of KI. They believe that the petitioner has not provided any compelling reasons why additional Federal requirements are needed or how they would benefit the health and safety of the public. These State and local government commenters reject the view that the States have not had access to sufficient technical information regarding potassium iodide, and that without accurate and current information on KI—including the Chernobyl experience and the consensus of international experts—States cannot make an informed judgment. They conclude that this assertion is without merit, as there has been no shortage of information related to the use of potassium iodide available to State radiological emergency planners, and oppose the implication that State and local governments, absent Federal actions, are incapable of making informed decisions regarding the protection of their citizens during a radiological emergency. One commenter stated that by issuing this rule, the Commission is ignoring the views of States where KI has been stockpiled or pre-distributed, and where experience shows the system is ineffective.

The commenters opposing the proposed rule on this basis also note that reliance on the Chernobyl experience discounts the vast technical, political, and socio-economic differences between the United States and Eastern European countries at the time of the Chernobyl accident. The efficacy of any protective measure will depend on a large number of factors, including but not limited to: the type of reactor involved; accident sequences and timing; source term; timeliness of notification; the manner in which protective action decisions are made and transmitted to the public; the mobility of the public; and the receptiveness of the general public to official instructions. These commenters believe that the above factors have

already been considered by State and local governments in the development of existing emergency response plans.

Response. The Commission did not intend to imply that States are not capable of making informed decisions regarding the protection of their citizens during a radiological emergency. In fact, the final rule calls on offsite authorities to make their own decision on this matter. Additionally, the Commission recognizes that most State and local governments have already considered the use of KI in the event of an emergency as part of their planning. Nevertheless, the Commission believes it appropriate to provide information that may be of aid to offsite authorities in their consideration of this matter. Offsite authorities may, of course, use this information as they see fit.

Several States have welcomed the NRC's efforts in developing information relating to the benefits and risks associated with using KI as a supplemental protective measure for the general public. This information is intended to supplement and update information already available on this subject, including experience from State and foreign governments that have made KI available to the public. As noted earlier, this information will be in a revised NUREG-1633, which is scheduled for publication for comment after the FDA issues its draft guidance and in an information brochure.

The Commission finds that KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering for specific local conditions. Through its decision to require that the use of KI be "considered" (rather than being required), the Commission is acknowledging that the efficacy of any protective measure will depend upon a number of factors, including those noted by the commenter, that can vary not only between countries but in individual States. Thus, the Commission concluded that decisions on the use of KI need to be resolved on a State-by-State basis. As part of this consideration, State and local governments can weigh all relevant factors.

Issue C: The Importance of Information in the Decisionmaking Process Concerning the Public Use of KI

In the proposed rule, the Commission noted that NUREG-1633 was being revised to provide information about experience in the United States and abroad with distribution of KI, and that an information brochure was also being prepared. According to some commenters, distribution of information on the benefits and risks associated with

the use of KI should not be limited to people living within nuclear power plant emergency planning zones. Further, commenters note that a comprehensive public information program outlining the potential range of benefits and risks of using KI and how to employ it most effectively in the event of a radiological emergency would be necessary to allow personal decisionmaking. Making the information and the KI itself available directly to members of the public provides them with the ability to decide for themselves how best to take advantage of the benefits associated with the use of KI as supplementary protection. One vehicle currently used for disseminating regular preparedness information which could be used to provide information on KI is the public information brochures and calendars already required to be distributed annually within each emergency planning zone. In this commenter's view, making information and KI available provides the greatest level of protection for the greatest number of people.

Some State government organizations were concerned that making provisions for KI might give the public a false sense of security that they are fully protected, and that the public might not evacuate. Thus, these organizations believe that there is a need for public information concerning the supplemental role that the use of KI could play.

Several of the commenters stated that it is desirable that the NRC would work with other appropriate Federal agencies to develop and promulgate clear and necessary guidance on the subject, similar to the guidance on sheltering and evacuation. These commenters also believe that the final decision should lie at the discretion of the State and local governments. A few commenters expressed the view that the rule puts the burden of assessment on States who have fewer technical resources than the NRC, the EPA or the FDA.

One commenter thought that the decisionmaking about stockpiling KI must include rigorous assessments to ensure sufficient quantities of KI will be available for distribution to members of the public, in both the plume exposure pathway and the ingestion exposure pathway.

Response. The Commission recognizes that once a State decides to include KI as a protective measure for the general public, it would be up to the State to decide how and when to conduct an educational program on the benefits and risks associated with using KI and to supply KI for appropriate distribution to the general public.

Additionally, the Commission agrees that more detailed guidance on the use of KI would be useful in assisting States to assess the merits of stockpiling KI for the general public, including logistics, amounts and public information needs. The Commission has formed a KI "Core Group" consisting of representatives of State, local, and Federal agencies whose responsibility is to develop clear guidance relating to the use of KI. This guidance (NUREG-1633, Rev. 2) should be published for comment after FDA issues its draft guidance, which was issued for public comment on January 4, 2001 (66 FR 801). The NRC is continuing to work with other Federal agencies through the FRPCC to coordinate government policies concerning radiation protection and emergency planning. Further, a public information brochure to be published later will assist States and individuals in making an informed decision on KI.

Issue D: Making KI Available to the General Public

A range of comments were submitted concerning ways by which KI could be made available to the general public in the event of a radiological emergency. Many commenters simply asked NRC to "make KI available" without further detail. In the proposed rule, the NRC discussed Federal stockpiles of KI as part of Federal response to terrorist acts. One commenter indicated that expanding this supply may be the best approach. Another commenter stated that the public is not interested in stockpiles, but instead wants information to make their own decisions. Of those comments related to specific methods of availability, these can be generally grouped into individual availability, State stockpiles in the vicinity of nuclear power plants, or regional stockpiles.

Individual Availability

One State submitted, as part of its comments, a report that discussed a plan they have developed that would allow citizens to gain access to KI in advance of an accident. The plan calls for the State to secure agreements with KI manufacturers to sell the medication directly to individuals or retail outlets, and to urge local pharmacies to stock KI as an over-the-counter drug. Information concerning KI availability and use would be included in the annual emergency information mailings prepared by nuclear power plant staffs and distributed to every property owner within the emergency planning zones. The State concluded that this method would allow individuals to make their own decisions about the use of KI. This

State noted that one can envision this activity being conducted in conjunction with existing programs designed to remind and encourage family members to periodically check home first aid kits, smoke detectors, spare batteries for flashlights and radios, and other items that they might employ for their comfort and protection in the event of any emergency. In addition, one commenter noted that KI is now available via the Internet from at least two vendors at an affordable price. (See also comments above in issue C about decisionmaking.)

State Stockpiles

A number of commenters believe that KI should be stockpiled in schools, fire houses or reception centers near nuclear power plants. These commenters state that this is the advice of the experts, for instance the World Health Organization and Dr. Jean Temeck, from FDA. These commenters believe that the young are the most vulnerable; and, in the words of Dr. Temeck, "in an emergency you want to get it to the children as quickly as possible and the teacher is right there on the spot. * * * You do not need to be medically trained to give KI. A permission slip to administer KI can be sent out by the school at the beginning of each year." Further, it makes sense to these commenters that this time-critical medicine be available nearby, such as in a local school, hospital, or fire-station. Thus, these commenters believe that State stockpiles are appropriate because regional stockpiles will not adequately protect the public since KI must be taken prior to exposure, or very shortly thereafter (within about six hours), to be an effective blocking agent.

Regional Stockpiles

A number of commenters, including emergency preparedness and response officials and FEMA, are concerned about the regional stockpiling and distribution process and its potential for reducing the effectiveness of measures which will provide much greater protection to the public. In their view, the complex logistics of storage and distribution of regional stockpiles far outweigh the usefulness of such a stockpile and that regional stockpiles of potassium iodide would complicate, not strengthen radiological emergency preparedness. These commenters believe regional stockpiling has disadvantages as compared to State stockpiling. The administration of KI is time-critical and regional stockpiling means critical time will be spent transporting the drug from a regional stockpile to the area where it is needed. For these reasons, they believe that

regional stockpiles should supplement, not substitute for State stockpiles.

Response. If a State decides to use KI as a supplemental protective measure, the Commission agrees that the State should focus on the early administration of KI to children. A decision to make KI available to the general public will require some planning by the State for its own supplies of KI and methods of distribution. Such planning (for implementation of protective actions) is a normal part of a State's emergency planning activities. As noted earlier, the NRC plans to issue a guidance document (NUREG-1633) to assist the States. The Commission recognizes the logistical challenges associated with the distribution of KI to the general public. For this reason, the staff intends to include a discussion of experience with KI distribution in the United States and abroad in the guidance document NUREG-1633.

There are different approaches that a State can use in incorporating KI as a supplemental protective measure for the general public. One approach is that mentioned by a commenter to distribute information about the over-the-counter availability of KI. Making KI available over the counter would provide members of the public with the opportunity to decide for themselves if they wanted to store and use KI. In fact, some KI manufacturers have indicated that they would make KI available to any person who requests it, at a fee. This approach would minimize the need for State stockpiles or predistribution and would put KI in the hands of the public before an accident occurs, rather than attempting to distribute the KI from stockpiles after an emergency is declared.

The concerns about the effectiveness of regional stockpiles for rapid deployment of KI to the public are also acknowledged. FEMA has stated that in its view, regional stockpiles will not enhance local radiological emergency preparedness because of complex logistics. The Commission agrees. As part of its decision on this final rule, the Commission has decided to provide funding for a supply of KI for States that request such funding through FEMA and to discontinue support of regional stockpiles. The Commission believes that in light of logistic difficulties, it is doubtful that regional stockpiles of KI could be effectively employed in the unlikely event of a radiological emergency at a commercial nuclear power plant.

Issue E: Requiring versus Considering Use of KI

Several commenters thought that the proposed rule should be modified to require the use of KI, not just the consideration by State and local officials. These commenters believe, for instance, that the tragic comedy of errors surrounding attempts to distribute KI in the wake of the Three Mile Island partial core melt accident only serves to highlight the need for pre-distribution. The health of our children is too important to leave their protection to the consideration of states. These commenters ask that if the U.S. system is adequate, why do other industrialized nations believe that sheltering and evacuation alone are insufficient? Some of these commenters want all commercial reactor licensees to distribute KI to all individuals within the EPZ and to make KI available to anyone within a 50-mile radius of the reactor upon request. These commenters believe that the prophylactic use of KI for the general public should be a *mandatory* emergency planning requirement and should not be merely an optional consideration, because, if given the choice, many States may not adequately protect their citizens. Another reason cited for wanting NRC to require KI is that "without a federal mandate for stockpiling KI, the nuclear industry will simply shift its fight against the policy to the State and local levels."

Response. Because the Commission believes that current emergency planning and protective measures—evacuation and sheltering—are adequate and protective of public health and safety, the Commission will not *require* use of KI by the general public. Rather, the Commission recognizes the *supplemental* value of KI and the prerogative of the State to decide on the appropriateness of the use of KI by its citizens. The Commission believes the final rule together with the Commission's decision to provide funding for the purchase of a State's supply of KI strikes a proper balance between encouraging (but not requiring) the offsite authorities to take advantage of the benefits of KI and acknowledging the offsite authorities' role in such matters.

The use of KI is intended to supplement, not to replace, other protective measures. This rule change thus represents no alteration in the NRC's view that the primary and most desirable protective action in a radiological emergency is evacuation of the population before any exposure to radiation occurs. The Commission

recognizes that there may be situations when evacuation is not feasible or is delayed. In-place sheltering is an effective protective action in such a situation. Depending on the circumstances, KI may offer additional protection to one radiation-sensitive organ, the thyroid, if used in conjunction with evacuation and sheltering. In addition, the Commission notes that issues surrounding the prophylactic use of KI following such accidents do not lend themselves to across-the-board solutions. Therefore, the Commission has chosen to leave this decision to State and local emergency response planners, who may find that KI should be a supplementary protective measure, rather than to mandate its use. Additionally, the Commission's amendment to require explicitly that planners consider the use of KI, rather than require the use of KI, recognizes the important role of the States and local governments in matters of emergency planning and the use of medicinal protective measures by their citizens.

Issue F: Funding

Some commenters, including FEMA, state that the recent decision of the Commissioners *not* to fund the purchase of KI is an unfortunate reversal to the goal of providing supplementary protection for the general public. Thus, citing the Chernobyl accident, they urge the Commission to reconsider its position in light of the proven usefulness of KI in preventing childhood thyroid cancer. One State commenter was concerned that after two years of efforts made toward implementing this supplementary protection, the Commission's recent actions undermine that State's effort. While understanding the Commission's financial concerns leading to this decision, this commenter proposed that the Commission could approach Congress for a supplemental appropriation.

Another commenter stated that the Commission's withdrawal of the offer to pay for State KI stockpiles sends a message that KI preparedness is not important, and that States who were considering plans to establish stockpiles have dropped such plans. Further, some commenters believe that the NRC reversal of position regarding funding of KI for States that elect to stockpile it adversely affects the implementation of the policy proposed by the Federal Radiological Preparedness Coordinating Committee (FRPCC). [That draft policy currently provides that if a State chooses to add KI as a supplement to its evacuation and sheltering protective

actions, the State will inform FEMA, which will forward the request to the NRC for payment.] Another commenter noted that the Kemeny Commission supported stockpiling KI, and that the Commission should fulfill an earlier NRC commitment to do so.

Several States expressed the view that the requirement that use of KI be considered is an unfunded State mandate and is contrary to an Executive Order of 8/5/99.

A number of commenters stated that they thought the utilities should pay for supplies of KI in the vicinity of the power plants. Some utilities expressed concern that the rulemaking might result in requests to the utilities from State and local organizations for such funding.

Response. The Commission decision not to fund State stockpiles has been reversed as the result of public comment on this rulemaking. Promulgation of this final rule underscores the Commission's views on the importance of emergency preparedness, including consideration of the use of KI. The Commission has decided to fund State and, in some cases, local stockpiles of KI, subject to certain restrictions and limitations (see Staff Requirements Memorandum for the Affirmation Session on December 22, 2000). The Commission believes that in light of logistical difficulties, it is doubtful that regional stockpiles of KI could be effectively employed in the unlikely event of a radiological emergency at a commercial nuclear power plant. The Commission's offer to fund the purchase of a supply of KI for a State choosing to use KI prophylaxis as a supplemental protective measure retains the FRPCC's proposal that the State remain responsible for all other funding connected with the incorporation of KI, such as preparing guidelines for its stockpiling, maintenance, distribution and use, and for all other ancillary costs.

The Commission agrees that, in the past, licensees may have found it in their own self interest to assist State and local governments by providing resources for emergency planning needs. The Commission expects that those States who decide to use KI for the general public will make suitable arrangements to fund costs other than the initial purchase of a supply of KI. After funding the initial purchases of KI, the Commission may consider extending the program to fund stockpile replenishment, but has made no commitments in this regard. As with other aspects of offsite emergency planning, the NRC will not require licensees to fund State activities, but the

States can, of course, act in cooperation and coordination with licensees.

As to the issues whether the rule constitutes an "unfunded State mandate" or is contrary to an Executive Order of August 5, 1999, the Nuclear Regulatory Commission, as an independent regulatory agency, is not subject to the requirements of Title II of the Unfunded Mandates Reform Act of 1995 or Executive Order 13132, "Federalism," August 5, 1999.

Issue G: Whether This Rulemaking Is a Backfit

A commenter representing nuclear utilities raised a concern that if licensees would be required to expend significant resources in considering the use of KI in emergency plans, then the proposed rule is clearly a backfit and a backfitting analysis should be performed. Thus, the commenter requested that the NRC either limit the specific actions which would be required to be taken by licensees to demonstrate that the adequate consideration required by the proposed rule has been implemented, or the required backfitting analysis should be conducted and a suitably revised proposed rule should be published for comment.

Response. This notice contains a "Backfit Analysis" section, which notes that the Commission concludes that the 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 responsibility 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. The final rule imposes no binding requirement for State or local governments to alter emergency 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 § 50.47(b)(10). Once again, the rule does not impose new requirements on nuclear power plant licensees who are the intended beneficiaries of the Backfit Rule provisions. Therefore, no backfit is involved.

Issue H: State Liabilities in Providing KI for the General Public

State and local government organizations raised concerns about legal implications should a member of the general public be given KI at their directive or recommendation and the individual has an extreme allergic reaction. Commenters note that the

Federal Register notice does not address legal issues for States who decide to adopt KI and for States who do not decide to adopt or administer KI to the public. Further, if the NRC decides to require stockpiling of KI for the general public, the commenters ask whether NRC has considered what liability may arise from any adverse health effects. Another concern was about who would assume liability if the KI was used prior to a Governor ordering its use.

Response. These 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. As stated in the proposed rule FR notice, the question of whether a State or 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 as a result of promulgation of this rule. To the extent that commenters are raising the potential for Federal government liability for the promulgation of this proposed rule, the proposed rule FRN notes NRC views 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.*, which protects the Federal Government from liability. The Commission's offer to fund State stockpiles would similarly be subject to the "discretionary function" exception. The Commission has directed the staff to ensure that NRC funding for KI is accompanied by appropriate disclaimers to ensure that the NRC and any of its employees are not to be held responsible for any activity connected with transporting, storing, distributing, administering, using, or determining proper doses of KI for adults and children.

Issue I: FDA Input on KI

A few commenters thought that the dosage and intervention levels should be lowered from the values in the existing FDA guidance. For instance, they conclude that NRC should require using KI prophylaxis at one rem projected dose exposure not at the

current 25 rem. It was noted that Poland uses a 5 rem intervention level. The concern of these commenters is that continued use of the old guidance subjects children to greater risk than necessary.

Response. The FDA is the Federal agency responsible for decisions about appropriate thresholds and dosages for use of KI. Existing FDA guidance related to the use of KI on dosage intervention levels is contained in a June 29, 1982 notice (47 FR 28158). As stated therein, "FDA concludes in the final recommendations that risks from the short-term use of relatively low doses of potassium iodide for thyroid blocking in a radiation emergency are outweighed by the risks of radioiodine-induced thyroid nodules or cancer at a projected dose to the thyroid gland of 25 rem." That notice also provides recommended dosages for adults and children. New FDA guidance was published in the **Federal Register** for public comment on January 4, 2001 (66 FR 801). The Commission will incorporate it into its guidance documents.

Issue J: Original Petition Versus Revised Petition

A few commenters state that in the proposed rule, the Commission claims to have granted the alternative submitted in the amended petition, but did not actually do so. In their view, the amended petition contained the combination of three elements—the requirement to consider KI stockpiling, the unequivocal recommendation that States establish stockpiles, and the offer of Federally-funded State stockpiles. Since the promise of funding removed a major impediment to States adopting a pro-KI policy, the commenters believe that the petitioner felt that amending his petition to require only "consideration" of the use of KI would likely result in State decisions favorable to using KI. In their view, the amended PRM was premised on the now-withdrawn NRC offer of Federally-funded State stockpiles of KI, and therefore it would be entirely appropriate for the petitioner to rescind his amendment to PRM 50-63 and to insist that the NRC adopt what was requested in his original petition.

Response. The Commission agrees with this comment. Since the Commission has decided to reinstate its offer to fund a supply of KI for State or, in some cases, local governments that choose to incorporate KI prophylaxis in their emergency plans, the Commission believes that it is granting the amended petition (PRM-50-63A) in all respects.

Issue K: Meaning of "Consideration"

Several commenters stated that the proposed rule is vague in that it did not define "consideration." They believe that the rule should clarify that the KI "consideration" within the context of radiological emergency planning and preparedness needs to be performed only once by the responsible State agency, which would provide written notice of the consideration to the Commission. Thereafter, no further "consideration" should be required unless the State determines there is reason to reconsider its position and that the "consideration" process is not subject to continuing oversight or recurring evaluation by the NRC, or any other federal agency.

Another commenter questioned whether a State that considered the issue in the early 1980s, and rejected the use of KI, could now claim that the Commission's current proposal has already been fulfilled. Reliance upon the earlier consideration would violate the intent of the petitioner's proposal.

Another commenter questioned whether the following scenario would be considered acceptable and in compliance with the rule: a State considered the use of KI, but found the licensee unwilling to pay for it, so the State decided that although use of KI might be a good idea, it couldn't afford it.

Response. The Commission would expect that a State's "consideration" would involve at least an internal review of this notice and brief deliberation on the State's position on the use of KI by the general public. In NRC's experience, States periodically review their emergency plans and preparedness, typically on an exercise frequency basis, to ensure that plans are up to date and account for local changed circumstances. For those States that conduct such periodic reviews, the Commission would expect the States to undertake their "consideration" of the use of KI during the first periodic review conducted by the State of offsite emergency plans and preparedness following the effective date of this rule amendment and issuance of revised NUREG-1633 guidance. For those States that do not routinely conduct periodic reviews, the Commission would expect the States to undertake their "consideration" of the use of KI on the same frequency as periodic emergency preparedness exercises following the effective date of this rule amendment and issuance of guidance. The rule does not require States to provide written notice of their "consideration." The Commission expects that States will

inform FEMA and the NRC of the results of their consideration.

Additionally, the Commission agrees that the "consideration" process is not subject to continuing oversight or recurring evaluation by the NRC or any other Federal agency.

By issuing this rule, the Commission is stating its conclusion that consideration of the use of KI that might have been performed many years ago, needs to be reexamined in light of new information. Thus reliance upon such earlier evaluations would not be consistent with the rule requirement.

Issue L: Federal Distribution of KI

One commenter noted that the Commission's proposed rule would seem to support the same techniques used for forced KI distribution that were dictated by governments in Eastern Europe during the Chernobyl accident. The commenter urged the Commission to consider whether this posture would be endorsed by any government, be it Federal, State, or local. This commenter believes the NRC staff ignores the testimony of those States where KI is stockpiled or pre-distributed for the public and where experience shows the system is ineffective. Additionally, a commenter thought that the proposed rule is predicated on the false assumption that even if States decide not to stockpile KI for the general public, they will have access to Federal reserves of the drug. By the Commission's own admission, such reserves have yet to be established nor has the funding mechanism to support such reserves been identified. The proposal suggests that states "consider" the availability of resources that do not exist.

Likewise, a commenter stated that the proposed rule implies that even when a State decides as a matter of public policy against distribution of KI for the general population, the Federal government will develop plans to override that decision. The purpose of such plans is unclear in the context of the proposed rule. Once a State has given due consideration to the use of KI stockpiling as a supplemental protective action and determined it to be unwarranted, the commenter seeks the basis on which the Commission proposes to develop a contingency plan.

Response. The Commission has never endorsed "forced KI distribution." Under this final rule the use of KI continues to be a State option. Moreover, revised NUREG-1633 will discuss the benefits and risks associated with using KI and the U.S. and foreign experience with public distribution. While the Commission has always

recognized that distribution at the time of an accident will present difficulties if there has been no advance planning, the Commission believes that the States will take the distribution matters into account when they consider the use of KI for the general public under this rule.

The Commission has decided to withdraw its decision to provide funding for regional Federal KI stockpiles. However, it should be noted that Commission efforts in this regard were not intended to "override" a State decision not to use KI during an emergency; rather, they were intended to make KI available in the event that a particular State changed its views and decided to use KI in an actual emergency, and had nowhere else to go for KI. The Commission believes that in light of logistical difficulties, it is doubtful that regional stockpiles of KI could be effectively employed in the unlikely event of a radiological emergency at a commercial nuclear power plant.

Issue M: Importance of Emergency Planning

A few commenters feel that safe siting and Design-Engineered features alone do not optimize protection of the public health and safety and that the Commission should not rely upon probabilistic risk assessments to obviate the need for stockpiling and predistribution of KI. Another commenter is concerned that the premature aging of reactor components, the economics of utility restructuring, and the long-term storage of high-level waste at reactor sites all contribute to the need for KI stockpiling.

Response: The Commission agrees with the importance of emergency planning to complement site and design features and stated so in the August 19, 1980, **Federal Register** Notice (45 FR 55402) which codified the NRC's emergency planning regulations following the Three Mile Island accident: "The Commission's final rules are based on the significance of adequate emergency planning and preparedness to ensure adequate protection of the public health and safety. It is clear * * * that onsite and offsite emergency preparedness as well as proper siting and engineered design features are needed to protect the health and safety of the public. As the Commission reacted to the accident at Three Mile Island, it became clear that the protection provided by siting and engineered design features must be bolstered by the ability to take protective measures during the course of an accident."

The Commission did not rely upon probabilistic risk assessments in developing this final regulation on consideration of the use of KI.

The Commission interprets the third comment to relate to factors that the commenter believes could increase the likelihood of an accident and which, in the commenter's view, heighten the importance of emergency planning. The Commission's regulations recognize the importance of emergency planning by requiring development of a range of protective actions, which include sheltering and evacuation and, by this rulemaking, consideration of the use of KI for the general public.

Issue N: Cost of KI and Shelf-Life

One commenter feels that the NRC has exaggerated the estimated cost of KI, ignoring comments that point to the availability of inexpensive and long-lasting KI. This commenter thinks that market forces are likely to bring down the cost of KI and that savings in the NRC budget could be effected without diminishing the safety of America's children.

The U.S. Pharmacopeia wrote in its comment letter that the long-term viability of the drug was tested and it was found that 11 years after manufacture and eight years after the expiration date, the tablets were assayed at 99.1% of the labeled content of KI. The petitioner expressed the view that since the U.S. is currently engaged in a \$15 million study of radiation-caused thyroid disease in the Ukraine, it was hard to understand why the government was not willing to spend a fraction of that amount to prevent radiation caused thyroid disease at home.

Response. Cost estimates used in past documents were based upon information available at those times. NRC presently estimates the cost of KI to be about 18 to 20 cents per tablet if purchased in bulk, with a shelf life of 7 to 10 years. As a result, the Commission finds that KI is a reasonable, prudent and inexpensive supplement to evacuation and sheltering for the general public for specific local conditions.

As noted earlier, the Commission has decided to offer to provide funding for a supply of KI for State or, in some cases, local governments that choose to incorporate KI prophylaxis in their emergency plans.

Issue O: Safety of KI

Commenters believe that there is new information available from Poland and Belarus regarding use of KI following a radioactive release. They state that there were no reported serious adverse

reactions. Specifically, 18 million individuals received prophylactic KI with overall toxicity of 2.5% (mostly nausea) but with only a fraction of 1% having serious side-effects.⁴ Commenters state that this experience has been recognized by other countries who are stockpiling KI for use by the general public. This data has led some commenters to say that just because there are other lethal radionuclides to which people may be exposed, why deny them the availability of KI, which can counteract the deadly effects of radioactive iodine. Every drug has contraindications and the potential for allergic reactions. In an emergency as dire as a reactor accident where people risk illness and death, a possible adverse reaction to KI seems relatively minimal, and people absolutely should have the choice of making an informed decision and assuming possible risk.

Response. The Commission did consider the experience with mass distribution of KI during the Chernobyl radiological emergency (although the record on that distribution is not complete). That experience is still being investigated and evaluated by public health authorities worldwide. When the appropriate health agencies have established the applicability of the Polish experience to the United States, the findings will be followed in NRC guidance. The NRC acknowledges that KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering for specific local conditions. The Commission guidance on emergency planning has long taken KI into consideration (see NUREG-0654/FEMA-REP-1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," Rev. 1, p. 63, items e and f). The FDA has approved KI as an over-the-counter medication and has found it effective and safe as discussed in the response to issue I.

Commission Decision on the Petitions for Rulemaking

Based on the foregoing, and as noted herein, the action by the Commission to approve this final rule grants in part and denies in part the original petition (PRM 50-63) and grants in all respects the amended petition (PRM 50-63A). The rule change, which requires "consideration" of the use of KI, is responsive to the amended petition. Further, including in this **Federal Register** notice for the final rule, a

⁴ Comment letter from the Massachusetts Coalition To Stockpile KI dated September 10, 1999.

statement that "KI is a reasonable, prudent, inexpensive supplement to evacuation and sheltering for specific local conditions," is also responsive to both petitions. This statement does not use the petitioner's exact language but is responsive to the petitioner's request. The Commission's final position on funding of State stockpiles grants that part of the original and amended petition to include a statement of such support in the Statement of Considerations for the rule. However, the final rulemaking would deny that part of the original petition requesting that the Commission 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.

The Commission has found that "[I]n developing the range of actions for severe accidents at nuclear power plants, evacuation and sheltering provide adequate protection for the general public." (Proposed Rule, 64 FR at 31745). In addition, the Commission notes that issues surrounding the prophylactic use of KI following such accidents do not lend themselves to across-the-board solutions. Therefore, the Commission has chosen to leave such decisions to State and local emergency response planners to determine whether their emergency plans should include the use of KI as a supplementary protective measure for the general public. The Commission's decision is implemented through this final rule that changes 10 CFR 50.47(b)(10). This final rule completes NRC action on PRM 50-63 and PRM 50-63A.

Rationale for the Commission Decision

The Commission has considered the KI policy question on numerous occasions since 1984. The history of the Commission deliberations shows that reaching consensus on this policy question has been an elusive goal. An important reason for this historical lack of consensus is that this policy question is not a clear-cut one. Individual Commissioners, past and present, have differed in their views with respect to the relative importance to be given to factors bearing on the KI issue. These honest differences have led to divided Commission views on how to resolve the policy question. The Commission agrees that its historical difficulty in reaching consensus on the KI policy question underscores the reality that this policy question is not a simple one, is not one that is easily resolved and, as a result, has been the subject of protracted deliberation.

After 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 amend 10 CFR 50.47(b)(10), by adding a sentence similar to the one suggested in the revised petition. Specifically the following sentence is inserted in § 50.47(b)(10), 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 finds that KI is a reasonable, prudent and inexpensive supplement to evacuation and sheltering for specific local conditions. The Commission's guidance on emergency planning has long taken KI into consideration (NUREG-0654/FEMA-REP-1, Rev. 1, p. 63, items e and f). However, since the last revision of that guidance, there has been experience with the mass distribution of KI during an international radiological emergency, and though the record on that distribution is not complete, the indications thus far are that mass distribution is effective in preventing thyroid cancer and causes few threatening side effects. Moreover, many nations in Europe and elsewhere—nations as different in their circumstances, politics, and regulatory structures as France, Canada, and Japan—have stockpiled KI and planned for its use. So have some U.S. States. The World Health Organization and the International Atomic Energy Agency recommend its use. Therefore, in order to achieve greater assurance that KI will receive due attention by planners, it is reasonable to take a further small step and, continuing to recognize the important role of the States and local governments in matters of offsite emergency planning, explicitly require that planners consider the use of KI.

The amendment should not be taken to imply that the NRC believes that the present generation of nuclear power plants is any less safe than previously thought. On the contrary, present indications are that nuclear power plant safety has significantly improved since the current emergency planning requirements were put in place after the Three Mile Island-2 accident in 1979.

The use of KI is intended to supplement, not to replace, other protective measures. This amendment does not change the NRC's view that the primary and most desirable protective action in a radiological emergency is

evacuation of the population before any exposure to radiation occurs. The Commission recognizes that there may be situations when evacuation is not feasible or is delayed. In-place sheltering is an effective protective action in such a situation. Depending on the circumstances, KI may offer additional protection to one radiation-sensitive organ, the thyroid, if used in conjunction with evacuation and sheltering. 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. In appropriate circumstances, KI can provide additional protection. In addition, the Commission notes that issues surrounding the prophylactic use of KI following such accidents do not lend themselves to across-the-board solutions. Therefore, the Commission has chosen to leave such decisions to State and local emergency response planners, who may find that KI should be a supplementary protective measure.

The NRC recognizes that any decision to use KI as a supplemental protective measure for the general public presents issues of how best to position and distribute the medicine, to ensure: (1) That optimal distribution takes place in an emergency, with first priority given to protecting children; (2) that persons with known allergies to iodine not take it; and (3) that members of the public understand that KI is not a substitute for measures that protect the whole body. To date, these issues have been addressed in different ways in the numerous countries that currently use KI as a protective measure for their citizens. The NRC is working with States and other Federal agencies to develop guidance on these and other issues relating to the use of KI. The NRC believes that these implementation issues can be solved, given the level of expertise in the relevant Federal and State agencies, and the experience of numerous nations that have built KI into their emergency plans.

Commission Decision on Funding of State Stockpiles or Supplies of KI

The Federal Register notice for the proposed rule (64 FR 31737) stated the Commission's then-held position only to support funding of regional stockpiles or other supplies of KI as opposed to funding of State stockpiling of KI. As described above, in its deliberations on this final rule, the Commission has withdrawn its support for funding of regional KI stockpiles and has reinstated its offer to provide NRC funding of State or, in some cases, local stockpiles,

subject to various restrictions and limitations (see Staff Requirements Memorandum for the Affirmation Session on December 22, 2000).

In doing this, the Commission has responded to comments from FEMA and other commenters. The Commission is supporting the 1996 FRPCC's Ad Hoc Subcommittee on Potassium Iodide recommendation that the Federal government (NRC through FEMA) should fund the purchase of State, or in some cases local, KI stockpiles. The Commission recognizes that this policy contradicts the Commission's historical policy that funding for State and local emergency planning is the responsibility of those governments often working with licensees. The Commission is making this exception to the long-standing policy on the basis of the FRPCC's recommendation and recent petitions received. The Commission has determined that for a State that has decided to stockpile KI, NRC funding for purchase of KI for use by that State during a radiological emergency would directly contribute to fulfilling NRC's regulatory mission. The Commission also recognizes that any State choosing to incorporate KI prophylaxis as a supplemental protective action in its emergency planning will face costs, other than the cost of the purchase of KI. Consistent with the long-standing policy, these ancillary costs will remain the responsibility of the State government. Depending on how the State incorporates KI prophylaxis in its emergency plans, the ancillary costs could significantly exceed the cost of the purchase of the KI supply.

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.

National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC is amending its emergency planning regulations to require that consideration be given to including potassium iodide as a

protective measure for the general public that would supplement sheltering and evacuation in the event of a severe reactor accident. This action does not constitute the establishment of a consensus standard that contains generally applicable requirements to which the provisions of the Act apply.

Environmental Assessment and Finding of No Significant Impact for Completing Action on the Petitions for Rulemaking Relating to the Use of Potassium Iodide (KI) for the General Public

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 NRC 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 petitioner 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, that requested two things:

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

On June 26, 1998, the Commission disagreed with the NRC staff's recommendation in SECY-98-061 dated March 31, 1998, "Staff Options for Resolving a Petition for Rulemaking (PRM 50-63 and 50-63A) Relating to a Re-evaluation of the Policy Regarding the use of Potassium Iodide (KI) by the General Public after a Severe Accident at a Nuclear Power Plant," to deny the revised petition for rulemaking (PRM 50-63A) and directed the NRC staff to

grant the petition by revising 10 CFR 50.47 (b)(10). This final rule responds to this directive.

Alternatives were essentially considered in previous documents. In SECY-97-124 (June 16, 1997), "Proposed Federal Policy Regarding Use of Potassium Iodide after a Severe Accident at a Nuclear Power Plant," the NRC 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.

On April 22, 1999, the Commission voted to approve publication in the **Federal Register** of a proposed rule that would grant the revised petition for rulemaking (PRM 50-63A). The proposed rule was published on June 14, 1999 (64 FR 31737). In the petitioner's comment letter on the proposed rule, he stated that in light of the Commission decision not to fund State stockpiles of KI, the Commission should consider his original petition (PRM 50-63) to be incorporated by reference and resubmitted in his comment letter. He also requested the Commission to grant the petition as originally submitted. The Commission, by undertaking this final rulemaking, is denying in part the original petition for rulemaking (PRM 50-63), which would *require* the use of KI for the general public. In so doing, the Commission has decided to continue to recognize the important role of the State by explicitly requiring that planners *consider* (PRM 50-63A) the use of KI for the general public. The Commission is granting in all respects the amended petition, including reinstating its support for funding State stockpiles of KI.

II. Need for Action

In SECY-97-245, the NRC staff proposed options for resolving the original petition for rulemaking. In an SRM on SECY-98-061, the Commission directed the NRC staff to proceed with the rulemaking. In so doing, the Commission found that KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering for specific local conditions. The Commission's guidance on emergency planning has long taken KI into consideration (NUREG-0654/FEMA-REP-1, Rev. 1, p. 63 items e and f). However, since the last revision of that guidance, there has been experience with the mass distribution of KI during an international radiological emergency. Although the record on that distribution is not complete, the indications thus far are that mass distribution is effective in

preventing thyroid cancer and causes few threatening side effects. Therefore, in order to achieve greater assurance that KI will receive due attention by planners, it seems reasonable, while continuing to recognize the important role of the States in matters of offsite emergency planning, to explicitly require that planners consider the use of KI. The rule is needed to ensure that the States are aware of and take into consideration the costs, risks, and benefits of KI in their decision making process in order to optimize emergency planning for the public health and safety.

III. Environmental Impact of the Final Action

The environmental impacts of the final action and its alternative (deny the petitions in their entirety and take no action) are considered negligible by the NRC staff, given that the final 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 NRC staff is not aware of any environmental impacts as a result of this final action.

IV. Alternative to the Final Action

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

V. Agencies and Persons Consulted

Cognizant personnel from the States, FEMA, and FDA were consulted, as was the petitioner, as part of this rulemaking activity.

VI. Finding of No Significant Environmental 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 amendment is 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 consideration be given to evacuation, sheltering, and as a supplement to these, the prophylactic use of KI. This action will not have a significant impact upon the environment.

Paperwork Reduction Act Statement

This final 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 (OMB) approval numbers 3150-0009 and 3150-0011.

Public Protection Notification

If a means used to impose 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 Final Rulemaking Completing Action on Petitions for Rulemaking (PRM 50-63) and (PRM 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 NRC staff provided three options for the Commission's consideration 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 petitioner 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."

In the petitioner's comment letter on the proposed rule, he stated that in light of the Commission decision not to fund State stockpiles of KI, the Commission should consider his original petition (PRM 50-63) to be incorporated by reference and resubmitted in his

comment letter. He also requested the Commission to grant the petition as originally submitted. The Commission, by undertaking this rulemaking, is granting the amended petition and is granting in part and denying in part the original petition. The Commission is denying that portion of the original petition for rulemaking (PRM 50-63), which would *require* the use of KI for the general public. In so doing, the Commission has decided to continue to recognize the important role of the State in matters of emergency planning by explicitly requiring that planners *consider* (PRM 50-63A) the use of KI for the general public.

In SECY-97-245, the NRC staff proposed options for resolving the original petition for rulemaking. By SRM dated June 26, 1998, on SECY-97-245, "Staff Options for Resolving a Petition for Rulemaking (PRM 50-63) Relating to a Re-evaluation of the Policy Regarding use of Potassium Iodide (KI) after a Severe Accident at a Nuclear Power Plant," the Commission directed the NRC staff to revise 10 CFR 50.47(b)(10). This final rule responds to this directive.

Alternatives were essentially considered in previous documents. In SECY-97-124 dated June 16, 1997, "Proposed Federal Policy Regarding Use of Potassium Iodide after a Severe Accident at a Nuclear Power Plant," the NRC 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. Given that the Commission considered the options and directed the NRC staff to grant the amended petition, the only alternatives considered here are the Commission-approved option and the baseline, no-action alternative.

The final rule does not "require" any action of licensees. States are to "consider" the use of KI along with evacuation and sheltering as protective actions. It is estimated that no more than 30 States will need to make this consideration. The rule does not impose any substantive requirements on States to actually stockpile or plan for the use of KI. Therefore, States would not accrue the costs associated with such actions. However, the Commission recognizes that consideration of using KI as a supplemental protective measure may result in some State expenditures. The NRC staff estimates that the labor needed by the States could range from a staff-week, to half of a staff-year. The latter would be 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, prorated secretarial and managerial assistance, but not overhead), the range of estimates would be from \$2800 to \$63,000 per State. Using a base of 30 States, the range of impacts for the States to make the KI consideration is from \$84,000 to \$1.9 million.

The Commission notes that when it amended its emergency planning regulations on November 3, 1980, the regulatory standards for emergency planning were a restatement of basic joint NRC-FEMA guidance to licensees and to State and local governments incorporated in NUREG-0654; FEMA-REP-1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants for Interim Use and Comment." This guidance was cited in the regulation and addresses the use of radioprotective drugs by the general public, including quantities, storage, and means of distribution and State and local plans for decision making with respect to their use. The Commission removed the citations of the guidance from the regulation in 1987, but the guidance has continued in use for planning purposes by States and licensees and by the Federal agencies for evaluating emergency plans. As a result, it is believed that all of the 30 affected States have at some point considered the use of KI. A few of the 30 affected States have made the decision to stockpile KI. Thus, in practical terms, the projected costs will occur only in those States that have not previously elected to stockpile KI and choose stockpiling in light of the Chernobyl accident, recent international practice, and the NRC requirement to consider the use of KI.

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

Nonetheless, the Commission notes that this rule will introduce another

element in the context of emergency planning requirements for which licensees are ultimately responsible. Licensees 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, the extent is considered minimal when viewed in the overall licensee burden of complying with all of the existing emergency planning requirements.

Additionally, the rule does not articulate any implementation date or inspection criteria.

As stated above, this analysis focuses on the rule being codified as the result of petitions for rulemaking and on the Commission direction to grant the amended petition in all respects and to grant in part the original petition.

This 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 will not have a significant economic impact on a substantial number of small entities. This final rule would affect only States and indirectly licensees of nuclear power plants. These States and 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).

Compatibility of Agreement State Regulations

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" that was approved by the Commission on June 30, 1997, and published in the **Federal Register** on September 3, 1997 (62 FR 46517), Part 50 is classified as compatibility Category "NRC." The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act or provisions of Title 10 of the Code of Federal Regulations.

Plain Language

The President's Memorandum dated June 1, 1998, entitled "Plain Language in Government Writing" directed that the government's writing be in plain language. This memorandum was published June 10, 1998 (63 FR 31883). In complying with this directive, editorial changes have been made in the final revisions to improve the organization and readability of the

existing language of the paragraphs being revised. These types of changes are not discussed further in this notice.

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 § 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 applicable to 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 final rule imposes no new requirements on licensees, nor does it alter procedures at nuclear facilities. Rather, it is directed to State or local governments, the entities with the important role to determine the appropriateness of the use of KI for their citizens, calling on these governments to

"consider" KI as one of the elements of their offsite emergency planning. However, the rule imposes no binding requirement to alter plans and procedures on State or local governments. 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 § 50.47(b)(10). On this basis, the final rule does not impose new substantive requirements on anyone. After consideration of these factors, no backfit is involved and no backfit analysis as defined in § 50.109 is required.

Commission precedent also makes clear that the amendment 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; November 3, 1987). The Commission's final 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 42084). Likewise, when the Commission altered its emergency planning requirements in 1987 to change the timing 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 final 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 final 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 is 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 final rule itself does not impose any requirement or burden on the licensee. Accordingly, the Commission concludes that the final rule would not impose any backfits as defined in 10 CFR 50.109.

Nonetheless, the Commission notes that this rule will introduce another element in the context of the emergency planning requirements that licensees are ultimately responsible for, whereby licensees have the obligation to confirm that offsite authorities have considered the use of KI as a supplemental protective action for the general public. That ultimate responsibility could have practical implications, with some associated burdens, the extent of which is considered minimal when viewed in the overall licensee burden of complying with all of the existing emergency planning requirements.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects in 10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, 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, and 5 U.S.C. 552 and 553, the NRC is adopting 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 Stat. 1242, as amended 1244, 1246, (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. Law 95-601, sec. 10, 92 Stat. 2951, as amended by Pub. Law 102-486, sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851). Sections 50.10 also issued under secs. 101, 185, 68 Stat. 936, 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. Law 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. Law 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under Pub. Law 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 has 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 9th day of January, 2001.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 01-1156 Filed 1-18-01; 8:45 am]

BILLING CODE 7590-01-P

sewage disposal hours of operation are 5:00am–8:00pm seven days per week, from May through September. Ocean Pines Marina is an 86-slip marina located near the Route 90 bridge in Ocean Pines on the St. Martins River. The marina has one fixed pumpout located at the end of pier A. The marina's sewage disposal hours of operation are 8:00am–6:00pm Monday through Friday, 7:00am–7:00pm Saturday and 7:00am–6:00pm Sunday, from May through October. Sunset Marina is a 204-slip marina located at the Ocean City Inlet in West Ocean City on Isle of Wight Bay. The marina has one fixed pumpout with two remote stands, each at the end of successive piers, one portable unit with potty wand attachment for emptying portable toilets, and one dump station on the bulkhead. The marina's sewage disposal hours of operation are 9:00am–5:00pm seven days per week, from May through September.

Townes of Nantucket II is a 92-slip marina located at Nantucket Point near the Delaware state line in Ocean City on Assawoman Bay. The marina has one fixed pumpout and one dump station for portable toilets, both located at the "A" bulkhead. The marina's sewage disposal hours of operation are 24 hours a day, seven days per week, from April through October.

Marinas participating in the Maryland Pumpout Program are required by law (Natural Resources Article § 8–707) to have an approved method of sewage disposal as determined by MDE and local (county or municipal) health inspectors. Four of the six marinas participated in the Maryland Pumpout Program, and therefore are in compliance with state and Federal laws. Information about the removal of pumpout waste from the other two marinas was obtained through marina surveys. Of the six marinas described above, five discharge to the Ocean City Wastewater Treatment Plant; the remaining marina discharges to the Ocean Pines Wastewater Treatment Plant.

The MDNR maintains records of all documented and registered boats in the state. In order to estimate the number of transient boaters, several methods were employed. First a marina survey was conducted where marina owners were asked to estimate the percentage of transient boaters that utilize their facility and the northern Coastal Bays. Second, information collected from a 1999 aerial survey of the northern Coastal Bays, conducted by the MDNR

Fisheries Department, was used to determine types and sizes of boats using the waters on a peak day in-season. Finally, a land survey was conducted where MDNR employees surveyed Coastal Bay vessel usage on a typical day during the season. All of these methods were employed to come up with a best estimate for transient usage. It was estimated, using the above techniques, that Ocean City/northern Coastal Bays have approximately 10,000 wet slips. It was also assumed that the transient boat population mirrored the resident population as far as relative percent of the size and numbers of boats. Based on this information the vessel population of the northern Coastal Bays based on length is 2,800 vessels less than 16 feet, 6,600 vessels between 16 and 26 feet, 600 vessels between 26 and 40 feet, and 100 vessels over 40 feet. Based on the number and size of boats, and using various methods to estimate the number of holding tanks and portable toilets, it was determined that the northern Coastal Bays need three pumpouts and five dump stations. There are currently eight operating pumpouts and one proposed pumpout in the northern Coastal Bays along with two dump stations and three pumpouts equipped to empty portable toilets making a total of five portable toilet waste facilities. There is also one proposed pumpout that would accept portable toilets by the start of the next boating season in early 2002.

Finding

The EPA hereby makes a final affirmative determination that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for Herring Bay, Anne Arundel County, Maryland, and the northern Coastal Bays (Ocean City Inlet, Ocean City commercial fish harbor (Swordfish Basin), Isle of Wight Bay and Assawoman Bay), Worcester County, Maryland. This final determination will result in a Maryland state prohibition of any sewage discharges, whether treated or not, from vessels into Herring Bay and the northern Coastal Bays.

Donald S. Welsh,
Regional Administrator, Region III.
[FR Doc. 02–627 Filed 1–9–02; 8:45 am]
BILLING CODE 6560–50–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

DATE & TIME: Tuesday, January 15, 2002 at 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. § 437g.

Audits conducted pursuant to 2 U.S.C. § 437g, § 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

DATE & TIME: Thursday, January 17, 2002 at 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes. Revised Draft Advisory Opinion 2001–17: DNC Services Corporation/ Democratic National Committee by counsel, Neil Reiff.

Draft Advisory Opinion 2001–18: BellSouth Corporation by counsel, Jan Witold Baran.

Draft Advisory Opinion 2001–19: Oakland Democratic Campaign Committee by Gary Kohut, Chair.

Administrative matters.

PERSON TO CONTACT FOR INFORMATION:

Mr. Ron Harris, Press Officer,
Telephone: (202) 694–1220.

Mary W. Dove,

Secretary of the Commission.

[FR Doc. 02–776 Filed 1–8–02; 2:32 am]

BILLING CODE 6715–01–M

FEDERAL EMERGENCY MANAGEMENT AGENCY

Federal Policy on Use of Potassium Iodide (KI)

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice of revised Federal policy.

SUMMARY: The Federal Radiological Preparedness Coordinating Committee (FRPCC) has revised the 1985 Federal policy regarding the use of potassium iodide (KI) as a thyroidal blocking agent by emergency workers, institutionalized persons and the general public in the vicinity of nuclear power plants. This policy is for use by State¹ and local

¹ Consistent with FEMA initiative 4.0–4.4. Include Native American Tribal Nations in the REP

agencies responsible for radiological emergency planning and preparedness in the unlikely event of a major radiological emergency at a commercial nuclear power plant.

The Federal position is that KI should be stockpiled and distributed to emergency workers and institutionalized persons for radiological emergencies at a nuclear power plant and its use should be considered for the general public within the 10-mile emergency planning zone (EPZ) of a nuclear power plant.

However, the decision on whether to use KI for the general public is left to the discretion of States and, in some cases, local governments.

EFFECTIVE DATE: The modifications to this policy are effective January 10, 2002.

FOR FURTHER INFORMATION CONTACT:

Russell Salter, Chair, Federal Radiological Preparedness Coordinating Committee; (202) 646-3030; russ.salter@fema.gov.

SUPPLEMENTARY INFORMATION:

Background

This revised Federal policy on the use of potassium iodide as a thyroidal blocking agent for the general public in the vicinity of nuclear power plant 10-mile emergency planning zones is part of a Federal interagency effort coordinated by FEMA for the FRPCC. FEMA chairs the FRPCC and assumes the responsibility for this publication. The FRPCC is an interagency organization, with membership from 17 Federal agencies, established to coordinate all Federal responsibilities for assisting State and local governments in emergency planning and preparedness for peacetime nuclear emergencies.

The issue is addressed in terms of two components of the population that might require or desire potassium iodide use: (a) Emergency workers and institutionalized individuals, and (b) general population. With respect to emergency workers and institutionalized individuals, the Nuclear Regulatory Commission (NRC) and FEMA have issued guidance to State and local authorities, as well as to licensees of operating commercial nuclear power plants, in NUREG-0654/FEMA-REP-1, Rev. 1. The NUREG and FEMA guidance recommends the stockpiling and distribution of KI to emergency workers and to institutionalized individuals for thyroidal blocking during emergencies.

The guidance provides information regarding protective actions to be taken in the event of an incident at a commercial nuclear power plant. NUREG 0654 and the 1985 FRPCC KI policy recommend thyroidal blocking for emergency workers and institutionalized individuals because they are thought to be more likely than other members of the public to be exposed to the radioiodine in an airborne radioactive release.

The decision for using KI as a protective measure for the general public is left to the discretion of States, or in some cases, local governments, since these entities are ultimately responsible for the protection of their citizens. The policy guidance in this *Federal Register* notice is intended for State and local governments that, within the limits of their authority, should consider these recommendations in the review of their emergency plans and in determining appropriate actions to protect the general public. In making a decision whether to stockpile KI, the States should be aware that the Federal government believes that the use of KI is a reasonable and prudent measure as a supplemental protective action for the public.

Revision of the policy to include members of the public reflects lessons learned from the Chernobyl Nuclear Power Plant accident of 1986, both about the consequences of an accident and about the safety and efficacy of KI. The Chernobyl accident demonstrated that thyroid cancer can indeed be a major result of a large reactor accident. Based on the experiences from Chernobyl, young children are at greatest risk of thyroid cancer from radioactive iodine exposure. Moreover, although the Food and Drug Administration (FDA) declared KI "safe and effective" as long ago as 1978, the drug had never been deployed on a large scale until Chernobyl. The experience of Polish health authorities during the accident has provided confirmation that large-scale deployment of KI is safe.² The Chernobyl experiences also led to wide-scale changes in international practice, specifically 1989 World Health Organization recommendations (updated in 1995 and 1999) and 1996 and 1997 International Atomic Energy Agency standards and guidance, which have led to the use of KI as a supplementary protective measure in

much of Europe, as well as in Canada and Japan.

The NRC published changes to its emergency planning regulations at 66 FR 5441-5443, January 19, 2001. For States within the 10-mile planning zone of a nuclear power plant(s), the NRC believes that the use of KI is a reasonable and prudent measure as a supplement to sheltering and evacuation and in response to specific local conditions. The NRC requires consideration in the formulation of emergency plans as to whether to include the use of KI as a supplemental protective measure.

The FDA has evaluated the medical and radiological risks of administering KI for emergency conditions, has concluded that it is safe and effective, and has approved over-the-counter sale of the drug for this purpose. FDA has concluded that " * * * the effectiveness of KI as a specific blocker of thyroid radioiodine uptake is well-established as are the doses necessary for blockage. As such, it is reasonable to conclude that KI will likewise be effective in reducing the risk of thyroid cancer in individuals or populations at risk for inhalation or ingestion of radioiodines." Since the FDA has authorized the nonprescription sale of KI, it may be available to individuals who, based on their own personal analysis, choose to have the drug immediately available. The FDA guidance is the definitive Federal guidance on medical aspects of KI prophylaxis.

Considerations

In making a decision whether to stockpile KI, States should be aware that the Federal government believes that the use of KI is a reasonable and prudent measure as a supplemental protective action for the public.

While there may be logistical difficulties in providing KI to the general public, any distribution scheme should take care to ensure that KI distribution does not impede or delay orderly evacuation. There also may be a few medical side effects in pre-distributing the drug to potentially affected individuals or in distributing the drug to the general public in a radiological emergency. Although the post-Chernobyl data from Poland revealed few serious medical side effects associated with this drug, this possibility cannot be discounted, especially in certain groups of people. For example, people who are allergic to iodine should not take KI.

Other considerations to be evaluated by the State and local authorities in deciding whether to institute a program for the use of KI by the general public

² Nauman, J., and Wolff, J., Iodide Prophylaxis in Poland After the Chernobyl Reactor Accident: Benefits and Risks, *American Journal of Medicine*, Vol. 94, p. 524, May 1993.

Preparedness Process, references to State governments include Tribal governments.

include: (a) Whether KI should be distributed to the population before an accident occurs or as soon as possible after an accident occurs; (b) whether the risks of exposure to radioactivity will be lower if the evacuation of the general population is initiated—with or without the use of KI—or if the general population is sheltered and the administration of KI initiated; (c) how KI will be distributed during the emergency; (d) if KI is pre-distributed, what assumptions should be made about its actual availability and use in the event of an incident; (e) what medical assistance will be available for the individuals who may have some adverse reaction to KI; (f) how medical authorities will advise the population to take KI and under what circumstances this advice will be given, i.e., methods for public education, information and instruction; and (g) how the authorities will provide KI to transient populations.

In addition, there are some site-specific considerations to evaluate. Any decision by State and local authorities to use KI following a specific emergency should be based on the site environment and conditions for the specific operating commercial nuclear power plant and would include detailed plans for distribution, administration and medical assistance.

Revised Policy

In most cases, evacuation and in-place sheltering are considered adequate and effective protective actions for the general public in the event of a radiological emergency at a commercial nuclear facility. However, the inclusion of KI as a supplemental protective measure is beneficial in certain circumstances. It should be noted that the timely use of KI effectively reduces the radiation exposure of only the thyroid gland. While this is an important contribution to the health and safety of the individual, it is not as effective as measures that protect the total body of the individual from radioactivity. Both in-place sheltering and precautionary evacuations can reduce the exposure to the thyroid and total body. The use of KI for thyroidal blocking is not an effective means by itself for protecting individuals from the radioactivity in an airborne release resulting from a nuclear power plant accident and, therefore, should only be considered in conjunction with sheltering or evacuation, or a combination thereof.

While the use of KI can clearly provide additional protection in certain circumstances, the assessment of the effectiveness of KI and other protective actions and their implementation

indicates that the decision to use KI (or other protective actions) should be made by the States and, when appropriate, local authorities on a site-specific basis. Thus, the decision on use of KI by the general public during an actual emergency is the responsibility of these authorities.

In summary, the Federal position is that KI should be stockpiled and distributed to emergency workers and institutionalized persons for radiological emergencies at a nuclear power plant, and its use should be considered for the general public within the 10-mile EPZ of a nuclear power plant. However, the decision on whether to use KI for the general public is left to the discretion of States and, in some cases, local governments.

This revised policy should not be taken to imply that the present generation of U.S. nuclear power plants is any less safe than previously thought. On the contrary, present indications are that nuclear power plant safety has steadily improved.

References

The following references are intended to assist State and local authorities in decisions related to use of KI:

1. Nuclear Regulatory Commission, final rule, Consideration of Potassium Iodide in Emergency Plans, 66 FR 5427, January 19, 2001.
2. World Health Organization, Guidelines for Iodine Prophylaxis Following Nuclear Accidents, 1999. http://www.who.int/environmental_information/Information_resources/documents/Iodine/guide.pdf.
3. National Council on Radiation Protection and Measures (NCRP) Protection of the Thyroid Gland in the Event of Releases of Radioiodine. NCRP Report No. 55, August 1, 1977.
4. Food and Drug Administration (Health and Human Services), Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency, 43 FR 58798, December 15, 1978.
5. Food and Drug Administration, Notice, Guidance on Use of Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies; Availability, 66 FR 64046, December 11, 2001.
6. Report of the President's Commission on the Accident at Three Mile Island, National Technical Information Service, Springfield, VA 22161.
7. Federal Emergency Management Agency, Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent, 50 FR 30258, July 24, 1985.
8. Nauman, J., and Wolff, J., Iodide Prophylaxis in Poland After the Chernobyl Reactor Accident: Benefits and Risks, *American Journal of Medicine*, Vol. 94, p. 524, May 1993.
9. International Atomic Energy Agency, International Basic Safety Standards for

Protection Against Ionizing Radiation and for Safety of Radiation Sources. Safety Series No. 115, 1996.

Dated: January 2, 2002.

Joe M. Allbaugh,

Director.

[FR Doc. 02-637 Filed 1-9-02; 8:45 am]

BILLING CODE 6710-02-P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 4, 2002.

A. Federal Reserve Bank of Chicago
(Phillip Jackson, Applications Officer)
230 South LaSalle Street, Chicago,
Illinois 60690-1414:

1. *Marshall & Ilsley Corporation*, Milwaukee, Wisconsin; to merge with Century Bancshares, Inc., Eden Prairie, Minnesota, and thereby indirectly acquire 100 percent of the voting shares of Century Bank, Eden Prairie, Minnesota.

ATTACHMENT 2

FOOD AND DRUG ADMINISTRATION
FINAL GUIDELINES
ON POTASSIUM IODIDE USE

Guidance

Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)**

**December 2001
Procedural**

Guidance

Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies

Additional copies are available from:

*Office of Training and Communications
Division of Communications Management
Drug Information Branch, HFD-210
5600 Fishers Lane
Rockville, MD 20857
(Tel) 301-827-4573*

(Internet) <http://www.fda.gov/cder/guidance/index.htm>

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)**

**December 2001
Procedural**

TABLE OF CONTENTS

I. INTRODUCTION.....	1
II. BACKGROUND.....	1
III. DATA SOURCES.....	2
A. Reliance on Data from Chernobyl.....	2
B. Thyroid Cancers in the Aftermath of Chernobyl.....	4
IV. CONCLUSIONS AND RECOMMENDATIONS.....	5
A. Use of KI in Radiation Emergencies: Rationale, Effectiveness, Safety.....	5
B. KI Use in Radiation Emergencies: Treatment Recommendations.....	6
V. ADDITIONAL CONSIDERATIONS IN PROPHYLAXIS AGAINST THYROID RADIOIODINE EXPOSURE.....	8
VI. SUMMARY.....	8
ACKNOWLEDGEMENTS.....	9
BIBLIOGRAPHY.....	10

Guidance

Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

I. INTRODUCTION

The objective of this document is to provide guidance to other Federal agencies, including the Environmental Protection Agency (EPA) and the Nuclear Regulatory Commission (NRC), and to state and local governments regarding the safe and effective use of potassium iodide (KI) as an adjunct to other public health protective measures in the event that radioactive iodine is released into the environment. The adoption and implementation of these recommendations are at the discretion of the state and local governments responsible for developing regional emergency-response plans related to radiation emergencies.

This guidance updates the Food and Drug Administration (FDA) 1982 recommendations for the use of KI to reduce the risk of thyroid cancer in radiation emergencies involving the release of radioactive iodine. The recommendations in this guidance address KI dosage and the projected radiation exposure at which the drug should be used.

These recommendations were prepared by the Potassium Iodide Working Group, comprising scientists from the FDA's Center for Drug Evaluation and Research (CDER) and Center for Devices and Radiological Health (CDRH) in collaboration with experts in the field from the National Institutes of Health (NIH). Although they differ in two respects (as discussed in Section IV.B), these revised recommendations are in general accordance with those of the World Health Organization (WHO), as expressed in its *Guidelines for Iodine Prophylaxis Following Nuclear Accidents: Update 1999* (WHO 1999).

II. BACKGROUND

Under 44 CFR 351, the Federal Emergency Management Agency (FEMA) has established roles and responsibilities for Federal agencies in assisting state and local governments in their radiological emergency planning and preparedness activities. The Federal agencies, including the Department of Health and Human Services (HHS), are to carry out these roles and responsibilities as members of the Federal Radiological Preparedness Coordinating Committee

(FRPCC). Under 44 CFR 351.23(f), HHS is directed to provide guidance to state and local governments on the use of radioprotective substances and the prophylactic use of drugs (e.g., KI) to reduce the radiation dose to specific organs. This guidance includes information about dosage and projected radiation exposures at which such drugs should be used.

The FDA has provided guidance previously on the use of KI as a thyroid blocking agent. In the *Federal Register* of December 15, 1978, FDA announced its conclusion that KI is a safe and effective means by which to block uptake of radioiodines by the thyroid gland in a radiation emergency under certain specified conditions of use. In the *Federal Register* of June 29, 1982, FDA announced final recommendations on the administration of KI to the general public in a radiation emergency. Those recommendations were formulated after reviewing studies relating radiation dose to thyroid disease risk that relied on estimates of *external* thyroid irradiation after the nuclear detonations at Hiroshima and Nagasaki and analogous studies among children who received therapeutic radiation to the head and neck. Those recommendations concluded that at a projected dose to the thyroid gland of 25 cGy or greater from ingested or inhaled radioiodines, the risks of short-term use of small quantities of KI were outweighed by the benefits of suppressing radioiodine-induced thyroid cancer.¹ The amount of KI recommended at that time was 130 mg per day for adults and children above 1 year of age and 65 mg per day for children below 1 year of age. The guidance that follows revises our 1982 recommendations on the use of KI for thyroid cancer prophylaxis based on a comprehensive review of the data relating radioiodine exposure to thyroid cancer risk accumulated in the aftermath of the 1986 Chernobyl reactor accident.

III. DATA SOURCES

A. Reliance on Data from Chernobyl

In epidemiological studies investigating the relationship between thyroidal radioiodine exposure and risk of thyroid cancer, the estimation of thyroid radiation doses is a critical and complex aspect of the analyses. Estimates of exposure, both for individuals and across populations, have been reached in different studies by the variable combination of (1) direct thyroid measurements in a segment of the exposed population; (2) measurements of ¹³¹I (iodine isotope) concentrations in the milk consumed by different groups (e.g., communities) and of the quantity of milk consumed; (3) inference from ground deposition of long-lived radioisotopes released coincidentally and presumably in fixed ratios with radioiodines; and (4) reconstruction of the nature and extent of the actual radiation release.

All estimates of individual and population exposure contain some degree of uncertainty. The uncertainty is least for estimates of individual exposure based on direct thyroid measurements.

¹ For the radiation emitted by ¹³¹I (electrons and photons), the radiation-weighting factor is equal to one, so that the absorbed dose to the thyroid gland expressed in centigrays (cGy) is numerically equal to the thyroid equivalent dose expressed in rem (1 cGy = 1 rem).

Uncertainty increases with reliance on milk consumption estimates; is still greater with estimates derived from ground deposition of long-lived radioisotopes, and is highest for estimates that rely heavily on release reconstruction.

Direct measurements of thyroid radioactivity are unavailable from the Hanford, Nevada Test Site, and Marshall Islands exposures. Indeed, the estimates of thyroid radiation doses related to these releases rely heavily on release reconstructions and, in the former two cases, on recall of the extent of milk consumption 40 to 50 years after the fact. In the Marshall Islands cohort, urinary radioiodine excretion data were obtained and used in calculating exposure estimates.

Because of the great uncertainty in the dose estimates from the Hanford and Nevada Test Site exposures and due to the small numbers of thyroid cancers occurring in the populations potentially exposed, the epidemiological studies of the excess thyroid cancer risk related to these radioiodine releases are, at best, inconclusive. As explained below, the dosimetric data derived in the studies of individual and population exposures following the Chernobyl accident, although not perfect, are unquestionably superior to data from previous releases. In addition, the results of the earlier studies are inadequate to refute cogent case control study evidence from Chernobyl of a cause-effect relationship between thyroid radioiodine deposition and thyroid cancer risk.²

The Chernobyl reactor accident of April 1986 provides the best-documented example of a massive radionuclide release in which large numbers of people across a broad geographical area were exposed acutely to radioiodines released into the atmosphere. Therefore, the recommendations contained in this guidance are derived from our review of the Chernobyl data as they pertain to the large number of thyroid cancers that occurred. These are the most comprehensive and reliable data available describing the relationship between thyroid radiation dose and risk for thyroid cancer following an environmental release of ¹³¹I. In contrast, the exposures resulting from radiation releases at the Hanford Site in Washington State in the mid-1940s and in association with the nuclear detonations at the Nevada Test Site in the 1950s were extended over years, rather than days to weeks, contributing to the difficulty in estimating radioactive dose in those potentially exposed (Davis et al., 1999; Gilbert et al., 1998). The exposure of Marshall Islanders to fallout from the nuclear detonation on Bikini in 1954 involved relatively few people, and although the high rate of subsequent thyroid nodules and cancers in the exposed population was likely caused in large part by radioiodines, the Marshall Islands data provide little insight into the dose-response relationship between radioactive iodine exposure and thyroid cancer risk (Robbins and Adams 1989).

Beginning within a week after the Chernobyl accident, direct measurements of thyroid exposure were made in hundreds of thousands of individuals, across three republics of the former Soviet Union (Robbins and Schneider 2000, Gavrillin et al., 1999, Likhtarev et al., 1993, Zvonova and Balonov 1993). These thyroid measurements were used to derive, in a direct manner, the thyroid doses received by the individuals from whom the measurements were taken. The thyroid measurements were also used as a guide to estimate the thyroid doses received by other people, taking into account differences in age, milk consumption rates, and ground deposition densities, among other things. The thyroid doses derived from thyroid measurements have a large degree

² We have included in this guidance an extensive bibliography of the sources used in developing these revised recommendations.

of uncertainty, especially in Belarus, where most of the measurements were made by inexperienced people with detectors that were not ideally suited to the task at hand (Gavrilin et al., 1999 and UNSCEAR 2000). However, as indicated above, the uncertainties attached to thyroid dose estimates derived from thyroid measurements are, as a rule, lower than those obtained without recourse to those measurements.

It is also notable that the thyroid radiation exposures after Chernobyl were virtually all *internal*, from radioiodines. Despite some degree of uncertainty in the doses received, it is reasonable to conclude that the contribution of external radiation was negligible for most individuals. This distinguishes the Chernobyl exposures from those of the Marshall Islanders. Thus, the increase in thyroid cancer seen after Chernobyl is attributable to ingested or inhaled radioiodines. A comparable burden of excess thyroid cancers could conceivably accrue should U.S. populations be similarly exposed in the event of a nuclear accident. This potential hazard highlights the value of averting such risk by using KI as an adjunct to evacuation, sheltering, and control of contaminated foodstuffs.

B. Thyroid Cancers in the Aftermath of Chernobyl

The Chernobyl reactor accident resulted in massive releases of ^{131}I and other radioiodines. Beginning approximately 4 years after the accident, a sharp increase in the incidence of thyroid cancer among children and adolescents in Belarus and Ukraine (areas covered by the radioactive plume) was observed. In some regions, for the first 4 years of this striking increase, observed cases of thyroid cancer among children aged 0 through 4 years at the time of the accident exceeded expected number of cases by 30- to 60-fold. During the ensuing years, in the most heavily affected areas, incidence is as much as 100-fold compared to pre-Chernobyl rates (Robbins and Schneider 2000; Gavrilin et al., 1999; Likhtarev et al., 1993; Zvonova and Balonov 1993). The majority of cases occurred in children who apparently received less than 30 cGy to the thyroid (Astakhova et al., 1998). A few cases occurred in children exposed to estimated doses of < 1 cGy; however, the uncertainty of these estimates confounded by medical radiation exposures leaves doubt as to the causal role of these doses of radioiodine (Souchkevitch and Tsyb 1996).

The evidence, though indirect, that the increased incidence of thyroid cancer observed among persons exposed during childhood in the most heavily contaminated regions in Belarus, Ukraine, and the Russian Federation is related to exposure to iodine isotopes is, nevertheless, very strong (IARC 2001). We have concluded that the best dose-response information from Chernobyl shows a marked increase in risk of thyroid cancer in children with exposures of 5 cGy or greater (Astakhova et al., 1998; Ivanov et al., 1999; Kazakov et al., 1992). Among children born more than nine months after the accident in areas traversed by the radioactive plume, the incidence of thyroid cancer has not exceeded preaccident rates, consistent with the short half-life of ^{131}I .

The use of KI in Poland after the Chernobyl accident provides us with useful information regarding its safety and tolerability in the general population. Approximately 10.5 million children under age 16 and 7 million adults received at least one dose of KI. Of note, among newborns receiving single doses of 15 mg KI, 0.37 percent (12 of 3214) showed transient increases in TSH (thyroid stimulating hormone) and decreases in FT4 (free thyroxine). The side

effects among adults and children were generally mild and not clinically significant. Side effects included gastrointestinal distress, which was reported more frequently in children (up to 2 percent, felt to be due to bad taste of SSKI solution) and rash (~1 percent in children and adults). Two allergic reactions were observed in adults with known iodine sensitivity (Nauman and Wolff 1993).

Thus, the studies following the Chernobyl accident support the etiologic role of relatively small doses of radioiodine in the dramatic increase in thyroid cancer among exposed children. Furthermore, it appears that the increased risk occurs with a relatively short latency. Finally, the Polish experience supports the use of KI as a safe and effective means by which to protect against thyroid cancer caused by internal thyroid irradiation from inhalation of contaminated air or ingestion of contaminated food and drink when exposure cannot be prevented by evacuation, sheltering, or food and milk control.

IV. CONCLUSIONS AND RECOMMENDATIONS

A. Use of KI in Radiation Emergencies: Rationale, Effectiveness, Safety

For the reasons discussed above, the Chernobyl data provide the most reliable information available to date on the relationship between internal thyroid radioactive dose and cancer risk. They suggest that the risk of thyroid cancer is inversely related to age, and that, especially in young children, it may accrue at very low levels of radioiodine exposure. We have relied on the Chernobyl data to formulate our specific recommendations below.

The effectiveness of KI as a specific blocker of thyroid radioiodine uptake is well established (II' in LA, et al., 1972) as are the doses necessary for blocking uptake. As such, it is reasonable to conclude that KI will likewise be effective in reducing the risk of thyroid cancer in individuals or populations at risk for inhalation or ingestion of radioiodines.

Short-term administration of KI at thyroid blocking doses is safe and, in general, more so in children than adults. The risks of stable iodine administration include sialadenitis (an inflammation of the salivary gland, of which no cases were reported in Poland among users after the Chernobyl accident), gastrointestinal disturbances, allergic reactions and minor rashes. In addition, persons with known iodine sensitivity should avoid KI, as should individuals with dermatitis herpetiformis and hypocomplementemic vasculitis, extremely rare conditions associated with an increased risk of iodine hypersensitivity.

Thyroidal side effects of stable iodine include iodine-induced thyrotoxicosis, which is more common in older people and in iodine deficient areas but usually requires repeated doses of stable iodine. In addition, iodide goiter and hypothyroidism are potential side effects more common in iodine sufficient areas, but they require chronic high doses of stable iodine (Rubery 1990). In light of the preceding, individuals with multinodular goiter, Graves' disease, and autoimmune thyroiditis should be treated with caution, especially if dosing extends beyond a few days. The vast majority of such individuals will be adults.

The transient hypothyroidism observed in 0.37 percent (12 of 3214) of neonates treated with KI in Poland after Chernobyl has been without reported sequelae to date. There is no question that the benefits of KI treatment to reduce the risk of thyroid cancer outweigh the risks of such treatment in neonates. Nevertheless, in light of the potential consequences of even transient hypothyroidism for intellectual development, we recommend that neonates (within the first month of life) treated with KI be monitored for this effect by measurement of TSH (and FT4, if indicated) and that thyroid hormone therapy be instituted in cases in which hypothyroidism develops (Bongers-Schokking 2000; Fisher 2000; Calaciura 1995).

B. KI Use in Radiation Emergencies: Treatment Recommendations

After careful review of the data from Chernobyl relating estimated thyroid radiation dose and cancer risk in exposed children, FDA is revising its recommendation for administration of KI based on age, predicted thyroid exposure, and pregnancy and lactation status (see Table).

Threshold Thyroid Radioactive Exposures and Recommended Doses of KI for Different Risk Groups				
	Predicted Thyroid exposure(cGy)	KI dose (mg)	# of 130 mg tablets	# of 65 mg tablets
Adults over 40 yrs	≥500	130	1	2
Adults over 18 through 40 yrs	≥10			
Pregnant or lactating women	≥ 5			
Adoles. over 12 through 18 yrs*		65	1/2	1
Children over 3 through 12 yrs		32	1/4	1/2
Over 1 month through 3 years		16	1/8	1/4
Birth through 1 month				

*Adolescents approaching adult size (≥ 70 kg) should receive the full adult dose (130 mg).

The protective effect of KI lasts approximately 24 hours. For optimal prophylaxis, KI should therefore be dosed daily, until a risk of significant exposure to radioiodines by either inhalation or ingestion no longer exists. Individuals intolerant of KI at protective doses, and neonates, pregnant and lactating women (in whom repeat administration of KI raises particular safety issues, see below) should be given priority with regard to other protective measures (i.e., sheltering, evacuation, and control of the food supply).

Note that adults over 40 need take KI only in the case of a projected large internal radiation dose to the thyroid (>500 cGy) to prevent hypothyroidism.

These recommendations are meant to provide states and local authorities as well as other agencies with the best current guidance on safe and effective use of KI to reduce thyroidal radioiodine exposure and thus the risk of thyroid cancer. FDA recognizes that, in the event of an emergency, some or all of the specific dosing recommendations may be very difficult to carry

out given their complexity and the logistics of implementation of a program of KI distribution. The recommendations should therefore be interpreted with flexibility as necessary to allow optimally effective and safe dosing given the exigencies of any particular emergency situation. In this context, we offer the following critical general guidance: ***across populations at risk for radioiodine exposure, the overall benefits of KI far exceed the risks of overdosing, especially in children, though we continue to emphasize particular attention to dose in infants.***

These FDA recommendations differ from those put forward in the World Health Organization (WHO) 1999 guidelines for iodine prophylaxis in two ways. WHO recommends a 130-mg dose of KI for adults and adolescents (over 12 years). For the sake of logistical simplicity in the dispensing and administration of KI to children, FDA recommends a 65-mg dose as standard for all school-age children while allowing for the adult dose (130 mg, 2 X 65 mg tablets) in adolescents approaching adult size. The other difference lies in the threshold for predicted exposure of those up to 18 years of age and of pregnant or lactating women that should trigger KI prophylaxis. WHO recommends a threshold of 1 cGy for these two groups. As stated earlier, FDA has concluded from the Chernobyl data that the most reliable evidence supports a significant increase in the risk of childhood thyroid cancer at exposures of 5 cGy or greater.

The downward KI dose adjustment by age group, based on body size considerations, adheres to the principle of minimum effective dose. The recommended standard dose of KI for all school-age children is the same (65 mg). However, adolescents approaching adult size (i.e., >70 kg) should receive the full adult dose (130 mg) for maximal block of thyroid radioiodine uptake. Neonates ideally should receive the lowest dose (16 mg) of KI. Repeat dosing of KI should be avoided in the neonate to minimize the risk of hypothyroidism during that critical phase of brain development (Bongers-Schokking 2000; Calaciura et al., 1995). KI from tablets (either whole or fractions) or as fresh saturated KI solution may be diluted in milk, formula, or water and the appropriate volume administered to babies. As stated above, we recommend that neonates (within the first month of life) treated with KI be monitored for the potential development of hypothyroidism by measurement of TSH (and FT4, if indicated) and that thyroid hormone therapy be instituted in cases in which hypothyroidism develops (Bongers-Schokking 2000; Fisher 2000; Calaciura et al., 1995).

Pregnant women should be given KI for their own protection and for that of the fetus, as iodine (whether stable or radioactive) readily crosses the placenta. However, because of the risk of blocking fetal thyroid function with excess stable iodine, repeat dosing with KI of pregnant women should be avoided. Lactating females should be administered KI for their own protection, as for other young adults, and potentially to reduce the radioiodine content of the breast milk, but not as a means to deliver KI to infants, who should get their KI directly. As for direct administration of KI, stable iodine as a component of breast milk may also pose a risk of hypothyroidism in nursing neonates. Therefore, repeat dosing with KI should be avoided in the lactating mother, except during continuing severe contamination. If repeat dosing of the mother is necessary, the nursing neonate should be monitored as recommended above.

V. ADDITIONAL CONSIDERATIONS IN PROPHYLAXIS AGAINST THYROID RADIOIODINE EXPOSURE

Certain principles should guide emergency planning and implementation of KI prophylaxis in the event of a radiation emergency. After the Chernobyl accident, across the affected populations, thyroid radiation exposures occurred largely due to consumption of contaminated fresh cow's milk (this contamination was the result of milk cows grazing on fields affected by radioactive fallout) and to a much lesser extent by consumption of contaminated vegetables. In this or similar accidents, for those residing in the immediate area of the accident or otherwise directly exposed to the radioactive plume, inhalation of radioiodines may be a significant contributor to individual and population exposures. As a practical matter, it may not be possible to assess the risk of thyroid exposure from inhaled radioiodines at the time of the emergency. The risk depends on factors such as the magnitude and rate of the radioiodine release, wind direction and other atmospheric conditions, and thus may affect people both near to and far from the accident site.

For optimal protection against inhaled radioiodines, KI should be administered before or immediately coincident with passage of the radioactive cloud, though KI may still have a substantial protective effect even if taken 3 or 4 hours after exposure. Furthermore, if the release of radioiodines into the atmosphere is protracted, then, of course, even delayed administration may reap benefits by reducing, if incompletely, the total radiation dose to the thyroid.

Prevention of thyroid uptake of ingested radioiodines, once the plume has passed and radiation protection measures (including KI) are in place, is best accomplished by food control measures and not by repeated administration of KI. Because of radioactive decay, grain products and canned milk or vegetables from sources affected by radioactive fallout, if stored for weeks to months after production, pose no radiation risk. Thus, late KI prophylaxis at the time of consumption is not required.

As time is of the essence in optimal prophylaxis with KI, timely administration to the public is a critical consideration in planning the emergency response to a radiation accident and requires a ready supply of KI. State and local governments choosing to incorporate KI into their emergency response plans may consider the option of predistribution of KI to those individuals who do not have a medical condition precluding its use.

VI. SUMMARY

FDA maintains that KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland, under certain specified conditions of use, and thereby obviate the risk of thyroid cancer in the event of a radiation emergency. Based upon review of the literature, we have proposed lower radioactive exposure thresholds for KI prophylaxis as well as lower doses of KI for neonates, infants, and children than we recommended in 1982. As in our 1982 notice in the *Federal Register*, FDA continues to recommend that radiation emergency response plans include provisions, in the event of a radiation emergency, for informing the public about the magnitude of the radiation hazard, about the manner of use of KI and its potential benefits and

risks, and for medical contact, reporting, and assistance systems. FDA also emphasizes that emergency response plans and any systems for ensuring availability of KI to the public should recognize the critical importance of KI administration in advance of exposure to radioiodine. As in the past, FDA continues to work in an ongoing fashion with manufacturers of KI to ensure that high-quality, safe, and effective KI products are available for purchase by consumers as well as by state and local governments wishing to establish stores for emergency distribution.

KI provides protection only for the thyroid from radioiodines. It has no impact on the uptake by the body of other radioactive materials and provides no protection against external irradiation of any kind. FDA emphasizes that the use of KI should be as an adjunct to evacuation (itself not always feasible), sheltering, and control of foodstuffs.

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ATTACHMENT 3
GLOSSARY OF TERMS

GLOSSARY OF TERMS

Acute Radiation Thyroiditis: Inflammation and necrosis of thyroid tissue as a result of radiation doses greater than 200 Gy (20,000 rem) to the thyroid; symptoms are usually mild and abate in a few weeks, but can lead to a dangerous release of stored thyroid hormones (thyroid storm).

Deterministic Effects: Early deleterious radiation effects on living tissue (e.g., body, organ or tissue death, cataracts, tissue or organ damage), which generally occur only above a threshold dose and whose severity depends on the level of dose absorbed. They become evident within a short period of time from the irradiation (hours, days or weeks, depending on the dose received). Deterministic effects are expressed in grays (Gy).

Dose: A general term denoting a quantity of radiation. Depending upon its application it can be qualified as "absorbed dose", "equivalent dose", and "effective dose".

Absorbed dose: Quantity of energy imparted by radiation to a unit mass of matter such as tissue. Absorbed dose is measured in grays (Gy), where 1 Gy equals 1 joule of energy absorbed per kilogram of matter. One Gy produces a different intensity of biological effects on tissue depending on the type of radiation (alpha, beta, gamma, neutron). One common submultiple of the Gy, the milligray (mGy) is often used. One mGy is equal to 1/1000 of 1 Gy.

Effective dose : Weighted sum of the "equivalent doses" to various organs and tissues multiplied by weighting factors reflecting the differing sensitivities of organs and tissues to radiation. The weighting factor for each organ or tissue expresses the fractional contribution of the risk of death or serious genetic defect from irradiation of that organ or tissue to the total risk from uniform irradiation of the whole body. Effective dose is measured in sieverts (Sv). Some submultiples of the Sv used are millisievert (mSv) and microsievert (μ Sv). One mSv is equal to 1/1000 of 1 Sv and 1 μ Sv is equal to 1/1,000,000 of 1 Sv.

Equivalent dose Quantity obtained by multiplying the "absorbed dose" in an organ (e.g., thyroid) or tissue by a factor representing the different effectiveness of the various types of radiation in causing harm to the organ or tissue. This factor, whose value varies between 1 and 20 depending on the type of radiation, has been introduced in order to allow grouping or comparing biological effects due to different radiations. Equivalent dose is measured in sieverts (Sv). One Sv produces the same biological effect, irrespective of the type of radiation.

Goiter: An enlargement of the thyroid gland.

Hyperthyroidism: A condition caused by excessive secretion of the thyroid gland.

Hypothyroidism: A condition caused by deficiency of the thyroid secretion resulting in lowered basal metabolism; may be radiogenic, estimated to be 100 percent for a dose of 600 Gy (60,000 rem) or more.

Neoplasm: Any new or abnormal growth, such as a tumor; neoplastic disease refers to any disease that forms tumors, whether malignant or benign.

Potassium Iodide: Colorless or white crystals, having a faint odor of iodine; used as an expectorant and as an amebicidal and bacteriocidal agent, as well as an additive to table salt and animal feed to eliminate iodine deficiency. Iodine is the active agent; iodines are also used as (inorganic) calcium iodide and as (organic) iodinated glycerol and other similar compounds.

Thyroiditis: Inflammation of the thyroid gland; may involve an enlarged thyroid and hypothyroidism and may require lifelong therapy with thyroid hormone.

Stochastic Effects: Late deleterious radiation effects (e.g., leukemia, tumors) whose severity is independent of dose and whose probability of occurring is assumed to be proportional to the dose received. It is also assumed that there is no threshold dose below which stochastic effects occur, therefore, at doses lower than those producing deterministic effects and may manifest themselves after a long time (years, decades) from the irradiation. Stochastic effects are expressed in sieverts (Sv).