[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN: 3150-AG11

# Consideration of Potassium Iodide in Emergency Plans

AGENCY: Nuclear Regulatory Commission.

ACTION: 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: 90 days after publication in the Federal Register.

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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 <u>including sheltering</u>, <u>evacuation and prophylactic use of iodine</u> have been developed for the plume exposure pathway EPZ [emergency planning zone] for emergency workers and the public.

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

In the 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. <u>In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate</u>. 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) <u>Federal Register</u> 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, 1999, (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 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 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]. 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 initial 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, intention that "most likely the NRC" would fund the purchase of State stockpiles of KI, absent Congressional funding specifically for this purpose, NRC is not prepared to fund State stockpiles of KI.

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.

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[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).

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 by interceding in the State's prerogative to make its own decisions on whether to use KI, the Federal Government (NRC, or through FEMA), should fund the purchase of a stockpile for a State that decides to incorporate KI as a protective measure for the general public. (2) The language in the 1985 policy should be softened to be more flexible, 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 a 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.

On June 16, 1997, the NRC staff forwarded to the Commission 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. 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, that 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 will 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 should be reached by mid-2000.

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 notes that the development of regional stockpiles of KI has not progressed. The substance of the specific comments attached to the FEMA letter are addressed by the issues in the public comment evaluation.

The Commission also directed the staff to revise its guidance document, NUREG-1633, 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 has 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 Agency, 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 in mid-2000, following receipt of the FDA's draft revised position on exposure action levels and proper dosage of KI, expected to be issued for public comment early in 2000.

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[2] comment letters were received. Letters in favor of granting the petition came from 5 environmental groups, 22 members of the public (including 1 from the petitioner), and the American Thyroid Association. Letters 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, 1 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

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

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[3] comment letters were received. 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.

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[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.

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 Food and Drug Administration 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 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 (or sheltering when appropriate) 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. 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 if used in conjunction with evacuation and/or 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 explicitly require 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 judgement. 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 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 in mid- 2000 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 the consideration, the 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 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 [U.S. Environmental Protection Agency], 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 in mid-2000. 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. (see also discussion at end of the comment evaluation concerning NRC activities related to Federally-funded stockpiles or other supplies of KI). 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 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. This is why the Commission has concluded that Federally-funded regional stockpiles or other supplies of KI are intended as a backup, and that States should not rely upon the existence of such supplies in their consideration of the merits of use of KI as part of their emergency planning measures. FEMA has stated that in their view, regional stockpiles will not enhance local radiological emergency preparedness because of complex logistics. The Commission's decision on support for funding of regional stockpiles or other Federally-funded supplies as compared to funding of State supplies is discussed elsewhere in this notice.

The Commission recognizes that regional stockpiles or other supplies of KI at the time of an accident may result in distribution difficulties that will reduce the effectiveness of the supplemental protective action. Nevertheless, the Commission notes that: (1) evacuation and in-place sheltering provide adequate protection for the general public and remain the primary protective actions; (2) those States that decide to use KI for the general public are also expected to prearrange for the KI supplies or stockpiles that they will need and not rely on Federally arranged supplies; and (3) Federal regional stockpiles or arrangements for supplies at the time of an accident are only intended as a contingent supply of last resort for those States who decide not to use KI for the general public but who change their minds at the time of an actual emergency and desire to distribute KI without preplanning (or in the event that State supplies are insufficient).

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 to 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 the 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 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. Depending on the circumstances, KI may offer additional protection if used in conjunction with evacuation and/or 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 explicitly require 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 to not 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 re 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 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 is discussed in detail in the proposed rule FR notice and also at the conclusion of this notice. If a State or local government decides to use KI for the public, the Commission expects those governments to make their own arrangements for their supply of KI, since the Commission has determined that it will not fund State KI stockpiles.

Promulgation of this final rule underscores the Commission's views on the importance of emergency preparedness, including consideration of the use of KI. However, just as NRC has not funded other offsite protective actions (e.g., State and local government planning for evacuation and sheltering, KI for response personnel/emergency workers and institutionalized persons), the Commission has decided not to fund State supplies of KI for the general public.

Obviously, the State will factor the funding matter into its consideration of the use of KI for the general public, just as it would consider funding in developing other aspects of emergency planning and preparedness. Additionally, the Commission is not aware of any States that have dropped plans to establish stockpiles due to the Commission decision about funding for KI supplies.

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 their supply of KI. 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.

The Kemeny Commission criticized the failure to stockpile KI and recommended that regional stockpiles be established. For States that initially decide not to use KI for the public, the NRC is working to develop an approach to provide contingent supplies of KI so that it will be available on short notice in the event that State supplies are insufficient or for States who change their minds on the use of KI at the time of an actual emergency. It should be emphasized that the regional stockpiles (or ad hoc supplies or other arrangements) are not to be used for obtaining KI in advance, as part of the planning process; rather, they are intended to be used in the event of an emergency by States who have not otherwise provided for their own KI stockpile. However, no agreement has been reached on Federally supported supplies

of KI and such supplies are not currently available. NRC and FEMA are also working with other Federal agencies through the FRPCC to revise the Federal policy on KI.

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.

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 Food and Drug Administration 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 is scheduled for publication in the Federal Register for public comment by early 2000 with final publication scheduled for late 2000. Once this new information is available, 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's position on funding of KI stockpiles is set forth in the proposed rule FRN and in the section of this FRN titled, "Commission Decision on Funding of Regional Stockpiles or Supplies of KI." In the petitioner's comments on the proposed rule, the petitioner in essence, refiled his original petition and the Commission has evaluated the merits of both petitions for rulemaking (PRM 50-63 and PRM 50-63A). This rulemaking, while not adopting the exact language suggested by the petitioner in his revised petition (PRM 50-63A), grants in part aspects of both the original and amended petitions and denies other aspects, and completes NRC action on both petitions. The amended petition notes that the petitioner requested "only two things": a statement recommending KI as a 'reasonable and prudent measure' and a rule change to include KI, along with evacuation and sheltering in the "range of protective actions" stated in 10 CFR 50.47(b)(10). Nonetheless, the proposed Statement of Consideration portion of the amended petition does refer to a June 30, 1997, Commission decision on funding. Specifically, the petitioner states this decision is "to support a change in Federal policies by which supplies of KI will be made available paid for by the Federal Government to States that request it." Thus, the Commission's decision to not fund State stockpiles would deny the part of the amended petition that would have included a statement of NRC support for State stockpiles.

The NRC intends to work with other cognizant agencies in an attempt to establish regional stockpiles or other Federally supported supplies of KI. The regional stockpiles or other supplies could be available in the event that State supplies prove to be insufficient or for use by States that have not established their own stockpiles and wish to make use of the regional stockpiles or supplies at the time of a severe nuclear power plant accident.

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. This will facilitate better contingency planning to the extent of possible development of Federally-funded supplies of KI and ad hoc use in an actual emergency.

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.

Under the scenario in the last comment, the Commission believes that the State would have considered the benefits and costs associated with using KI for the general public.

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 not endorsed "forced KI distribution," under this final rule and 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. 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. Additionally, the Commission has directed the NRC staff to work with FEMA in an attempt to establish and maintain Federally-funded supplies of KI but such supplies have not yet been established.

In any event, the States are aware of the fact that NRC will not fund State stockpiles and that the State must make its own arrangements for a supply of KI. Further, Federally-funded KI contemplated in regional stockpiles or through other supply arrangements will only be available, if at all, as a last resort to those States who have decided against the use of KI but change their minds in an actual emergency (or in the event that a State stockpile is insufficient). Commission efforts in this regard are not intended to "override" a State decision not to use KI during an emergency; rather, they are intended to make KI available in the event that a particular State changes its views and decides to use KI in an actual emergency, and has nowhere else to go for KI.

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 O: 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.

The information gained to date from Chernobyl relating to the usefulness of KI in preventing thyroid cancer was considered by the Commission. However, just as NRC has not funded other offsite protective actions (e.g. State and local government planning for evacuation and sheltering, KI for response personnel/emergency workers and institutionalized persons), the Commission has decided not to fund State supplies of KI for the general public.

Issue P: 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 potassium iodide with overall toxicity of 2.5% (mostly nausea) but with only a fraction of 1% having serious side-effects. 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 H.

## 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 both petitions (PRM 50-63 and 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 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. However, the final rulemaking would deny those parts of the original petition requesting that the Commission: 1) amend 10

CFR 50.47(b)(10) to require that the range of protective actions developed for the plume exposure pathway EPZ include sheltering, evacuation, and the prophylactic use of iodine, and 2) declare, as a matter of policy, that the NRC is willing to provide a stockpile of the drug or arrangements for supplies of KI at the time of an emergency to States and localities. The change in position on funding of State stockpiles denies that part of the amended petition to include a statement of such support in the Statement of Considerations for the rule.

Further, the final rule would deny the aforementioned parts of the original petition, while supporting the creation of regional stockpiles of the drug or arrangements for supplies of KI at the time of an emergency as a backup for States who decide at the time of an actual emergency that they would like to distribute KI to the general public but have not created their own stockpiles or otherwise planned for such distribution (see further discussion below).

As stated in that FRN, 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." (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 a radiological emergency, and though the record on that distribution is not complete, the indications thus far are that mass distribution is effective in preventing thyroid cancer and causes remarkably few threatening side effects.

Moreover, many nations in Europe and elsewhere, nations as different in their circumstances, politics, and regulatory structures as France, Canada, and Japan, have stockpiled KI 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 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 (evacuation protects the whole body, whereas KI protects only a single gland, the thyroid). Depending on the circumstances, KI may offer additional protection if used in conjunction with evacuation and/or sheltering. 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 Regional Stockpiles or Supplies of KI

On June 30, 1997, the Commission voted to approve the NRC staff recommendation to endorse the FRPCC recommendations for the Federal government to fund the purchase of KI for States at their request. The Commission also endorsed the FRPCC recognition of the potential availability of the Federal stockpile of KI to State and local governments for purposes of mitigating the consequences of terrorist use of nuclear, biological, or chemical (NBC) weapons. At that time it was believed that the NRC was the likely Federal agency to fund the state stockpiling.

Historically, however, funding for State and local emergency response planning has been the responsibility of those governments often working with licensees. After further consideration of the matter of funding specific State stockpiles of KI (See Staff Requirements Memorandum on COMJSM 98-002 - Funding for Potassium Iodide Stockpiles, April 22, 1999), the Commission determined that absent Congressional funding specifically for this purpose, the

NRC is not prepared to fund State stockpiling of KI. Nevertheless, the Commission supports the position that the Federal government should fund the purchase of KI for Federal stockpiles at appropriately located regional centers or other arrangements to expeditiously provide quantities of KI when needed in an actual emergency.

The NRC intends to continue to work with other cognizant agencies in an attempt to establish regional stockpiles or other Federally supported supplies of KI. At this time, NRC and FEMA have been unable to reach an agreement relating to regional stockpiles, but the two agencies have explored a concept for those States who seek KI at the time of an actual emergency. Under this concept, a funding mechanism for multiple regional stockpiles of KI would not be required. Rather, this concept would rely on the Center for Disease Control "pipeline" approach, which is part of the evolving U.S. infrastructure to respond to terrorist efforts. It should be noted that this "pipeline" concept as it pertains to KI has not been approved by either NRC or FEMA. Resolution of the Commission's policy on funding of KI stockpiles is not needed to support the rule as written.

The Federal Register notice for the proposed rule (64 FR 31737) sets forth in detail the basis for the Commission determination only to support funding of regional stockpiles or other supplies of KI as opposed to state stockpiling of KI. That notice also describes the petitioner's position on this and related issues.

The Commission recognizes that regional stockpiles or other supplies of KI at the time of an accident may result in distribution difficulties that will reduce the effectiveness of the supplemental protective action but the Commission notes that: (1) evacuation and in-place sheltering provide adequate protection for the general public and remain the primary protective actions; (2) those States that decide to use KI for the general public are also expected to prearrange for the KI supplies or stockpiles that they will need and not rely on Federally arranged supplies, and (3) Federal regional stockpiles or arrangements for supplies at the time

of an accident are only intended as a contingent supply of last resort for those States who decide not to use KI for the general public but who change their minds at the time of an actual emergency and desire to distribute KI without prior planning, or in the event that State stockpiles prove insufficient.

It should be noted that Federally supported supplies of KI (in regional stockpiles or otherwise) do not now exist (except for limited supplies in stockpiles for Response to Nuclear, Biological, or Chemical Terrorism) and may never be established. State and local governments should not rely on the existence of Federal supplies when they consider their position on the use of KI for the general public.

## 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.

## 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 some experience with the mass distribution of KI during a 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 include sheltering, evacuation, and the prophylactic use of KI. This action will not have a significant impact upon the environment.

## Paperwork Reduction Act Statement

This 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 in part and denying in part both petitions. The Commission is denying that portion of the original petition for rulemaking (PRM 50-63), which would <u>require</u> 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 that licensees are ultimately responsible for, 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 a petitions for rulemaking and on the Commission direction to grant in part those petitions.

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 <u>licensees</u> (and <u>applicants</u>) 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 at 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

10 CFR Part 50

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

For the reasons set out in the preamble and under the authority of the Atomic Energy Act for 1954, as amended, the Energy Reorganization Act of 1974, as amended, 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. L. 95-601, sec. 10, 92 Stat. 2951, as amended by Pub. L. 102 - 486, sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851). Sections 50.10 also issued

under secs. 101, 185, 68 Stat. 936, 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L. 91 - 190, 83 Stat. 853 (42 U.S.C. 4332). Section 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80, 50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

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

§ 50.47 Emergency plans.

* * * * *

(b) * * *

(10) A range of protective actions 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 _____ day of _____, 2000.

For the Nuclear Regulatory Commission.

_____
Annette Vietti-Cook,
Secretary of the Commission.