

June 16, 1997

FOR: The Commissioners

FROM: L. Joseph Callan /s/  
Executive Director for Operations

SUBJECT: PROPOSED FEDERAL POLICY REGARDING USE OF POTASSIUM IODIDE AFTER A SEVERE ACCIDENT AT A NUCLEAR POWER PLANT

## PURPOSE:

To provide the Commission with 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.

## SUMMARY:

As part of the Federal effort to reevaluate the Federal policy on KI based on a request by a petitioner, the Federal Radiological Preparedness Coordinating Committee (FRPCC) adopted recommendations that would result in a revised Federal policy statement. NRC staff has participated in the FRPCC activities and has worked closely with the Federal Emergency Management Agency (FEMA) in this area.

There are three options that can be taken with regard to the FRPCC recommendations: (1) recommend no change in the existing Federal policy, (2) recommend the adoption of the FRPCC recommendations, with the added recognition of recent developments regarding medicinal stockpiles for nuclear, biological, and chemical events, or (3) recommend modifications to the FRPCC recommendations.

The staff recommends either option 2 or option 3(b). In light of the fact that this is a national policy issue, Commission guidance is requested.

## BACKGROUND:

**Federal Policy on KI (1985)**

The current Federal guidance to State and local governments on the distribution of KI was promulgated in 1985 by FEMA in its capacity as Chair of the FRPCC (50 FR 30285) and as the Federal agency charged with establishing policy and providing leadership via the FRPCC (44 CFR 351 Subpart C). The FRPCC was established in accordance with 44 CFR Part 351 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 are: Federal Emergency Management Agency (FEMA), Nuclear Regulatory Commission (NRC), Environmental Protection Agency (EPA), Department of Health and Human Services (HHS), Department of Energy (DOE), Department of Transportation (DOT), Department of Agriculture (USDA), Department of Defense (DOD), Department of Commerce (DOC), Department of Interior (DOI), Department of State (DOS), Department of Veterans Affairs (DVA), General Services Administration (GSA), National Communication System (NCS), and National Aeronautics and Space Administration (NASA).

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. It recognizes, however, that options on the distribution and use of KI rest with the States. Hence, the policy statement permits State and local governments, within the limits of their authority, to take measures beyond those recommended or required nationally.

**DPO (1989)**

In 1989, Peter G. Crane, a member of the NRC staff, filed a Differing Professional Opinion (DPO) which alleged that there were deficiencies in the original cost-benefit analysis (NUREG/CR-1433) provided to the FRPCC by the NRC. The DPO suggested that the staff discussion at a November 1983 Commission briefing on KI might have left Commissioners and members of the public with insufficient understanding of the adverse consequences (thyroid disease) that the use of KI could avert. The DPO also suggested that the cost-benefit analysis, by simply balancing the dollar costs of a KI program against the dollar costs of treating radiation-caused thyroid illness, did not adequately consider the non-monetary costs of an illness.

In SECY-91-321, the DPO panel developed a simplified analysis of the value and impact of the KI policy, including revisions to several factors used in NUREG/CR-1433. The panel concluded that no change in the Federal policy was warranted. However, in order to consider all of the issues raised by the DPO and incorporate new data, the Office of Nuclear Regulatory Research performed a detailed update of the NRC's KI policy basis, taking into account both qualitative and quantitative factors.

The staff presented its recommendation to resolve the DPO in SECY-93-318 (November 23, 1993) and SECY-94-087 (March 29, 1994). The staff recommended that the NRC, in coordination with HHS and FEMA, revise current Federal KI policy as a matter of prudence to make KI available to the States. The Commission's vote on the above staff recommendation was split 2 to 2 (SRM dated May 6, 1994). Thus, the policy remained unchanged.

**American Thyroid Association's Request and Establishment of KI Subcommittee (1989)**

In September 1989, the American Thyroid Association (ATA) submitted a letter to the Chairman of the FRPCC requesting that the Committee reconsider

the issues involved in stockpiling KI. The ATA proposed that:

"As best as can be determined at this time, no substantial stockpile of potassium iodide is available for public use. Despite the unlikely event of an emergency requiring its use, the ATA believes that the option of potassium iodide distribution should be available for consideration to those responsible for public health measures. To this end, the ATA believes that it would be prudent to have available at central locations a suitable stockpile of KI for possible distribution should its use be contemplated."

In response, the FRPCC established an Ad Hoc Subcommittee on Potassium Iodide and asked the HHS to review the medical and clinical status of the use of KI. In an initial response, HHS reviewed the then current scientific literature on KI and its use as a blocking agent. HHS reported to the FRPCC in February 1990 that no new scientific data had been found that would affect the basis for the 1985 guidance to refrain from stockpiling or predistributing KI for the public. To ensure a more comprehensive review, HHS also decided to solicit new data, scientific opinions, and reports on the experience of States concerning KI use and distribution.

HHS convened a meeting of experts on July 24, 1990 in Atlanta, Georgia. Representatives of the State and Federal agencies responsible for medical research, drug regulation, and radiological emergency response, representatives of medical associations, and nationally recognized experts in the fields of endocrinology and nuclear medicine attended. Daniel A. Hoffman, Ph.D, M.H.P., Assistant Director for Science, Center for Environmental Health and Injury Control, Centers for Disease Control chaired the meeting.

Following the experts' meeting, HHS made the following recommendations to the FRPCC in October 1990:

1. The 1985 FRPCC guidance need not be changed at this time since no compelling evidence to support a modification was presented.
2. Existing stores of KI should be inventoried. The FDA would determine the locations and size of KI supplies by identifying large customers of KI manufacturers<sup>(1)</sup>. The FRPCC should request that the Conference of Radiation Control Program Directors identify appreciable supplies of KI within the States by surveying State Radiation Control Programs.
3. The FRPCC should establish a working group to address the issue of stockpiling. Group objectives should be to:
  - Review and catalog type, location, and expiration of existing suitable supplies of KI.
  - Review and determine feasibility of specific stockpiling recommendations made by meeting participants.
  - Make final recommendations to FRPCC on U.S. Government KI stockpiling policy.

The FRPCC Subcommittee on KI followed up on these recommendations.

### **An Analysis of KI for the General Public in the Event of a Nuclear Accident**

Under the sponsorship of NRC's Office of Nuclear Regulatory Research, S. Cohen & Associates completed a report entitled, "An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident" in April 1992. The analysis was updated and published in February 1995 (NUREG/CR-6310).

The analysis, whose central objective was to conduct a cost-benefit analysis of KI, assigned monetary values to thyroid health effects. The report addressed not only the scientific aspects of the use of KI but also the economic costs and benefits to society. The report indicated that a fair evaluation of KI cannot be limited to an assessment of the cost-benefit ratios, but must include a thorough understanding of how these ratios were derived.

The analysis utilized the technical insights from both the National Academy of Sciences, BEIR V Committee (NAS 1990) and the National Council on Radiation Protection and Measurements (NCRP 1987) regarding iodine and thyroid dosimetry.

The analysis also addressed the effectiveness of KI. According to the analysis, given the rapid uptake of iodine (radioactive or stable), there is a limited benefit of KI administration following exposure to radioiodines. For KI to serve as an efficient blocking agent, the report continued, it must be administered in sufficient quantities before or concurrently with radioiodine exposure.

This report estimated the cost/benefit ratio of stockpiling KI prophylaxis as a function of estimated population within radial distances from a plant. The results of this analysis showed that the cost-benefit ratio ranged from 2.22<sup>(2)</sup> for populations within 5 miles to 81.8 for populations within 50 miles. This means that for the 0- to 5-mile population cell, \$2.22 would be spent for stockpiling KI in order to avoid the economic equivalent cost of \$1.00. For the 0- to 50-mile population cell, \$81.8 would be spent to avoid the economic equivalent of \$1.00. The cost-benefit ratios for population cells increased nearly exponentially with distance.

As basis for the cost-benefit analysis, the authors used four accident categories postulated for the Surry nuclear power plant as described in NUREG-1150. The analysis used the accident consequence code to calculate the thyroid dose to individuals as a function of age, gender, and distance. For the worst case that was analyzed, the whole body doses close to the plant at the plume centerline were high and likely to be fatal<sup>(3)</sup>. Doses decrease with distance and away from the plume centerline. Within 5 miles, where the cost-benefit ratio for stockpiling KI was estimated to be 2.22, the whole body doses may still exceed thresholds for early health effects<sup>(4)</sup> for which administration of KI is ineffective. It was precisely such insights that led to the NRC's recommendation for prompt evacuation of areas close to the plant and five miles downwind as the preferred protective action. This guidance is contained in NUREG-0654 Rev. 1 Supp. 3 entitled Criteria for Protective Action Recommendations for Severe Accidents published in July 1996.

## State Survey (1994)

In June 1993, the April 1992 report was provided to the representatives of FEMA and HHS who co-chaired the FRPCC Potassium Iodide Subcommittee. The subcommittee reported on the NRC-sponsored analysis at a meeting of the FRPCC in September 1993. It recommended initiating two studies to secure State input on implementation strategies for providing KI to the public: (1) request the Conference of Radiation Control Program Directors (CRCPD) to survey those States with nuclear power plants for opinions regarding Federal purchase and stockpiling of KI and regarding the feasibility of States providing KI to the public under emergency conditions and (2) request the International Atomic Energy Agency to provide information on existing plans and procedures from member nations related to the storage, distribution, and dosage of KI. The latter study, which involved the IAEA, was never conducted. The first study, which consisted of a survey of States in connection with a Federal purchase and stockpiling of KI, was completed in mid-1994. All 32 States with nuclear power plants responded, as well as 11 States without plants. In general, the responses were as follows:

|   | Yes | No |
|---|-----|----|
| Does your State favor a Federal KI Stockpile? |     |    |
| - States with nuclear power plants            | 7   | 25 |
| - States without nuclear power plants         | 3   | 8  |
| Total   | 10  | 33 |

The primary reason given by States for not supporting Federal purchase and stockpiling of KI was that the State policy did not include KI as a protective measure for the general public. The State use of KI was specified only for emergency workers. Many States emphasized that the distribution of KI to the general public would be difficult in the event of a radiological emergency. The difficulty stems from logistical challenges presented for timely distribution of KI to permanent and non-permanent populations and the liabilities associated with the misuse of KI.

Of the 10 States that supported the Federal purchase and stockpiling of KI, one State preferred one centrally located national stockpile, four preferred Federal regional stockpiles, and five preferred a stockpile within their State.

In early 1995, the FRPCC subcommittee was prepared to recommend that:

1. The FRPCC Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent (50 FR 30258), should not be changed.
2. The Federal government should not purchase and stockpile KI for use by the public.

The basis for these recommendations were:

1. The results of the State survey,
2. The 1992 NRC cost-benefit study,
3. The lack of new data challenging the 1985 guidance on KI stockpiling,
4. The lack of justification that the subcommittee could find for a Federal stockpile, and
5. The lack of support for such an initiative by the States and the primary Federal regulatory agency (FEMA).

However, FEMA did not issue the results of these findings because of a petition for reconsideration.

## Petition for Rulemaking (1995)

On September 9, 1995, Mr. Crane, who filed the DPO, filed a petition for rulemaking (PRM-50-63) with the NRC as a private citizen. He requested that the NRC amend its emergency planning regulations to require that emergency planning protective actions include sheltering, evacuation, and the prophylactic use of KI. The request would amend one of the 16 planning standards in 10 CFR 50.47, which licensees' and offsite agencies' emergency plans are required to meet, in order to assure that the option of using KI is included in emergency plans.

The staff's resolution of the petition is currently under consideration. The implications of the policy options on the petition are discussed later.

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

In June 1995, the White House issued Presidential Decision Directive 39 (PDD-39) on US Policy on Counterterrorism. The PDD-39 directed the Federal agencies to take a number of measures to reduce vulnerability to terrorism, to deter and respond to such acts, and to strengthen capabilities to prevent and manage the consequences of terrorist use of nuclear, biological, and chemical (NBC) weapons including weapons of mass destruction. The PDD-39

assigned to FEMA the task of ensuring that the Federal Response Plan (FRP) was adequate to respond to the consequences of terrorism.

FEMA, in coordination with the Catastrophic Disaster Response Group (CDRG)<sup>(5)</sup>, developed a draft report to the President entitled, "An Assessment of Federal Consequence Management Capabilities for Response to Nuclear, Biological or Chemical (NBC) Terrorism," dated June 12, 1996. The report recommended, among other things, that the Federal government purchase and stockpile thyroid blocking agents (KI) for the general public that could be used in the event of a nuclear terrorist event. The NRC was a member of the Core Group which generated the recommendations and was instrumental in adding KI to the list of medicinal supplies to be stockpiled nationally.

The Core Group concluded that as the result of recent events, significant threats over the past few years, and the increased availability and proliferation of nuclear, biological, or chemical materials, there is an increasing concern for the potential of terrorist incidents. NBC events, the report continued, may occur as a local event with potentially profound national implications. In responding to these events, the first responders must be able to provide critical resources to the victims. These include, but are not limited to, chemical nerve antidotes, vaccines for anthrax, and antibiotics<sup>(6)</sup>. It was therefore determined that there is a need to purchase and preposition stockpiles of adequate medical supplies at the Federal, State, and local level. While KI was not considered as vital as chemical nerve antidotes and vaccines, the NRC staff was successful in getting KI included with other medicinal supplies for NBC events because of the unusual characteristics of these events:

1. NBC events are unpredictable with many unquantifiable parameters. In contrast to nuclear power plant accidents, NBC events can occur in major metropolitan areas. The group postulated NBC scenarios for which evacuation and sheltering were not effective or even possible.
2. NBC events can have consequences ranging from low to disastrous. Some may not escalate beyond the threat stage while others may occur without a threat stage with devastating consequences, with everything in between.
3. Even with the significant amount of planning at the Federal, State, and local level, NBC events still have potential for mass casualties.

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

The staff believes that such a stockpile of KI substantially addresses the issue raised by the American Thyroid Association.

#### **FRPCC Subcommittee on KI (1996)**

In parallel with petitioning the NRC, Mr. Crane also requested that FEMA review his petition and reconsider the Federal policy. In early 1996 the FRPCC convened an Ad-Hoc Subcommittee on Potassium Iodide to request and review new information on this matter from interested parties. The subcommittee conducted a public meeting on June 27, 1996. The subcommittee evaluated all comments from the June 27 public meeting and concluded in its report to the FRPCC that "while the viewpoints presented at the public meeting were compelling, the 1996 Subcommittee on Potassium Iodide heard no new information that seriously challenges the bases for the 1985 recommendation concerning public use of KI." However, the Subcommittee made the following recommendation regarding the Federal KI policy:

1. Without changing the Federal policy by interceding in the State's prerogative to make its own decisions on whether to use KI, the Federal government (NRC, or through FEMA) should fund the purchase of a stockpile for a State that decides to incorporate KI as a protective measure for the general public;
2. The Subcommittee believes the language in the 1985 policy should be softened to be more flexible and balanced. For example, the problem many intervenors observe with the Federal policy is the italicized statement "The Federal position with...potassium iodide for use by the general public is that it should not be required." It would not be as negative if the last phrase were reworded to state "it [potassium iodide for use by the general public] is not required, but may be selected as a protective measure at the option of the State or, in some cases, local governments."
3. The subcommittee recommends that local jurisdictions who wish to incorporate KI as a protective action for the general public should consult with the State to determine if such arrangements are appropriate. If local governments have the authority or secure the approval to incorporate KI as a protective measure for the general public, they would need to include such a measure in their emergency plans.

#### **Proposed Federal Policy on KI (1996)**

The full FRPCC endorsed the subcommittee's recommendations with some modifications and plans to publish a revised Federal policy statement on distribution of KI. Because of the NRC's interest and recognized expertise in emergency planning around nuclear power plants, NRC staff agreed to work closely with FEMA to propose language that would integrate the FRPCC subcommittee's recommendations, the FRPCC's endorsement, and the recent developments in the areas regarding preparedness for terrorism.

#### **FRPCC and Interagency Assignments**

Under 44 CFR 351, the FRPCC is the Federal coordinating body responsible for assisting FEMA in providing policy direction for the program of Federal assistance to State and local governments in their radiological emergency planning and preparedness activities. FEMA, as chair of the FRPCC, establishes policy and issues guidance to State and local governments. The FRPCC member agencies jointly review and evaluate the status of emergency planning periodically. Part 351.21 (f) requires the NRC to assist FEMA in developing and promulgating guidance to State and local governments for the

preparation of radiological emergency plans. Part 351.21 (i) requires the NRC to provide representation to and support for the FRPCC. The NRC has fully participated in FRPCC activities. Because of its special interest in emergency planning for nuclear power plants, the NRC staff worked closely with FEMA and other Federal agencies in developing the proposed KI policy. The staff recognized the importance of working closely with health agencies such as HHS and DVA regarding the use of KI by the general public. Throughout this process, the staff worked collegially with other key Federal agencies to ensure a broader consensus on the Federal policy.

The NRC's representative to the FRPCC has agreed to propose language that integrates what was already recommended and endorsed by various Federal committees and working groups. By virtue of its regulatory functions, the NRC staff had to consider some additional fine points. For example, the NRC staff considered the licensing implications of the proposed KI policy, the need for additional guidance to the licensees or States, and the potential impact on FEMA's responsibilities in offsite emergency planning.

If accepted by the FRPCC, the proposed policy will be noticed in the *Federal Register*. Since FEMA chairs the FRPCC, it assumes the responsibility for this publication.

## Options

### Option 1. **Recommend no change in existing policy.**

This option would result in continuation of the present policy, i.e., stockpiling KI for use by emergency workers and institutionalized persons but predistribution or stockpiling of KI for use by the general public should not be required.

This option would require that NRC staff request that the FRPCC reconsider its current recommendations and not consider the existing Federal stockpile for NBC events. The staff does not believe that other key Federal agencies on the FRPCC would be receptive to this option because of the activities that have taken place since 1985.

This option does not update the current policy to reflect the recent developments. The staff believes that the time is appropriate to update the present policy. A Federal stockpile of KI, among other medicinal supplies, already was available for the Olympics and the national political conventions. There is a new national impetus for expanding the Federal preparedness to include medicinal supplies for NBC events. While the FRPCC determined that there is no new information that seriously challenges the basis of the current policy regarding reactor accidents, it did recommend that the Federal government fund the purchase of KI for any State upon their request and soften the language in the present policy.

### Option 2. **Recommend the adoption of the FRPCC recommendations recognizing the recent developments in preparation for NBC events.**

This is one of the options favored by the staff. As pointed out in option 1, the staff believes that the present policy should be updated. [Attachment 1](#) contains a proposed Federal policy on KI that reflects the key elements of this option. It incorporates changes recommended by the FRPCC's Subcommittee on Potassium Iodide, acknowledges the developments in the area of NBC events regarding KI but does not alter the current emergency planning requirements. The principal differences between option 2 and the 1985 version are the addition of the willingness of the Federal Government to purchase a supply of KI for States at their request, and the establishment of a Federal stockpile.

The highlights of option 2 proposed policy are as follows:

- KI should be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies. In developing the range of public protective actions for severe accidents at commercial nuclear facilities, the best technical information indicates that evacuation and in-place sheltering provide adequate protection for the general public. However, the State (or in some cases, the local government) is ultimately responsible for the protection of its citizens. Therefore, the decision for local stockpiling and use of KI as a protective measure for the general public is left to the discretion of the State or, in some cases, the local government.
- The Federal government will establish funding for the purchase of a supply of KI. It is recognized that the State or the local government, within the limits of their authority, can take measures beyond those recommended or required. The availability of KI as a protective measure for the general public supplements other options for public officials responsible for protective action decisions. A few States have indeed included KI as a protective action for the general public. The FRPCC does not want to usurp the State prerogative to incorporate the use of KI as a protective measure for the general public. Therefore, to ensure that States have available to them the option to use KI if they so elect, the Federal government will be prepared to provide funding for the purchase of a supply of KI. Any State or local government which selects the use of KI as a protective measure for the general public may notify FEMA and request funding for the purpose of purchasing a supply of KI. Guidance would have to be developed in this area jointly with FEMA.
- A stockpile of KI is being established by the Federal government. The Federal government is required to prepare for a wider range of radiological emergencies<sup>(7)</sup>. To that end, and as an added assurance for radiological emergencies in which the location and timing of an emergency are unpredictable and for which, unlike licensed nuclear power plants, there is little planning possible, a stockpile of KI is being established by the Federal government. This Federal stockpile will be available to any State for any type of radiological emergency at any time.
- Those States or local governments which opt to include KI for the general population will be responsible for the maintenance, distribution, and any subsequent costs associated with this program.

- The incorporation of a program for KI stockpiling, distribution, and use by any State or local government into the emergency plans will not be subject to Federal evaluation. This is based on the recognition that the use of KI by the State for the general public is a supplemental protective measure, and that the existing emergency planning and preparedness guidance for nuclear power plants are effective and adequate to protect the public health and safety.

### **Analysis of Option 2 Proposed Policy**

To ensure that the KI policy adheres to the principles of good public policy, NRC staff identified key factors that should be taken into account:

1. The preeminent role of State and local governments in the protection of offsite public health and safety;
2. The application of good science to the development of any new guidance regarding KI;
3. The value added of any new guidance in the context of existing planned protective measures;
4. The recognition that KI is not without side effects which have been discussed at length throughout the past years. Before the NRC actually participates in the purchase and supply of KI, it will prepare through consultation with HHS, a suitable product warning to be used by the State and local governments.
5. The implementation challenges of any new guidance.

The NRC staff considered these factors in developing the proposed Federal policy on KI. Furthermore the staff believes that the proposed policy does the following:

1. Integrates the subcommittee's recommendations with the recent developments in the area of preparedness for NBC events, namely the establishment of national medicinal stockpiles, including KI;
2. Recognizes the central role of State and local governments in protecting public health and safety, and honors the State's prerogative to determine whether it wishes to add KI as a supplemental protective measure for the general public;
3. Does not encumber the States and local governments who choose to retain their existing plans if they believe that the implementation of a KI program may reduce the effectiveness of implementing prompt evacuation as a preferred protective action for the general public;
4. Provides added assurance to those States and local governments that a Federal stockpile of KI is available, should it be needed;
5. Is consistent with the recently published draft guidance (NUREG-0654 FEMA-REP-1 Rev. 1 Supplement 3) by NRC and FEMA on "Criteria for Protective Action Recommendation for Severe Accidents;"
6. Does not result in a rule change which is a two-year process and may require a backfit analysis;
7. Maintains the foundation of offsite emergency planning by confirming that the existing guidance and requirements are adequate.

The proposed policy is also strengthened by the already existing stockpile of KI that was available for the Olympics and the national political conventions. The staff believes that given these stockpiles, unlike the TMI experience, KI could be made available in a more timely manner if needed in the future.

This option has some fiscal implications for the NRC associated with its offer to purchase KI for any State that requests it.

### **Fiscal Implications of Proposed KI Policy**

The option 2 proposed Federal policy contains an offer by the Federal government (most likely the NRC) to fund the purchase of a supply of KI for any State that chooses to add KI to its options of protective actions in response to an emergency at a NRC licensed nuclear power plant. To fulfill this proposed obligation, staff's estimate of the range of NRC costs is given in three scenarios in [Attachment 2](#). Currently, resources are not budgeted for the purchase of KI and funds would have to be reprogrammed should a State (or States) request funding through FEMA.

The cost estimate does not include the administrative costs associated with the KI purchase. The more likely scenario is that several sites may request funding each year for a few years. In that case, the estimate is about \$50,000 each year for a period of three years and repeated every seven years, thereafter.

#### **Option 3. Recommend modifications to the FRPCC recommendations.**

There are a number of possible modifications to the FRPCC recommendations that can be recommended. The staff has prepared a limited number of cases to scope the wide range of possibilities.

- a) **Endorse FRPCC recommendations without the offer to fund the purchase of KI.**  
There are already two States which have KI for the general public under the current policy. The staff is not aware of any cases where

funding to purchase a supply of KI is the obstacle for adding KI as a protective measure for the general public. The staff believes that the costs associated with a KI program could be significant when activities such as public education and the logistics associated with the distribution are added to the cost to purchase KI supplies. The FRPCC's offer to fund the purchase of KI is intended to demonstrate a good faith effort on behalf of the Federal government to assure that if any State wishes to add this supplemental measure, there is no implicit discouragement from the Federal government.

If this option is selected, the staff would have to request that the FRPCC reconsider its recommendation regarding Federal funding for the purchase of KI.

b) **Recommend that the staff, in coordination with HHS and FEMA, revise current Federal KI policy to make KI available to the States.**

This was recommended by the staff in SECY-94-087. The revised policy would state that:

KI will be purchased by the Federal government (most likely by the NRC) and made available through FEMA to the States. While the NRC encourages the stockpiling of KI, the decision to stockpile, distribute, and use KI would be the responsibility of the individual States. At the option of the State, procedures incorporating the use of KI in State emergency plans would be developed with the assistance of FEMA. The details regarding this option would be developed and coordinated through the FRPCC.

This option contains some of the essential elements of option 2 and is the other option favored by the staff. For example: (1) it is a State option to determine whether it wishes to include KI in its plans, and (2) the Federal government (most likely the NRC) will purchase KI for the States. This option could have fiscal implications up to scenario 3 in option 2. The principal difference with option 2 is that in this option the Federal government openly encourages the stockpile of KI by States for prudence.

The States may perceive the NRC encouragement to stockpile KI by the States as going beyond what is necessary. This is based on the statements presented by States' representatives at the public meeting conducted by the subcommittee on KI in 1996. Not only were they not convinced that there is a benefit to a KI stockpile, but believed that it may hamper the implementation of prompt evacuation which is the preferred protective measure. Indeed, it was after these testimonies and a careful examination of issues and information presented to the subcommittee, that FRPCC recommended a position that reflected a more subtle encouragement (as reflected in option 2).

SECY-94-087 was silent on cases where States did not opt to have a local stockpile of KI. In today's environment, those States could rely on the NBC stockpile to use KI on an ad hoc basis if needed.

This option was favored by the staff in 1994 and, in recognition of the NBC development, remains one of the two recommended options today.

c) **Direct the staff to effect a rule that requires KI as a protective measure for the general public.**

This option is based on the presumption that stockpiling KI for limited populations located close to operating nuclear power plants, if not cost-beneficial, is, nonetheless, prudent.

The option would require that emergency plans be revised to include a KI distribution system for the public and the criteria for its administration in an accident.

This option would be at odds with the FRPCC recommendations and according to the polls, the States would not view this option favorably. The FRPCC recommendations were, in part, based on the notion that the State or local governments are ultimately responsible for the decisions regarding protective actions and their implementation. To have a national stockpile of KI allows the States to use KI on an ad hoc basis if needed.

This option would also have wide-spread implications for emergency planning. It would require the States and local governments to make significant changes to their plans and procedures in order to ensure that KI can be distributed to the public (permanent and transient populations) in a timely manner, preferably without reducing the effectiveness of prompt evacuation if necessary. It would require that Federal agencies develop additional guidance for FEMA evaluation of the changed plans. The NRC and staff would have to revise the existing Federal guidance on protective actions for severe accidents, such as Supplement 3 to NUREG-0654. The State and local officials would have to conduct public training for public use of KI. Public health officials and school officials would need specific instructions for dispensing KI to the general public and school children.

For the purpose of placing this option in perspective using the two States which currently stockpile KI for the general public, the staff contacted officials from Alabama and Tennessee. In each case, KI supplies would be made available at reception centers following an accident. Under the direction of the Health Officer, KI tablets would be administered to members of the public reporting to these centers. Neither State has a planned distribution system to provide KI to the members of the public in case evacuation would not be feasible. Under these circumstances, KI would be distributed on an ad-hoc basis.

In short, this option has the potential to undo the web of emergency planning without any significant added benefit.

### **Implications of Options on the Petition for Rulemaking**

Before discussing the implications of the options on the Petition for Rulemaking, the contributions of Mr. Peter Crane of the NRC, the petitioner, should be recognized for their value in illuminating all aspects of this issue. He has persevered, over many years and in the face of technical disagreement on intangible issues, in keeping this important issue before the agency and without his efforts even the policy changes recommended in this paper would not likely have been made.

**Option 1: No change to existing policy.**

If this option were approved, then the petition would be denied. The staff could still grant part of the petition by referencing the NBC developments which will result in a Federal stockpile.

**Option 2: Endorse FRPCC recommendations recognizing the recent developments in preparation for NBC events.**

If the proposed Federal policy is accepted, there will be no rule change to amend 10 CFR 50.47 to require that KI be included in the emergency plans. Thus, the petition would be denied. However, the staff believes that the Federal offer to fund the purchase of KI for the States at their request and the Federal stockpile of KI for NBC events<sup>(8)</sup> substantially addresses the fundamental concerns behind the petition, without requiring changes in State and local emergency plans.

There are currently two States which stockpile or distribute KI for the general public around nuclear power plants. More States may choose to add KI to their protective actions for the general public.

**Option 3 (a): Endorse option 2 with no funding.**

The petition would be denied. The Federal stockpile for NBC events partly addresses the fundamental concerns behind the petition.

**Option 3 (b): In coordination with HHS and FEMA, revise current policy to make KI available to the States.**

The petition would be denied. The availability of KI would substantially address the fundamental concerns behind the petition.

**Option 3 (c): Effect a rule change.**

This option would grant the petition by directing the staff to make the requested rule change.

**Coordination**

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer has no objection to the resource estimates contained in this paper.

**RECOMMENDATION:**

The staff requests that the Commission approve either option 2 or option 3(b).

L. Joseph Callan  
Executive Director for Operations

CONTACT: Frank J. Congel, AEOD  
(301) 415-7476

Attachments: 1. Proposed Federal Policy on KI  
2. Estimation of Cost

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ATTACHMENT 1

Billing Code 6718-06-P

April 16, 1997

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FEDERAL EMERGENCY MANAGEMENT AGENCY  
DRAFT

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**Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent**

**AGENCY:** Federal Emergency Management Agency.

**ACTION:** Issuance of Federal Policy on Potassium Iodide.

**SUMMARY:** The Federal Radiological Preparedness Coordinating Committee (FRPCC) is issuing this revised Federal policy concerning the purchase, stockpiling, and use of potassium iodide (KI) as a prophylaxis for the thyroid in the unlikely event of a major radiological emergency at a commercial nuclear power plant. Taken in time, KI blocks the thyroid's uptake of airborne radioactive iodine, and thus could help reduce thyroid diseases caused by such exposure.



The Federal policy is that KI should be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies. In developing the range of public protective actions for severe accidents at commercial nuclear facilities, the best technical information indicates that evacuation and in-place sheltering provide adequate protection for the general public. However, the State (or in some cases, the local government) is ultimately responsible for the protection of its citizens. Therefore, the decision for local stockpiling and use of KI as a protective measure for the general public is left to the discretion of State ( or, in some cases, local government.)

It is recognized that the State (or in some cases, the local government), within the limits of its authority, can take measures beyond those recommended or required. The availability of KI as a protective measure for the general public supplements other options for public officials responsible for protective action decisions. A few States have indeed included KI as a protective action for the general public. The FRPCC does not want to usurp the State prerogative to incorporate the use of KI as a protective measure for the general public. Therefore, to ensure that States have the option to use KI if they so elect, the Federal government is prepared to provide funding for the purchase of a supply of KI. Any State (or in some cases, local government) which selects the use of KI as a protective measure for the general public may so notify FEMA, and may request funding for the purpose of purchasing a supply of KI.

In addition, the Federal government is also required to prepare for a wider range of radiological emergencies<sup>(9)</sup>. To that end, and as an added assurance for radiological emergencies in which the location and timing of an emergency are unpredictable and for which, unlike licensed nuclear power plants, there is little planning possible, a stockpile of KI is being established by the Federal government. This Federal stockpile will be available to any State for any type of radiological emergency, at any time.

The policy herein incorporates changes recommended by the FRPCC's Subcommittee on Potassium Iodide, and supersedes the 1985 Federal policy (50 FR 30258). The principal difference between this revised policy and the 1985 version are the addition of the offer of the Federal Government to purchase a supply of KI for States at a State's request and the establishment of a Federal stockpile. The Federal Emergency Management Agency (FEMA) chairs the FRPCC, thereby assuming the responsibility for this publication.

**For Further Information Contact:** William F. McNutt, Senior Policy Advisor, Room 634, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-2857; facsimile (202) 646-4183.

## **Background**

This policy on use of KI as a thyroidal blocking agent is the result of a Federal interagency effort coordinated by FEMA for the FRPCC. On March 11, 1982, FEMA issued a final regulation in the Federal Register (47 FR 10758), which delineated agency roles and responsibilities for radiological incident emergency response planning (44 CFR 351). One of the responsibilities assigned to the Department of Health and Human Services (HHS) and in turn delegated to the Food and Drug Administration (FDA) was providing guidance to State and local governments on the use of radioprotective substances and prophylactic use of drugs (e.g., KI) to reduce radiation doses to specific organs including dosage and projected radiation exposures at which such drugs should be used.

In the June 29, 1982 Federal Register (47 FR 28158), FDA published recommendations for State and local agencies regarding the projected radiation dose to the thyroid gland at which State and local health officials should consider the use of KI. The Federal policy on stockpiling and distribution of KI was published in the July 24, 1985 Federal Register (50 FR 30258). On September 11, 1989, the American Thyroid Association requested FEMA, as Chair of the FRPCC, to reexamine the 1985 policy and to revisit the issue of stockpiling and distribution of KI for use by the general public. In response, the FRPCC established an Ad Hoc Subcommittee on Potassium Iodide. On December 5, 1994, the FRPCC adopted the report and recommendations of the Ad Hoc Subcommittee on Potassium Iodide, which reaffirmed the Federal position as expressed in the 1985 policy.

On April 3, 1996, in connection with a September 9, 1995 Petition for Rulemaking submitted to the Nuclear Regulatory Commission (NRC) on this issue, the FRPCC established a new Subcommittee on Potassium Iodide to review current information. The Subcommittee conducted a public meeting on June 27, 1996. Based on the information collected, the Subcommittee concluded that there was no new information that seriously challenges the bases for the 1985 recommendations concerning public use of KI for radiological emergencies at nuclear power plants. However, several recommendations were made to the FRPCC. The Subcommittee's three recommendations were: 1) without changing the Federal policy by interceding in the State's prerogative to make its own decisions on whether or not to use KI, the Federal government (NRC, or through FEMA) should fund the purchase of a stockpile for any State that, hereinafter, decides to incorporate KI as protective measure for the general public; 2) The Subcommittee believes the language in the 1985 policy should be softened to be more flexible and balanced. For example, the problem many intervenors observe in the Federal policy is in the italicized statement "The Federal position with...potassium iodide for use by the general public is that it should not be required." It would not be as negative if the last phrase were reworded to state "it [potassium iodide for use by the general public] is not required, but may be selected as a protective measure at the option of the State or, in some cases, local governments." and 3) The subcommittee recommends that local jurisdictions who wish to incorporate KI as a protective action for the general public should consult with the State to determine if such arrangements are appropriate. If local governments have the authority or secure the approval to incorporate KI as a protective measure for the general public, they would need to include such a measure in their emergency plans.

The full FRPCC endorsed the subcommittee's recommendations with some modifications.

## **Policy on Distribution of KI Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent**

The purpose of this document is to provide Federal policy and guidance with regard to distribution of KI, and its usage as a thyroid blocking agent, around operating nuclear power generating facilities. The issue has been addressed in terms of two components of the population that might require or desire KI use: (1) Emergency workers and institutionalized individuals close to the nuclear power plant site, and (2) the nearby general population. This

guidance is for those State and local governments who, within the limits of their authority, need to consider these recommendations in the development of emergency plans and in determining appropriate actions to protect the general public.

The Federal policy is that KI should be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies. In developing the range of public protective actions for severe accidents at commercial nuclear facilities, the best technical information indicates that evacuation and in-place sheltering provide adequate protection for the general public. However, the State (or in some cases, the local government) is ultimately responsible for the protection of its citizens. Therefore, the decision for local stockpiling and use of KI as a protective measure for the general public is left to the discretion of State ( or, in some cases, local government.)

It is recognized that the State (or in some cases, the local government), within the limits of its authority, can take measures beyond those recommended or required. The availability of KI as a protective measure for the general public supplements other options for public officials responsible for protective action decisions. A few States have indeed included KI as a protective action for the general public. The FRPCC does not want to usurp the State prerogative to incorporate the use of KI as a protective measure for the general public. Therefore, to ensure that States have the option to use KI if they so elect, the Federal government is prepared to provide funding for the purchase of a supply of KI. Any State (or in some cases, local government) which selects the use of KI as a protective measure for the general public may so notify FEMA, and may request funding for the purpose of purchasing a supply of KI.

In addition, the Federal government is also required to prepare for a wider range of radiological emergencies<sup>(10)</sup>. To that end, and as an added assurance, for radiological emergencies in which the location and timing of an emergency are unpredictable and for which, unlike licensed nuclear power plants, there is little planning possible, a stockpile of KI is being established by the Federal government. This Federal stockpile will be available to any State for any type of radiological emergency, at any time.

The bases for these recommendations are given below.

The NRC and FEMA issued guidance to State and local authorities as well as licensees of operating commercial nuclear power plants in NUREG-0654/FEMA-REP-1, Revision 1, in 1980. This guidance recommends the stockpiling and distribution of KI during emergencies to emergency workers and to institutionalized individuals. Thyroid blocking for emergency workers and institutionalized individuals was recommended because these individuals are more likely to be exposed to radiiodine in an airborne radioactive release than other members of the public. In addition, the number of emergency workers and institutionalized individuals potentially affected at any site is relatively small and requires a limited supply of KI that can be readily distributed.

For the general public, in the event of a radiological emergency at a commercial nuclear facility, evacuation and in-place sheltering are considered adequate and effective protective actions. It is well-recognized that the inclusion of KI as a protective measure, in addition to evacuation and sheltering, is beneficial only in very remote circumstances. The use of KI is not without controversy. On the one hand, KI has been shown to be an effective drug for protecting the thyroid from thyroid nodules or cancer caused by the uptake of radioiodine, especially in children fifteen years of age or younger. On the other hand, there are logistical difficulties, and potential medical side effects associated with the drug, in distributing the drug to the general public in a radiological emergency. Also, KI effectively reduces the radiation exposure of only the thyroid gland from ingested or inhaled radioiodines. While this is an important contribution to the health and safety of the individual, it is not as effective as measures which protect the total body. Both in-place sheltering and precautionary evacuations can reduce the exposure to the thyroid and the total body. It is very important to remember that the use of KI is not an effective means by itself for protecting individuals from the radioactivity in an airborne release resulting from a nuclear power plant accident and, therefore, should only be considered in conjunction with sheltering, evacuation, or other protective methods. Therefore, while the use of KI can provide additional protection in certain circumstances, the assessment of the effectiveness of KI and other protective actions and their implementation indicates that the decision to use KI (and/or other protective actions) should be made by the States and, if appropriate, local authorities on a site-specific, accident-specific basis.

Those States or local governments which opt to include KI for the general population will be responsible for the maintenance, distribution, and any subsequent costs associated with this program.

The incorporation of a program for KI stockpiling, distribution and use by any State or local government into the emergency plans will not be subject to Federal evaluation. This is based on the recognition that the use of KI by the State for the general public is a supplemental protective measure, and on the Federal government's determination that the existing emergency planning and preparedness guidance for nuclear power plants is effective and adequate to protect the public health and safety.

The FDA has evaluated the medical and radiological risks of administering KI for emergency conditions and has concluded that it is safe and effective and has approved over-the-counter sale of the drug for this purpose. FDA guidance states that risks from the short term use of relatively low doses of KI for thyroidal blocking in a radiological emergency are outweighed by the risks of radioiodine induced thyroid nodules or cancer at a projected dose to the thyroid gland of 25 rem or greater. Since FDA has authorized the nonprescription sale of KI, it is available to individuals who, based on their own personal analysis, choose to have the drug immediately available.

Attached is a list of ten references intended to assist State and local authorities in decisions related to the use of KI.

## **Conclusion**

The FRPCC did not find any new information that would require a change in the basis of the existing Federal policy concerning the stockpile or pre-distribution of KI for the general public in the event of a radiological emergency at a commercial nuclear plant. The policy is that KI should be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies, but leaves the decision for the stockpiling,

distribution, and use of KI for the general public to the discretion of State, and in some cases, local governments. Any State or local government that selects the use of KI as a protective measure for the general public may so notify FEMA and may request funding for the purpose of purchasing an adequate supply.

The incorporation of a program for KI stockpiling, distribution and use by any State or local government into the emergency plans will not be subject to Federal evaluation. This is based on the recognition that the use of KI by the State for the general public is a supplemental protective measure, and on the Federal government's determination that the existing emergency planning and preparedness guidance for nuclear power plants is effective and adequate to protect the public health and safety.

Those States or local governments which opt to include KI for the general population will be responsible for the maintenance, distribution, and any subsequent costs or legal liabilities associated with this program.

As an added assurance, for a broader range of radiological emergencies in which the location and timing of an emergency are unpredictable and for which, unlike licensed nuclear power plants, there is little planning possible, a stockpile of KI will be established by the Federal government. Such a stockpile would consist of individual KI caches at VA hospitals in major metropolitan centers across the country. This supply would be available to any State or local government for any type of radiological emergency.

**References**

1. National Council on Radiation Protection and Measures (NCRP), "Protection of the Thyroid Gland in the Event of Releases of Radioiodine," NCRP Report No. 55, August 1, 1977.
2. Food and Drug Administration (HHS), Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency, 43 FR 58798, December 15, 1978.
3. Halperin, J. A., B. Shleien, S. E. Kahans, and J. M. Bilstad; "Background Material for the Development of the Food and Drug Administration's Recommendations on Thyroid Blocking with Potassium Iodide," FDA 81-8158, U.S. Department of Health and Human Services (March 1981).
4. Food and Drug Administration; Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Final Recommendations on Use (Notice of Availability) 47 FR 28158, June 29, 1982).
5. Food and Drug Administration; Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Recommendations on Use. (April 1992). Prepared by the Bureau of Radiological Health and Bureau of Drugs, Food and Drug Administration, Department of Health and Human Services.
6. Nuclear Regulatory Commission; Examination of the Use of Potassium Iodide (KI) as an Emergency Protective Measure for Nuclear Reactor Accidents (NUREG/CR-1433, March 1990). Prepared by Sandia National Laboratories for the NRC.
7. Nuclear Regulatory Commission; An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident (NUREG/CR-6310, February 1995). Prepared by S. Cohen and Associates, Inc. and Scientech, Inc. for the NRC.
8. Nuclear Regulatory Commission; Re-Evaluation of Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant (SECY-93-318, November 23, 1993).
9. Nuclear Regulatory Commission; Addendum to SECY-93-318, Re-Evaluation of Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant (SECY-94-087, March 29, 1994).

Signed:

O. Megs Hepler, III  
 Chair  
 Federal Radiological Preparedness Coordinating Committee

ATTACHMENT 2

**Estimation of the Cost to Purchase KI  
 for the States in Using Three Scenarios**

The option 2 proposed Federal policy contains an offer by the Federal government (most likely the NRC) to fund the purchase of a supply of KI for any State that chooses to add KI to its options of protective actions in response to an emergency at a NRC licensed nuclear power plant. Currently, resources are not budgeted for the purchase of KI and funds would have to be reprogrammed should a State (or States) request funding through FEMA.

To fulfill this proposed obligation, staff's estimate of the range of NRC costs is given below:

|  | No. of Sites Added Each Year | No. of Years | Cost in k\$/yr Year 1-3 | Cost in k\$/yr Year 4-5 | Cost in k\$ Year 8 | Cost k\$/yr Year 9-10 | Cost in k\$/yr Year 11-12 |
|--|------------------------------|--------------|-------------------------|-------------------------|--------------------|-----------------------|---------------------------|
|--|------------------------------|--------------|-------------------------|-------------------------|--------------------|-----------------------|---------------------------|

|                        |    |   |       |     |       |     |     |
|------------------------|----|---|-------|-----|-------|-----|-----|
| <b>Scenario 1 (11)</b> | 3  | 3 | 48    |     | 48    | 48  |     |
| <b>Scenario 2</b>      | 10 | 5 | 160   | 160 | 160   | 160 | 160 |
| <b>Scenario 3</b>      | 70 | 1 | 1,120 |     | 1,120 |     |     |

Table: Cost of KI purchase in \$1000 for three scenarios

The cost estimate does not include the administrative costs associated with the KI purchase. Although the cost/benefit ratio to purchase KI for the population in the 10-mile Emergency Planning Zone (EPZ) may be excessive for most sites, the NRC staff used the 10-mile EPZ population as the basis for cost estimation. The cost range is from \$48,000/year for the first three years and repurchased every seven years, to a maximum of \$1,280,000 the first year and repurchased every seven years. The higher estimate assumes all sites would request funding for the purchase of KI in the first year, which staff believes is highly unlikely. The more likely scenario is that several sites may request funding each year for a few years. In that case, the estimate is about \$50,000 each year for a period of three years and repeated every seven years, thereafter.

Three scenarios were used to estimate the cost to purchase KI for the States who request such funding. The first is based on the assumption that one State per year (with three sites) requests funding for a period of three years. The second scenario assumes three States per year (with a total of 10 sites) request funding for a period of five years. The third scenario assumes every State with a nuclear power plant requests funding the first year.

The staff assumed the entire 10-mile EPZ population in the cost estimation. Although the KI package contains an insert instructing the user to take one tablet a day for 10 days unless directed otherwise by State or local public health officials, the cost estimation was based on a two-day supply.

Our estimate of the range of costs are as follows:

#### Scenario 1

One State (with three sites) per year requests funding for a period of three years.

Number of sites added per year, S: 3

Average number of people per site (within 10-mile EPZ), P: 80,000

Average number of KI tablets/person, T: 2

Average cost/KI tablet, c: \$0.10

Average shelf life of KI, L: 7 years

The start-up cost would be:  $C = S * P * T * c = 3 * 80,000 * 2 * 0.1 = \$48,000/\text{year}$ , or \$146,000 over three years.

| Scenario 1         | 1998 | 1999 | 2000 |
|--------------------|------|------|------|
| No. of Sites Added | 3    | 3    | 3    |
| Cost (\$1000)      | 48   | 48   | 48   |

The replacement cost would be the same plus inflation, every seven years.

#### Scenario 2

Three States per year (containing a total of 10 sites) request funding for a period of five years.

Number of sites added per year, S: 10

Average number of people per site (within 10-mile EPZ), P: 80,000

Average number of KI tablets/person, T: 2

Average cost/KI tablet, c: \$0.10

Average shelf life of KI, L: 7 years

The start-up cost would be:  $C = S * P * T * c = 10 * 80,000 * 2 * 0.1 = \$160,000/\text{year}$ , or \$800,000 for five years.

| Scenario 2         | 1998 | 1999 | 2000 | 2001 | 2002 |
|--------------------|------|------|------|------|------|
| No. of Sites Added | 10   | 10   | 10   | 10   | 10   |
| Cost (\$1000)      | 160  | 160  | 160  | 160  | 160  |

The replacement cost would be the same plus inflation, every seven years.

**Scenario 3**

Number of sites, S: 70

Average number of people per site (within 10-mile EPZ), P: 80,000

Average number of KI tablets/person, T: 2

Average cost/KI tablet, c: \$0.10

Average shelf life of KI, L: 7 years

If every State with a nuclear power plant site requested funding in the first year, the start-up cost would be:  $C = S * P * T * c = 70 * 80,000 * 2 * 0.1 = \$1,120,000$

| Scenario 3    | 1998  |
|---------------|-------|
| No. of Sites  | 70    |
| Cost (\$1000) | 1,120 |

The replacement cost would be \$1,120,000, plus inflation, every seven years.

1. According to FEMA, the FDA inquiry conducted in late 1996 showed that Carter Wallace, one of the largest manufacturers of KI, had an inventory of 70 cases of KI. Each case contains 1000 bottles. Each bottle contains 14 tablets, a 14-day supply. According to this inquiry, Carter Wallace can manufacture 40-50 cases a day if necessary. Roxanne, another manufacturer of KI, has an unknown inventory of liquid KI in 30 ml bottles.
2. In SECY-94-087, the staff applied correction factors to the cost-benefit ratios and produced a modified ratio of 11 instead of 2.2.
3. Assuming no protective actions, such as evacuation or sheltering.
4. The health effects include nausea, fatigue, vomiting, epilation, diarrhea, and hemorrhage.
5. The CDRG is the headquarters-senior-level coordinating group which addresses policy issues regarding the Federal Response Plan (FRP). The CDRG is chaired by FEMA and comprises representatives of Federal departments and agencies with responsibilities under the FRP. The NRC is represented by the Incident Response Division Director.
6. Some of these medicines can save lives only when administered urgently. The timely distribution remains an issue.
7. In response to new threats, the Federal government broadened the scope of emergency response preparedness to include terrorism involving nuclear, biological, and chemical agents. As a result, and in support of State and local governments, new resources were identified to be needed in response to such events. About two dozen Metropolitan Medical Strike Teams (MMST) are being established for response to such events. Medical supplies, including KI, are being stockpiled nationally for the use by MMSTs in three locations: East coast (Washington, DC), Central (Denver), and West coast (Los Angeles). The quantity of supplies stockpiled uses a planning basis of 100,000 people for a period of two days.
8. As pointed out in the proposed Federal policy, the Federal stockpile of KI will be available to any State for any type of radiological emergency.
9. In response to new threats, the Federal government broadened the scope of emergency response preparedness to include terrorism involving nuclear, biological, and chemical agents. As a result, and in support of State and local governments, new resources were identified to be needed in response to such events. About two dozen Metropolitan Medical Strike Teams (MMST) are being established for response to such events. Medical supplies, including KI, are being stockpiled nationally for the use by MMSTs in three locations: East coast, Central, and West coast. The quantity of supplies stockpiled uses a planning basis of 100,000 people for a period of two days.
10. In response to new threats, the Federal government broadened the scope of emergency response preparedness to include terrorism, involving nuclear, biological, and chemical agents. As a result, and in support of State and local governments, new resources were identified to be needed in response to such events. About two dozen Metropolitan Medical Strike Teams (MMST) are being established for response to such events. Medical supplies, including KI, are being stockpiled nationally for the use by MMSTs in three locations: East coast, Central, and West coast. The quantity of supplies stockpiled uses a planning basis of 100,000 people for a period of two days.
11. The three scenarios are described in Attachment 2.