Federal Guidelines for Requesting Potassium Iodide (KI) from the Strategic National Stockpile
DRAFT

I. Purpose

In accordance with the provisions of Section 127 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107-188, (the Bioterrorism Act), this document provides guidelines for States and local agencies regarding acquisition of potassium iodide (KI) from the Strategic National Stockpile and for the State or local stockpiling and/or distribution of KI and its utilization in the event of a radiation release from a nuclear power plant. In accordance with the requirements of the Bioterrorism Act, the federal government is expanding the area for which KI will be made available from a circle of 10-mile radius around each nuclear power plant to a circle of 20-mile radius. The timely use of KI is an accepted intervention to block the thyroid gland from incorporating radioactive iodine that individuals have either ingested or inhaled. KI is neither a panacea for radiation exposure nor a substitute for more effective response measures (e.g., evacuation and decontamination). In particular, evacuating the area proximate to the incident, decreasing external contamination, and avoiding consumption of contaminated food and water supplies are the principal response strategies.

II. Background

A. Radiological Emergency Preparedness (REP) Program

On December 7, 1979, following the Three Mile Island nuclear power plant accident in Pennsylvania, President Carter transferred the Federal lead role in offsite radiological emergency planning and preparedness from the U.S. Nuclear Regulatory Commission (NRC) to the Federal Emergency Management Agency (FEMA). FEMA established the REP Program to:

1. Ensure that the health and safety of citizens living near nuclear power plants would be adequately protected in the event of a nuclear power plant accident, and

2. Inform and educate the public about radiological emergency preparedness.

REP Program responsibilities encompass only offsite activities, that is, State, local and tribal government emergency planning and preparedness activities that take place beyond the nuclear power plant boundaries. Onsite activities remain the responsibility of the NRC.

At the beginning of the REP Program, the Federal government established the Federal Radiological Preparedness Coordinating Committee (FRPCC) to assure a consolidated Federal position on radiological preparedness. The FRPCC's initial position on KI was that it should only be stockpiled and distributed to emergency workers and institutionalized persons within the 10-mile Plume Exposure Pathway Emergency Planning Zone (EPZ) for radiological emergencies at nuclear power plants. Because of the very low probability of an accident that would include a significant risk from exposure to radioactive iodine, the FRPCC determined that State and local governments should determine themselves whether to create plans that support stockpiling and distribution of KI for their citizens. It should be noted that KI is available as an over-the-counter medication for persons wishing to acquire it in instances where it is not provided by a government program.

In 2001, the NRC modified its emergency planning regulations to require States explicitly to consider incorporating KI as a supplemental protective measure for the general public in their emergency plans. This rule change only applied to the population within the 10-mile EPZ. The FRPCC supported the NRC rule change with a modification to the Federal KI policy in 2002. The current Federal policy is that, in response to specific local conditions, the use of KI as a thyroid blocking agent is a prudent adjunct to sheltering and evacuation. However, the decision on whether to use KI for the general public in an actual event is still left to the discretion of State authorities. The NRC committed to providing the initial supply of KI to those State governments that requested it. To date, 19 out of a total of 31 states with reactors have requested KI tablets through this program.

B. The Bioterrorism Preparedness and Response Act of 2002

Section 127 of the Bioterrorism Act established new Federal requirements for the distribution and use of KI within 20 miles of nuclear power plants. It requires that KI tablets be made available through the Strategic National Stockpile (SNS) to State and local governments for stockpiling and for distribution, as appropriate, to public facilities, such as schools and hospitals, in quantities sufficient to provide adequate protection for the population within 20 miles of a nuclear power plant. Although the Homeland Security Act of 2002, Public Law 107-296, established joint management of the SNS by the Department of Homeland Security (DHS) and the Department of Health and Human Services (HHS), the SNS was transferred back to HHS under the Project BioShield Act of 2004, Public Law 108-276. This transfer became effective on August 13, 2004 and HHS is now the Federal agency responsible for implementing Section 127 requirements.

In addition, Section 127 requires:

- Development of guidelines for stockpiling, distribution and utilization of KI;
- Submission of a Report to Congress on measures taken to implement the Act, including whether KI has been made available; and
- A National Academy of Sciences (NAS) study on the most effective and safe way to distribute and administer KI.

HHS funded the NAS KI study and in December 2003 the NAS released "Distribution and Administration of Potassium Iodide in the Event of a Nuclear Incident." Information on how to access the full report appears later in these guidelines. Five recommendations regarding KI Distribution addressed the following issues:

- The importance of understanding other KI distribution plans
- The responsibility state and local authorities have to make decisions regarding their KI distribution programs
- Availability of Federal resources to support implementation and sustainment
- Central Federal maintenance of a stockpile and distribution supplement to State plans
- Adequate availability of KI tablets for targeted populations.

C. Relationship between the REP Program and Section 127 Implementation

NUREG 0654/FEMA-REP-1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," is the guidance document for the REP program. NUREG 0654/FEMA-REP-1 supports two NRC emergency planning zones for nuclear power plants, as defined in NRC regulations. The first zone, the Plume Exposure Pathway Emergency Planning Zone (EPZ), has a radius of about 10 miles. Within this zone, emergency plans and response mechanisms are particularly important because of the relatively short time that may be available to implement immediate protective measures (e.g., sheltering, thyroid blocking with KI, evacuation). Therefore, all existing REP Program preparation and evaluation criteria for the plume exposure pathway contained in NUREG 0654/FEMA-REP-1 remain applicable to all State, local and tribal governments with populations within 10 miles of the nuclear power plant. In addition, any existing requirements for nuclear power plant licensees are still valid notwithstanding the additional requirements of Section 127. Thus, the new plans or changes to existing plans required by Section 127 will be evaluated every two years as part of the existing biennial exercise cycle. The 10-mile EPZ has been reviewed and accepted by the EPA, NRC, and FEMA as the appropriate EPZ size for nuclear power plant licensees to use in developing emergency plan in cooperation with State and local governments. It is not within the scope of these guidelines to question the appropriateness of the 10-mile EPZ under NRC regulations.

The second zone, the Ingestion Pathway Emergency Planning Zone (IPZ), has a radius of about 50 miles and, unlike the EPZ, the primary concern in this zone is for ingestion, not inhalation, of radioactive materials from the plume. Section 127 of the Bioterrorism Act extends provision of KI 10 miles beyond that already covered in the EPZ for a total of 20 miles from a nuclear power plant. It does not cover the entire IPZ. Plans for KI distribution and use for the population within the 10 to 20 mile ring will be reviewed and evaluated as part of the six-year ingestion pathway exercises, as defined in NUREG 0654/FEMA REP-1. However, these reviews will not be considered in FEMA's findings of reasonable assurance for nuclear power plants. FEMA does not intend to modify the ingestion pathway zone evaluation criteria to incorporate consideration of inhalation exposure pathway criteria. Nuclear power plant licensees are not expected to modify their emergency plans.

III. Roles and Responsibilities

In order to facilitate implementation of the requirements of Section 127 and ensure coordination with the existing REP requirements, the roles and responsibilities of HHS, DHS, and State, local, and tribal governments are set forth below.

A. HHS

Within HHS, the Office of Public Health Emergency Preparedness (OPHEP) will be responsible for implementing the requirements of Section 127. The Office of Public Health Emergency Preparedness will:

1. Review and approve in writing all requests for KI after the Federal Emergency Management Agency (FEMA) in DHS has reviewed the requests for completeness and appropriateness;

2. Develop the procedures and mechanisms for distribution of KI to State, local, or tribal governments;

3. Provide subject matter expertise on KI and other technical support to State, local, and tribal governments, as requested;

4. Provide the initial approved quantity of KI and ensure sufficient supplies are available to replace used or expiring stocks; and

5. Submit Reports to Congress, as required in Section 127, for the following:
   - Measures taken by the Federal Government to implement Section 127
   - Whether KI has been made available to State, local, and tribal governments under Section 127 or other programs;
   - The extent to which State, local, and tribal governments have made KI available to their populations.

B. DHS

DHS, through FEMA, will:

1. Serve as the single point of contact for receipt of KI applications from State, local, and tribal governments;

2. Inform HHS of the date of receipt of each KI application and the anticipated date for providing the results of FEMA's evaluation of the application;

3. Ensure that plans that are submitted do not overlap with respect to coverage of populations.

4. Through FEMA's Regional offices, review and recommend approval or disapproval of State, local or tribal plans for KI distribution prior toforwarding KI requests to HHS

5. Assist HHS with Section 127 reporting requirements;
6. Ensure coordination of new plans with existing emergency plans; and

6. Ensure that local and tribal plans have been reviewed and certified by the State as being "not inconsistent with the State emergency plan." See Section 127(b)(2)(C).

C. NRC

Although Section 127 does not establish direct implementing requirements for the NRC, the NRC will maintain its current program for KI distribution and will approve all requests for the initial supply of KI within the 10 mile EPZ, consistent with NRC regulations, after FEMA has reviewed the requests for completeness and appropriateness.

D. State governments will:

1. Decide whether to add KI as a protective measure to their emergency plans;

2. Submit KI applications to HHS Office of Public Health Emergency Preparedness through FEMA at the address provided in Section V of this document;

3. Certify that the State has not already received sufficient KI from the Federal Government, see Section 127(b)(1)(B);

4. Approve local and tribal plans and certify that such plans are "not inconsistent with the State emergency plan;" See Section 127(b)(2)(C).

E. Local governments will:

1. Decide whether to add KI as a protective measure in their emergency plans;

2. Petition the State in which they are located to modify its plan to address their population (not to exceed a 20-mile radius from the plant). The State has 60 days to modify its plans.

3. Submit their plans to the State for approval and certification that the plan is 'not inconsistent' with the State emergency plan; and

4. Submit KI requests to the HHS Office of Public Health Emergency Preparedness through FEMA at the address provided in Section V of this document.

   NOTE: State approval and certification shall be obtained before HHS or DHS will accept a KI request from a local government for review and approval.

F. Tribal Governments

1. Decide whether to add KI as a protective measure in their emergency plans, if any.

2. Petition the state in which they are located to modify its plan to address their population (not to exceed a 20-mile radius from the plant). The state has 60 days to modify its plan.

3. In the event that (a) the State elects not to modify its plan and does not request KI for the population of the tribe and (b) the cognizant local government also elects not to request KI for the population of the tribe that resides within its jurisdiction, the tribal government may submit its plan to the State for approval and certification that the plan is not inconsistent with the state emergency plan; and

4. Submit a KI request to HHS' Office of Public Health Emergency Preparedness through FEMA at the address provided in Section V of this document

   NOTE: State approval and certification shall be obtained before HHS or DHS will accept a KI request from a tribal government for review and approval.

IV. Considerations for KI Use

The timely use of KI is an accepted intervention to block the thyroid from incorporating into the gland radioactive iodine that has been absorbed by the body through either inhalation or ingestion following a nuclear power plant release. KI does not prevent or reduce exposure to organs other than the thyroid gland, nor does it provide protection from other radioactive isotopes. The primary protection that KI provides is against the long-term risk of thyroid cancer occurring as a result of exposure of the thyroid to radioiodine. KI provides treatment for a specific situation and is not a general, universal radiation protectant. It offers no protection against radiation from radioactive iodine or any other radioactive substance deposited on clothing and skin. Therefore, decontamination, sheltering, evacuation, and avoidance of ingestion remain essential countermeasures.

The thyroid gland of the fetus and newborn child is very sensitive to iodine. Excessive iodine intake can impair thyroid gland function. Therefore, sheltering and evacuation are essential for pregnant women and newborn children who may be exposed to a plume containing radioactive materials. Preventing the ingestion of potentially contaminated food/milk, as part of the 50-mile ingestion pathway emergency zone planning, is the best way to protect the thyroid gland of the fetus or newborn child.

Some individuals may be predisposed to developing a skin reaction to KI. The public must be made aware of this possible side effect so individuals who know they have iodine sensitivity or are concerned about it can consult with their physician so they are able to make an informed decision on KI use.

Numerous other issues must be considered when the state, local or tribal government decides whether to utilize KI as a protective measure. These issues include the following:

- How will incorporation of KI affect existing emergency plans, procedures, and operations?
- Who will be responsible for the KI program? Is there an existing program that can take on this responsibility or must a new one be created?
- Who has the authority to make the recommendation that KI be taken? If the State government is not participating in the program, does the local government have the authority to recommend that KI be taken?
- How will the KI be stockpiled and distributed?
- How will the decision to use KI be made?
- How will the public be instructed to take KI during an incident? Is there a communication system available to notify the public of a nuclear incident? If so, who operates the system?
- How will KI be provided to transient populations?

- What medical assistance will be available for those individuals who experience an adverse medical reaction following KI administration?
- What is the liability associated with establishing a KI program?
- What procedures will be used to monitor the expiration of KI stocks and request replacement from the SNS? If it is stockpiled under controlled conditions, who will pursue shelf-life extension pursuant to the Food and Drug Administration's guidance? (See Reference O below.)

For additional information on the use of KI, please refer to National Academy of Sciences (NAS) Study, Distribution and Administration of Potassium Iodide in the Event of a Nuclear Incident, January 2004. Information on how to obtain a copy of the Study can be found at http://books.nap.edu/catalog/10868.html

V. Requests for KI

A. Requests for KI should be submitted to the:

Chief, Nuclear and Chemical Hazards Branch
Federal Emergency Management Agency
Room 202
500 C Street, SW
Washington, DC 20472

B. State KI requests must:

- Certify that the State has not already received sufficient quantities of KI from the Federal Government;
- Specify the quantity of KI needed and describe the method used to make this determination;
- Identify the location of the nuclear power plant within the State or within a 20-mile border strip inside an adjacent State; and

Contain the State's plans and procedures for stockpiling, distributing, and administering KI.
These plans must:

- Identify the office with the legal authority to recommend the use of KI by the general public;
- Identify the organization(s) responsible for implementing the KI use decision;
- Identify the single recipient responsible for receiving the KI from HHS;
- Specify the decision-making criteria for KI administration;
- Specify the criteria for issuing KI to the public (location, special need);
- Specify the method for making KI available to the public; pre-distribution or stockpiling;
- Specify the method for ensuring the supply of KI is sufficient for the targeted population, including the estimated transient/seasonal population that may be advised to take KI;

- If pre-distributing KI, specify the procedure for the public or special population groups to obtain KI;
- Specify the procedure for storing, monitoring, safeguarding, dispensing (to include, if applicable, tracking who received the drug, when, in what quantity, and maintenance of waivers from liability), and disposing of KI stocks;
- Identify the method for alerting and notifying the general public of the recommendation to take KI; and
- Specify how the plan is integrated into existing emergency response plans.

C. Local and Tribal Governments

KI requests from local and tribal governments must certify that:

- The State in which the local or tribal government is located does not have a FEMA-approved plan that includes KI as a protective measure for populations within 20 miles of a nuclear power plant; or has such a plan, but it does not address populations located beyond 10 miles from the nuclear power plant;

- The local or tribal government has petitioned the State in which it is located to modify the State plan to address populations within 20 miles of a nuclear power plant, and 60 days have elapsed without the State modifying the plan to accommodate the request;

- The local or tribal government KI plans have been approved by the State and certified to be 'not inconsistent' with the State emergency plan; and

- The local or tribal government has reached an agreement with the State that the State will serve as the single point of contact for receipt of KI shipments from the stockpile and will then redistribute the KI to the approved governments.

VI. Funding and Resource Requirements

State, local, and tribal governments are responsible for obtaining the funding and resources necessary to implement the KI program should they decide to request KI. Only the provision of KI and its transport to the recipient organization will be funded by the SNS.

Costs associated with the development and implementation of the KI program may be allowable charges to the CDC cooperative agreements with the State Health Departments for bioterrorism preparedness. State, local, or tribal governmental entities that wish to explore this possibility should contact their respective State Health Officials. Applicants in need of such funding also should consider seeking support from other public or private entities that sponsor efforts to enhance state and local disaster preparedness.

VII. References

A. NUREG-0654/FEMA-REP-1, Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants, March 1987.

B. NUREG-0396/EPA 520/1-78-016, Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants, December 1978.

C. National Academy of Sciences (NAS) Study, Distribution and Administration of Potassium Iodide in the Event of a Nuclear Incident, January 2004.

D. Federal Emergency Management Agency, Notice of revised Federal policy, Federal Policy on Use of Potassium Iodide (KI), 67 FR 1355, January 10, 2002.

E. Nuclear Regulatory Commission, Final rule, Consideration of Potassium Iodide in Emergency Plans, 66 FR, 5427, January 19, 2001.

F. World Health Organization, Guidelines for Iodine Prophylaxis Following Nuclear Accidents, 1999. http://www.who.int/environmental information/Information_resources/documents/Iodine/guide.pdf

G. 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.

H. Food and Drug Administration (Department of Health and Human Services), Potassium Iodide as a Thyroid-Blocking Agent in Radiation Emergencies; 66 FR 64046, December 11, 2001. http://www.fda.gov/cder/guidance/4825fnl.htm.

I. Report of the President's Commission on the Accident at Three Mile Island.

J. Federal Emergency Management Agency, Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agency, 50 FR, 30258, July 24, 1985.

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

L. International Atomic Energy Agency, International Basic Safety Standards for Protection Against Ionizing Radiation and for Safety of Radiation Sources. Safety Series No. 115, 1996.

M. Food and Drug Administration (Department of Health and Human Services) Guidance for Industry KI in Radiation Emergencies – Questions and Answers, http://www.fda.gov/cder/guidance/5386fnl.htm.

N. Food and Drug Administration (Department of Health and Human Services) Frequently Asked Questions on Potassium Iodide (KI). http://www.fda.gov/cder/drugprepare/KI _Q&A.htm.

O. Food and Drug Administration (Department of Health and Human Services) Guidance for Federal Agencies and State and Local Governments: Potassium Iodide Tablets: Shelf Life Extension. http//www.fds.gov/cder/guidance/5666fnl.pdf