Federal Guidelines for Requesting, Stockpiling, Distributing Potassium Iodide (KI) from the Strategic National Stockpile

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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 State, local, and tribal governments, for the distribution, stockpiling, and utilization of potassium iodide in the event of a radioactive iodine release from a commercial nuclear power plant accident. This document is being published in the federal register to permit public input from a wider range of interested entities than was accomplished with a previous draft. Respondents are invited to comment as to whether or not alternative measures of prophylaxis or existing preventive measures would render the establishment of this program unnecessary.

If individuals inhale or ingest radioactive iodine, administration of potassium iodide (KI), when given prior to or within several hours after exposure, can reduce the risk of thyroid cancer among certain categories of persons. KI does not provide protection from external exposure or contamination of radioactive iodine nor does it provide general protection from other sources of ionizing radiation. The primary protective actions are evacuation of the area near the source of the plume, external decontamination of individuals affected, and preventing potentially contaminated food and milk from reaching consumers. Because radioactive iodine exposure at distances beyond 10 miles is likely to be due to contamination of the food and water supply, avoiding the consumption of food or water is expected to the most effective protective measure for persons in this zone.

The Federal government, through the Nuclear Regulatory Commission, presently makes KI available to states for distribution to or stockpiling for individuals within 10 miles of a nuclear power plant. In order to comply with the requirements of the Bioterrorism Act, the Federal government, through the Strategic National Stockpile (SNS) in the Department of Health and Human Services (DHHS), will make KI available for the area up to 20 miles from a commercial nuclear power plant.

II. Background

Bioterrorism Act

Section 127 of the Bioterrorism Act established new Federal requirements for the distribution and use of KI within 20 miles of commercial nuclear power plants. It requires that KI tablets be made available through the SNS to State and local governments for stockpiling and 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 commercial nuclear power plant.

In addition, Section 127 requires:

- Development of guidelines by the U.S. Government for stockpiling, distribution and utilization of KI. Potential recipients under this program are required to submit plans for local stockpiling, distribution, and utilization of KI accompanied by certification that sufficient quantities of KI have not already been provided by the U.S. Government.
- Submission of a Report to Congress six months after publication of guidelines on measures taken to implement the Act, including whether KI has been made available.
- 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." Although the Homeland Security Act of 2002, Public Law 107-296, established joint management of the Strategic National Stockpile (SNS) by the Department of Homeland Security (DHS) and the Department of Health and Human Services (DHHS), the SNS was officially transferred back to DHHS under the Project BioShield Act of 2004, Public Law 108-276. This transfer became effective on August 13, 2004. The authority to implement Section 127 and the responsibility to execute any requirements or options have been delegated to HHS.

Potassium Iodide

KI is the scientist's designation for the chemical compound potassium iodide. It is a salt, similar to table salt and, in fact, KI is the ingredient that is routinely added to table salt, NaCl, to make it iodized.

Iodine is an important element in the formation of thyroid hormone, and in order to accomplish this, KI is 'taken up' by the thyroid gland and used in hormone synthesis. If KI is administered as a countermeasure just before or within 4 hours following exposure to inhaled or ingested radioactive iodine, it will saturate receptor capability within the thyroid gland so that radioactive iodine does not become concentrated within the thyroid, thereby protecting it from ionizing radiation. Significant internal exposures to radioactive iodine can increase the risk of thyroid diseases, notably thyroid cancers.

The use of KI has been recognized by the World Health Organization, the US Food and Drug Administration and the National Academy of Sciences as a safe and effective thyroid prophylaxis in the event of a significant release of

radioactive iodines from nuclear power plants. However, KI only offers protection for one radiation-sensitive organ, the thyroid, under conditions of inhalation or ingestion of radioactive iodine. It does not protect against external irradiation of the thyroid, as might happen if one is exposed to external iodine in a radioactive cloud as opposed to iodine that is inhaled or ingested. It is not a panacea for protection from radiation injury and has use in only this particular circumstance.

The health effect risks to the thyroid gland depend upon many factors, including: 1) the radiation dose to the thyroid, the delivery time of the dose (did the dose to the thyroid occur in minutes, hours, weeks or months?); 2) the age of the person at the time of exposure and ; 3) whether or not the individual is deficient in dietary iodine intake.

A review by The National Academy of Sciences of experience with thyroid cancer in populations exposed to the consequences of nuclear events shows that:

- Exposure to external radiation or internal radiation from radioactive iodine is linked to a dose-dependent increase in thyroid-cancer incidence.
- Young children are by far the most sensitive to the carcinogenic effect of radiation on the thyroid, especially after exposure to radioactive iodine in fallout.
- The risk of thyroid carcinoma in adults exposed to radioactive iodine in fallout is low for adults over 40 years of age.

Radiological Emergency Preparedness Program (REP)

The REP is designed to assure that off-site response organizations are capable of protecting public health in the event of an accident at a commercial nuclear power plant. The primary actions for protecting the public include evacuation and sheltering. Off-site response organizations base their initial protective action decisions on plant conditions, so that the people closest to the facility are evacuated before significant releases of radioactive materials occur. This ensures maximum protection of the public. The use of KI as a supplemental action to evacuation and sheltering is also sometimes recommended to protect public health. However, the use of KI should not interfere with the implementation of an effective evacuation strategy. Follow-on protective actions include decontamination of individuals that have external contamination and preventing potentially contaminated food and milk from reaching consumers. Because radioactive iodine exposure at distances beyond 10 miles is likely to be due to contamination of the food and water supply, avoiding the consumption of contaminated food or water is the most effective countermeasure.

Emergency Planning Zones

To permit protective measures to be taken effectively, two emergency planning zones (EPZ) are established around each commercial nuclear power plant. The zone within 16 km (10 miles) of the plant is designated the plume EPZ and the

region within 80 km (50 miles) from the plant the ingestion EPZ. Current analyses indicate that in the event of a power plant accident, direct exposure to the plume pose the greatest threat for persons near the plant, and people who had not evacuated would be exposed to radiation from the airborne radioactive material, material deposited on the ground or other surfaces, and materials taken into the body by inhalation. Within the plume EPZ, circumstances may result in levels, which if delivered in a short period of time, may be high enough to produce non-stochastic effects in exposed people Farther from the power plant, the dominant exposure would come from radioactive materials taken into the body, primarily by the consumption of contaminated foodstuffs if their consumption were not limited. The planned protective measures differ in the two zones, however there is flexibility in the emergency plans, and protective measures will be adapted to the circumstances at the time of the accident.

- **The 10 mile Emergency Planning Zone**

  The 10 mile EPZ predetermined protective actions include sheltering, decontamination, evacuation and the use of potassium iodide, as a supplement to sheltering and evacuation, where appropriate.

- **The 50 mile Emergency Planning Zone**

  In the area beyond 10 miles and out to approximately 50 miles, the primary exposure to radioactive materials is from ingestion and the protective actions for this exposure area includes a ban on consumption of contaminated food, milk and water.

Chernobyl

We have all learned a great deal since the accident at Chernobyl. We believe that design and safety features of U.S. nuclear power plants plus our emphasis on planning through the REP would make the recreation on U.S. soil of a scenario similar to the one in the Ukraine highly unlikely. Persons have tried to extrapolate a Chernobyl experience to the U.S. However, according to the National Academy of Sciences, “although the qualitative results after Chernobyl are valuable, the quantitative results cannot be transposed to the United States situation without many caveats.”

Terrorism and Nuclear Power Plants

The rigid design features of U.S. nuclear power plants coupled with heightened security measures at these facilities would present significant challenges to terrorists who would seek to make radioiodine releases from one of our power plant as the result of an attack.

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;

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:

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. See the NAS Study for examples of distribution options.

2. Submit KI applications to HHS Office of Public Health Emergency Preparedness;

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. We recommend that local governments review Appendix D of the NAS Study prior to making a decision on the use of KI.

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).

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

2. Submit KI requests to the HHS Office of Public Health Emergency Preparedness.

NOTE: State approval and certification shall be obtained before HHS 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. We recommend that tribal governments review Appendix D of the NAS Study prior to making a decision on the use of KI.

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).

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.

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

IV. Stockpiling, Distribution, Public Education

A. Considerations for KI Utilization

Numerous issues must be considered when making the decision whether to utilize KI as a protective action. These issues include, but are not limited to, the following:

- How will incorporation of KI as a protective measure impact existing emergency plans, procedures, and operations?
- What is the benefit to public health and safety from incorporating KI into emergency response plans?
- 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 distribution of KI be achieved, stockpiled or pre-distributed?
- How will incident specific emergency and environmental conditions be included in the decision to use KI?
- How will the public be notified during an incident when to take KI? Is there a communication system available to notify the pubic of a nuclear incident?
- How will KI be provided to transient populations?
- What medical assistance will be available for the rare individual who experiences an adverse medical reaction following KI administration?
- How will medical authorities advise the population to take KI, and under what circumstances will this advice be given, i.e., methods for public education, information, and instruction?
- What is the cost-benefit of the program? Are there better uses of the funding and resources that would result in a greater reduction in risk?
- What is the liability associated with establishing a KI program?
- What procedures will be used to monitor the expiration of KI stocks and request KI replacement from the stockpile?
- If KI is stockpiled under controlled conditions, will they pursue shelf-life extension pursuant to the Food and Drug Administration's guidance? (See Reference O below.)

B. Stockpiling and Distribution

The National Academy of Sciences report on KI distribution reviewed KI distribution programs in various countries as well as within the United States. An extensive discussion on these programs can be found in Chapter 6**,** EXISTING **DISTRIBUTION PLANS FOR POTASSIUM IODIDE. It is important to note that the report did not identify a preferred method of mass distribution of KI to the public. The report recognized that local conditions surrounding the power plants and existing emergency plans vary between the countries surveyed as well as between the States. The report recognized that the most successful KI plan will be that plan developed that takes into consideration existing State/local emergency planning as well as specific characteristics of the location and population around the nuclear power plants. A method for evaluation of KI distribution plans was developed and published in Appendix D to the KI distribution report. It is recommended that the National Academy of Sciences Report on KI distribution be reviewed for insights in development and implementation of KI plans and programs.**

C. Public Education

Public education is a key component to the success of a KI program. It is important that members of the public have a basic understanding about use and side effects, to warn of allergy, and to reinforce the idea that KI protects only the thyroid and that it is to be taken only at the direction of state officials. Several methods have been used by States with existing KI programs. These include: letters to physicians and residents, in-home visits by public health officials, newspaper ads, distribution through pharmacies, press releases and a press conference, a cable television program, KI distribution or “pick-up” days,and nuclear power plant public education materials. An expanded discussion of various public education methods are included in chapter 6 of the National Academy KI Report.

V. Health and Human Services KI Distribution Program

A. Requests for KI should be submitted to the:

B. State and Tribal Government 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 and Tribal Government'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.

M. Local Governments

KI requests from local governments must certify that:

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

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

- The local 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.

F. Shipment Concept

Upon notification from the Department of Health and Human Services that a state/local/tribal government has successfully submitted a plan for potassium iodide distribution that has subsequently been approved DHHS. DSNS will ship prescribed quantities of potassium iodide to designated locations inside the United States and/or to designated locations outside within *xxx* days of the request.

a) Shipment of potassium iodide will be non-emergent.
b) Product will be stored at manufacturer/vendor prior to shipment.
c) DSNS/manufacturer/vendor will have sufficient potassium iodide to support shipment.
d) Shipment requirements (quantity) will be known and request will be received from DHHS.
e) DHHS will provide a point of contact (POC) for the state/local/or tribal government (shipping location). Requests will include:
    - Name of POC,
    - Telephone number,
    - Email address,
    - Shipping address, and
    - Number of required tablets or bottles (liquid). [*min # of tabs or bottles? i.e. case quantities?]*

6. Shipment will take place via ground transportation.
7. A contract will be in place with the manufacturer/vendor to ship directly from their location.

A. Shipment Procedures:

1. DSNS Response Branch will:
    (a) Receive requests for potassium iodide from DHHS.
    (b) Each request will have:
        (i) POC information for the state/local/tribal government (shipping location).
        (ii) Required number of tablets or bottles (liquid). *[min # of tabs or bottles? i.e. case quantities?]*
    (c) Forward requests to DSNS Logistics

2. DSNS Logistics will:
    (a) Receive a request from Response Branch
    (b) Verify the receiving POC, shipment address, and # tabs/bottles (liquid) requested with the requesting state/local/tribal contact

(c) Create shipment folder
(d) Verify receiving POC, shipping address, and quantity information with requesting state/local/tribal contact
(e) Enter the request into the potassium iodide Tracking database
(f) Fax or email a distribution order to the manufacturer/vendor for packing and shipment
(g) Notify the receiving state of the tracking number and estimated delivery time of shipment
(h) Enter the tracking number into the potassium iodide Tracking database
(i) Verify delivery of the shipment using the shipper's webpage.
(j) Enter the confirmation of shipment delivery into the potassium iodide Tracking database
(k) Update the Shipment folder with all tracking and delivery verification information

3. Manufacturer/vendor or repository will:
   (a) Pack potassium iodide
   (b) Include in each shipment:
      (i) Packing list of shipment contents
   (c) Send the shipment via commercial ground transportation to receiving site
   (d) Tell DSNS Logistics the date and tracking number of the shipment

4. Receiving Site will:
   (a) Receive the shipping container and unpack its contents
   (b) Email confirmation of delivery to DSNS Response Branch

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 tablets/liquid will be funded through the stockpile.

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

P. National Council on Radiation Protection and Measures (NCRP) Report 138, Management of Terrorist Events Involving Radioactive Materials.