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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

AGENCY: Office of Public Health Emergency Preparedness (OPHEP), HHS.
SUMMARY: In accordance with the provisions of Section 127 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-188, (the Bioterrorism Act), this document provides guidelines for State, local, and tribal governments, for the expanded distribution, stockpiling, and utilization of KI in the event of a radioactive iodine release from a commercial nuclear power plant incident. This program would extend coverage from the current ten mile radius up to twenty miles from a commercial nuclear power plant. This document is being published in the Federal Register to permit public input on this expanded coverage from a wider

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range of interested entities than was accomplished with a previous draft. Respondents are also invited to include comments as to whether or not employing measures of prophylaxis other than KI or continuing reliance upon established preventive measures without expanding the area of KI coverage would render the deployment of this expanded KI distribution unnecessary. Further background follows later in these draft guidelines.

If individuals inhale or ingest radioactive iodine, administration of 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 with 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 be the most effective protective measure for persons in this zone.

The Federal Government, through the Nuclear Regulatory Commission, presently makes KI available to States upon their request for distribution to or stockpiling for individuals within 10 miles of a commercial nuclear power plant.

FOR FURTHER INFORMATION CONTACT: Office of Mass Casualty Planning,
Office of Public Health Emergency Preparedness, U.S. Department of
Health and Human Services, 200 Independence Avenue SW., Room 638G,
Washington, DC 20201, Tel: 202-260-1198.

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 Strategic National Stockpile (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. State, local, and tribal governments requesting KI 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.

The Department of Health and Human Services (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 (HHS), the SNS was officially transferred back to HHS under the Project BioShield Act of 2004, Public Law 108-276. This transfer became effective on August 13, 2004.

Potassium Iodide

KI is the chemical symbol 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, sodium chloride (NaCl), to make it ``iodized salt.''

Iodine is a necessary element for 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 minimizing its exposure to 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 U.S. 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 iodine from a nuclear power plant. However, KI offers protection for only 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.

The health effect risks to the thyroid gland depend upon many factors, including: (1) The radiation dose to the thyroid, including time (hours/days/weeks/months) required to deliver the dose); (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 (NAS) 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 cancer in adults exposed to radioactive iodine in fallout is low for adults over 40 years of age.

Radiological Emergency Preparedness Program (REPP)

The REPP, a program managed by the Nuclear and Chemical Hazards Branch within DHS, is designed to assure that off-site response organizations are capable of protecting the public in the event of an incident at a commercial nuclear power plant. The primary actions for protecting the public include evacuation and, as indicated, 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 population closest to the facility. The use of KI as a supplemental action to evacuation and sheltering is also sometimes recommended to protect the public. However, the use of KI should not be adopted as an alternative for the implementation of an effective evacuation strategy. Additional protective actions include decontamination of individuals that have external contamination and preventing potentially contaminated food and milk from being ingested by

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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 at this distance.

Emergency Planning Zones

To permit protective measures to be taken effectively, the Nuclear Regulatory Commission (NRC) established two Emergency Planning Zones (EPZ) around each commercial nuclear power plant. The zone within 10 miles (16 km) of the plant is designated the plume EPZ and the region within 50 miles (80 km) from the plant the ingestion EPZ. Current analyses indicate that in the event of a power plant accident, direct exposure to the plume poses 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 acute radiation effects in exposed people. Farther from the power plant, the predominant exposure threat would come from radioactive materials taken into the body, primarily by the consumption

of contaminated foods, milk, and water. 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 incident.

The NAS report, Chapter 5, PROTECTIVE MEASURES, page 81, states: ``Exposure to radioactive iodine is possible through the ingestion pathway, so it is important that plans address this situation. Monitoring of the environment and food products controls this route of exposure. Removing contaminated products from the market and isolating contaminated products until the radioactive iodine decays to safe levels are the most effective way to eliminate radiation exposure and damage to the thyroid. That also eliminates the need for the use of KI by the general public as a protective action [in the ingestion zone].''

The 10 mile Emergency Planning Zone (Plume EPZ)

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

The 50 mile Emergency Planning Zone (Ingestion EPZ)

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 include a ban on consumption of contaminated food, milk, and water.

The 10-mile EPZ has been reviewed and accepted by the EPA, NRC, and FEMA as the appropriate EPZ size for commercial nuclear power plant licensees to use in developing emergency plans 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, and nuclear power plant licensees will not be expected to modify their emergency plans.

Chernobyl

A great deal has been learned 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 REPP make it unlikely that a similar scenario could occur on U.S. soil. Persons have tried to extrapolate a Chernobyl experience to the U.S. However, according to the NAS, ``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 cause radioiodine to be released from one of our power plants as the result of an attack. As the National Academy of Sciences concluded, ``The terrorism threat does not appear to add significantly to the risk, because of the existing mechanisms and procedures.''

Roles and Responsibilities

In order to facilitate implementation of the requirements of Section 127 and ensure coordination with the existing REPP 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. OPHEP 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;

The findings of the NAS study.

B. DHS

Although Section 127 does not establish direct implementing requirements for the DHS, DHS will maintain its current activities in support of the NRC's current KI program.

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 DHS 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 the HHS' Office of Public Health Emergency Preparedness; such applications will include a plan for stockpiling and for distribution and use of KI in the event of a nuclear incident;
3. Certify that the State has not already received sufficient quantities of KI from the Federal Government, (See Section 127(b) (1) (B));
4. Consider FDA's Guidance, ``Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies'' in preparing emergency KI dosing plans;

E. Local Governments Will

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

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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);

3. Submit their plans for stockpiling, distribution, and using KI to the State for approval and certification that the plan is ``not inconsistent'' with the State emergency plan;

4. Consider FDA's Guidance, ``Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies'' in preparing emergency KI dosing plans;

5. Submit KI requests to the HHS Office of Public Health Emergency Preparedness, such applications will include a plan for stockpiling KI and for distribution and use of KI in the event of a nuclear incident.

Note: State approval and certification must 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. 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. Consider FDA's Guidance, ``Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies'' in preparing emergency KI dosing plans;

4. Submit a KI request to the HHS' Office of Public Health Emergency Preparedness.

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 KI be stockpiled and 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 public of a nuclear incident?

How will KI be provided to transient populations?

What medical assistance will be available for the 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 NAS's 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 commercial 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 take into consideration existing State/local emergency planning as well as specific characteristics of the location and population around the commercial 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 NAS's Report on KI distribution be reviewed by State, local, and tribal governments 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 knowledge about the use and side effects of KI, are aware that KI protects only the thyroid from internal exposure to radioactive iodine, and understand that it is to be taken only at the direction of authorized 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 commercial nuclear power plant public education materials. An expanded discussion of various public education methods is included in chapter 6 of the NAS KI Report.

Health and Human Services KI Distribution Program

A. Requests for KI should be submitted to the:
Office of Mass Casualty Planning, Office of Public Health Emergency Preparedness, U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 638G, Washington, DC 20201, Tel: 202-260-1198.

B. State Government KI requests must:

Certify that the State has not already received sufficient quantities of KI from the Federal Government;

Specify the quantity and formulation of KI needed and describe the calculation used to make this determination;

Identify the location of the commercial 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 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; provide

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a recipient address for the shipment of KI;

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;

Specify how the plan is integrated into existing emergency response plans; and

Specify quantities of KI (tablets and pediatric liquid oral formulation) that will be requested.

C. Local Governments

KI requests from local governments must certify that:

The State in which the local government is located does not have a DHS-approved KI distribution plan that includes KI as a protective measure for populations, or a DHS approved plan that does not address populations located beyond 10 miles from the commercial 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 commercial 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.

Funding and Resource Requirements

State, local, and tribal governments are responsible for obtaining

the funding and resources necessary to request and implement the KI program within their respective jurisdictions, should they decide to request KI. Only the provision of KI tablets/liquid will be funded through HHS.

Dated: August 24, 2005.
Robert G. Claypool,
Deputy Assistant Secretary, Office of Public Health Emergency
Preparedness, Department of Health and Human Services.

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