STATE OF WEST VIRGINIA
OFFICE OF THE GOVERNOR
CHARLESTON 25305

February 12, 2004

BOB WISE
GOVERNOR

Mr. Eric Weiss, Section Chief
Emergency Preparedness & Health Physics
U.S. Nuclear Regulatory Commission, MS 06H2
Washington, DC 20555

Dear Mr. Weiss:

In response to the letter from the U.S. Nuclear Regulatory Commission (NRC) dated December 20, 2001, I would like to accept the offer to receive two potassium iodide (KI) tablets per person in the 10-mile emergency planning zone (EPZ) for the First Energy Beaver Valley Power Station. The stockpile and distribution of KI would include the transient population and all persons that are institutionalized, residing in, working in, or attending school in Hancock County, West Virginia. For all persons estimated to be traveling or residing in the State of West Virginia during an emergency that requires distribution of KI within the 10-mile EPZ, this corresponds to 50,000 KI tablets for both citizens and transient populations within Hancock County. The State Radiological Emergency Plan (REP) will be updated within one year to support these measures to protect children and the general public in accordance with FEMA recommendations.

I respectfully request 30,000 130 milligram (mg) KI tablets and 20,000 65 mg KI tablets be shipped to Mr. Dan Hill, Radiological Health Program, Office of Environmental Health Services, 815 Quarrier Street, Suite 418, Charleston, West Virginia 25301-2616. The Radiological Health Program will coordinate delivery of the KI tablets with the Hancock County Health Department and the State or County Office of Emergency Services. If you have any questions or need additional information, please do not hesitate to call my office or Mr. Randy C. Curtis, P.E. Director, Radiation, Toxics and Indoor Air Division, Office of Environmental Health Services, at (304) 558-2981.

Sincerely,

Bob Wise
Governor

BW:dse

Enclosure: WV Bureau for Public Health Policy--Distribution and Use of Potassium Iodide

cc: Paul L. Nusbaum, Secretary, DHHR
Catherine C. Slemp, M.D., M.P.H., Acting State Health Officer
Chris Curtis, M.P.H., Acting Commissioner, BPH
Barbara S. Taylor, Director, OEHS
Randy C. Curtis, Director, RTIA Division
Dan Hill, Chief, Radiological Health Program
Stephen S. Kappa, Director, WVOES

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Bob Wise
Governor

Paul L. Nusbaum
Secretary

BUREAU FOR PUBLIC HEALTH
POTASSIUM IODIDE WORKING GROUP

The undersigned recommend the attached policy for distribution and use of potassium iodide in the State of West Virginia:

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Bureau for Public Health

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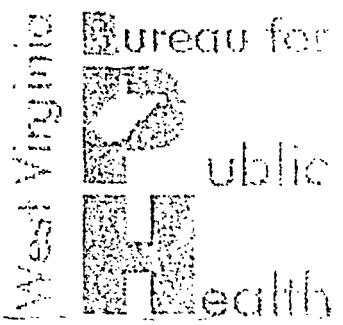
WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES

BUREAU FOR PUBLIC HEALTH
POLICY
DISTRIBUTION AND USE OF POTASSIUM IODIDE
(THYROID PROPHYLAXIS)

FOR THE AFFECTED WEST VIRGINIA POPULATION
IN A 10-MILE EMERGENCY PLANNING ZONE
SURROUNDING BEAVER VALLEY POWER STATION
(IN SHIPPINGPORT, PA)

OCTOBER 20, 2003



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POLICY STATEMENT

The West Virginia Department of Health and Human Resources - Bureau for Public Health (BPH) recommends:

- That evacuation remain the primary protective action for a nuclear power reactor accident involving a loss of containment and a release of radioactive material to the environment.

- The initial procurement of potassium iodide (KI) by accepting an offer from the U.S. Nuclear Regulatory Commission (NRC) for distribution to and subsequent use, as directed by the Bureau for Public Health (BPH), for the general public within a ten mile Emergency Planning Zone (as defined by the Beaver Valley Power Station emergency response plan).

- The distribution of KI to the general public within the 10-mile Emergency Planning Zone (EPZ) by the individual county health departments in accordance with a distribution plan developed by the individual county office of emergency services and local health department. This includes:
  1. pre-distribution of a package of tablets to the permanent residents that would provide each individual with a two-day supply. The pre-distribution program within a 10 mile EPZ should be based on a system where the general public voluntarily picks up the KI tablets at various convenient locations in and around the Emergency Planning Zone (EPZ); and
  2. stockpiling of the remaining KI tablets to be made available for the transient population at designated locations outside the 10 mile EPZ.

- The development of an educational outreach program to inform the public about the use of KI as a supplement to evacuation.

- When it is projected that a release is imminent or in progress that would deliver 5 rem committed dose equivalent to the thyroid:
  1. evacuation of the public from the recommended EPZ in accordance with instructions from the local health department and county office of emergency services; and
  2. the administration of KI to the general public, emergency workers, and institutionalized individuals within the 10-mile EPZ in accordance with the U.S. Food and Drug Administration (FDA) approved-dosage guidance. Any decision to take KI tablets by individuals is voluntary.

- The regular review and revision of this policy based on assessment of risk, lessons learned from policy implementation, and further development of expert or federal agency recommendations.

1. BACKGROUND

Epidemiological data from Chernobyl provides the most reliable information available to date on the relationship between thyroid radioactive uptake and cancer risk. The information suggests that the risk of thyroid cancer is inversely related to age, which puts young children at risk of thyroid cancer at low levels of radioactive exposure. The majority of thyroid cancer cases, following the Chernobyl incident, occurred in children who likely received less than 30 rem (beta/gamma dose equivalence) of radiation absorbed dose (rad) to the thyroid.

Affected Areas

Hancock County is the only area in West Virginia surrounding the Beaver Valley Power Station (in Shippingport, Pennsylvania) within the 10-mile EPZ. (The 10-mile EPZ also includes areas within Columbiana County in Ohio and Beaver County in Pennsylvania.)

Affected Population

In a nuclear power plant accident that results in the loss of containment, individuals within the 10-mile EPZ may be exposed to an airborne plume containing radioiodine. Populations of concern include full-time residents, part-time residents, transients, institutionalized groups, people with special needs, and emergency workers.

2. POTASSIUM IODIDE (KI)

Overview

Potassium iodide (chemical symbol KI) is a stable compound of iodine in the form of a salt. KI is useful for radiological emergency response; it can be taken orally to saturate the thyroid gland with nonradioactive iodine. It blocks the gland's ability to absorb radioactive iodine released following a nuclear reactor accident. The NRC has offered to fund the purchase of KI to states who request KI for the general public within the 10-mile EPZs around nuclear power plants. A delay in taking KI will reduce or eliminate its effectiveness in blocking the uptake of radioactive iodine by the thyroid. This increases the radiation dose to the thyroid, which increases the risk of thyroid cancer. KI is about 95% effective in blocking radioiodine deposition in the thyroid if taken several hours before, during, or immediately after inhalation or ingestion. The effectiveness of KI drops to about 50% when taken about 4 hours after exposure. After about eight hours from exposure, the ability to block radioiodine is essentially nonexistent. KI, in correct daily dosages, is appropriate as long as significant exposure continues. However, exposure should always be limited by rapid evacuation from the contaminated area. KI is only effective against radioiodine and provides no protection from the other inhaled or ingested mixed fission products that are also released during a nuclear power plant loss of containment accident. KI provides no protection against the external radiation exposure from an airborne release of radioactive material, or from radioactive material that has fallen to the ground. Prolonged external radiation exposure dose can cause serious health consequences. Typically buildings do not provide adequate shelter from penetrating radiation exposure during a release.

Evacuation is the primary protective action in the event of a release of radioactive material to the environment. KI is a voluntary supplement to evacuation and is recommended to be used only in the event of an actual or imminent release of radioiodine within the 10 mile EPZ.

Precautions and Contraindications

The administration of KI at thyroid blocking doses is generally safe for most adults and children if taken in appropriate doses for only a few days. Potential side effects of KI are small. However, persons with known iodine hypersensitivity or iodine-sensitive conditions should avoid KI. The guidance from the U.S. Food and Drug Administration (FDA) indicates that iodine-sensitive conditions include dermatitis associated with complications of celiac disease (dermatitis herpetiformis), Graves' disease, enlargement of the thyroid (multinodular goiter), auto-immune thyroiditis (which causes low thyroid reserve), and inflammation of the blood vessels due to lack of immune response mechanism in the blood (hypocomplementemic vasculitis).

Other precautions to consider include:

- The FDA has determined that pregnant or nursing women should be given KI, but should avoid repeat dosing.
- The FDA has concluded that the benefits of KI outweigh the risks to babies but that they should be medically monitored for transient hypothyroidism. Without immediate treatment, transient hypothyroidism may cause mental retardation.
- The FDA has determined that KI in breast milk can pose a risk of hypothyroidism in nursing infants; nursing babies exposed to KI through direct treatment or nursing should be medically monitored for transient hypothyroidism.

Administration of KI to the General Public

Members of the general public who are capable of evacuation must evacuate when instructed. Evacuation must not be delayed in order to locate a supply of KI within the evacuation area. If evacuation is completed without exposure to radioactive iodine, it is not necessary to take KI. BPH will recommend evacuation of the population within the 10-mile EPZ when it is projected that a release is imminent or in progress that would expose people to:

- 1 rem total effective dose equivalent (TEDE) to the whole body, or
- 5 rem committed dose equivalent (CDE) to a person's thyroid.

BPH will also make recommendations to local authorities to alert the general public within the 10-mile EPZ to begin taking KI when it is projected that a release is imminent or in progress that would deliver 5 rem CDE to the thyroid. The individual decision to take KI tablets by any individual of the general public is voluntary. During an emergency, KI does not have to be administered by or in the presence of medical workers. Parents or guardians who accompany their children would be personally responsible to administer the pre-distributed KI or stockpiled KI to their children. Adults will administer the KI to themselves. If a

release of radioiodine occurs within the 10-mile EPZ during school hours, parents or guardians of school children and, in some cases, pre-school-aged children, are not expected to be present at the time KI should be taken. Plans should be developed according to instructions from the local county health department and the office of emergency services in accordance with the local school board plan. The plan should default to allow administration of KI, in accordance with the FDA approved dosages, to the children unless a parent or guardian has a "deferral" in writing filed beforehand with the local school. The administration of KI should not delay evacuation.

Administration of KI to Institutionalized Populations

BPH will recommend evacuation within the 10-mile EPZ when a radioactive release is imminent or in progress that is projected to deliver:

- 1 rem (10 milliSieverts) total effective dose equivalent (TEDE) to the body, or·
- 5 rem (50 milliSieverts) committed dose equivalent (CDE) to the thyroid.

Those institutionalized individuals for whom evacuation is not feasible shall be administered KI by the institutions' supervising medical authority. The decision should be in accordance with official recommendations from the local county health department. BPH will advise the institutions to administer KI when a release of radioiodine is imminent or in progress that is projected to deliver 5 rem CDE to the thyroid. The individual decision to take KI tablets by any individual of the general public is voluntary.

Administration of KI to Emergency Workers

Emergency workers are notified in accordance with procedures used by the state, county and BVPS utility for administration of KI to those within the 10-mile EPZ according to the requirements of the BVPS emergency response plan. Those who need to enter an evacuated area through which the plume passes will be advised by BPH to take KI when a release of radioiodine is imminent or in progress that is projected to deliver a dose to the worker's thyroid in excess of the WVOES REP guideline. These guidelines are based on EPA Protective Action Guide Recommendations.

KI Dosage Recommendations

To minimize the risk of potential side effects, only the recommended dosage should be taken. One KI dose protects against thyroid uptake of radioiodine for about 24 hours. Taking more than a single dose at any one time increases the risk of side effects without providing additional benefit. If circumstances prevent an individual from evacuating and he/she is exposed to the airborne radioactive release plume, BPH recommends that the appropriate KI dose be taken once each day for the duration of the radioactive plume exposure period. If at all possible, the first dose should be taken prior to the plume exposure or soon after the initial exposure and should continue each day until exposure to the radioactive plume ends.

BPH recommends following the FDA approved guidance on the daily dosage for the public. Current FDA dosage recommendations can be found in Attachment A.

3. PROCUREMENT, DISTRIBUTION AND STORAGE

KI for the general public shall be obtained by BPH from the NRC. The NRC will not fund the costs of storage or distribution. BPH will work with the NRC, FEMA, WVOES, the affected Hancock County Office of Emergency Services (HCOES) and the county health department(s) to ensure that an adequate supply of KI is available for pre-distribution to provide a 2-day dosage to the entire population of the EPZ in West Virginia. State and county radiological emergency plans need to be revised to include public education, ordering, receipt, county distribution, pre-accident storage and public distribution of KI. Local plans should be acceptable to the State of West Virginia to meet the requirements of FEMA or Public Law 107-188[1].

Cost and Availability

The initial distribution of federally funded KI shall be provided to the general public within the 10 mile EPZ without cost.

Pre-Accident Distribution

BPH will procure KI for the initial distribution to the affected population residing within the 10-mile EPZ. BPH will work with local health departments to develop effective, efficient plans for pre-distribution of KI to the public. Plans may include the use of other organizations such as pharmacies to distribute KI. County OES that institute a pre-accident KI distribution program will need to revise their emergency plans accordingly.

The distribution program plan will describe how concerned individuals can collect their supplies of KI in advance of an accident. The plan will also make provisions for distribution of KI to people with special needs.

People who receive KI should be provided with approved copies of KI drug and dosing information. Staff should be available to answer questions about the use of KI. In addition to pre-event distribution of KI to residents within the 10 mile EPZ, BPH recommends stockpiling excess stocks of KI at designated locations outside the 10 mile EPZ according to local health department and HCOES plans.

After an emergency alert notification is made, BPH recommends that KI only be made available at designated facilities outside of the 10-mile EPZ, such as reception centers for evacuees, prioritizing people potentially contaminated by the plume.

Transient Population Distribution

KI made available for use by transient populations should be stockpiled and not pre-distributed. However, in the case of companies, organizations, recreational facilities, or similar entities that are located within the EPZ that have a known population, pre-distribution of KI should be utilized.

4. POLICY IMPLEMENTATION

BPH recognizes that evacuation is the most effective means of assuring protection of the public in the unlikely event of an accident at a nuclear power plant. BPH also recognizes that a program of providing KI to the general public is an effective supplemental protection measure to evacuation. Therefore, BPH recommends the development of a potassium iodide (KI) distribution program in West Virginia. Local efforts at the county level should focus on both public education and distribution in advance of the need. This policy should be regularly reviewed and revised based on assessment of risk, lessons learned from policy implementation, and further development of expert or federal agency recommendations.

APPROVED: Catherine C Slemp DATE: January 5, 2004
Catherine C. Slemp, MD, MPH
Acting State Health Officer

[1] Public Law 107-188: Public Health Security, Bioterrorism Preparation & Response Act (2002)

ATTACHMENT A

WV BPH KI POLICY DOSAGE RECOMMENDATIONS

Individuals taking KI tablets are advised to follow the FDA approved dosage guidance:

Threshold Thyroid Radioactive Exposures and Recommended Doses of KI for Different Risk Groups

	Predicted Thyroid Exposure (cGy)	KI dose (mg)	# of 130 mg tablets	# of 65 mg tablets
Adults over 40 yrs	≥500	130	1	2
Adults over 18 through 40 yrs	≥10			
Pregnant or lactating women	≥ 5			
Adoles. over 12 through 18 yrs*		65	1/2	1
Children over 3 through 12 yrs				
Over 1 month through 3 years		32	1/4	1/2
Birth through 1 month		16	1/8	1/4

*Adolescents approaching adult size (≥ 70 kg) should receive the full adult dose (130 mg)

These recommendations are the lowest effective dose. Emergency planners and others should understand that absolute precision in dosing is generally not critical to safety or efficacy when a single or two (2) dose regimen is followed. However, where feasible, adherence to FDA guidance should be attempted, especially when dosing infants.

POTASSIUM IODIDE (KI) can be harmful to some people.
Unless otherwise directed, people should NOT take KI if they:

- **have ever had thyroid disease (such as hyperthyroidism, thyroid nodules or goiter).**
- **know they are allergic to iodine (if they are allergic to shellfish, ask a doctor or pharmacist about taking KI).**
- **have certain skin disorders (such as dermatitis herpetiformis or urticaria vasculitis).**

Individuals should consult a doctor if they are uncertain about whether or not to take KI.