

# State of Ohio



## Ohio Department of Health

SUBJECT: Distribution and Use of Potassium Iodide (KI) For The 10-Mile Emergency Planning Zone Population	PAGE 1 OF 10
RELATED RULE/CODE:  None	NUMBER: 10-RAD-01
RELATED PHAB STANDARDS:  None	SUPERSEDES:  ODH KI Policy, Rev 3, May 2009
RELATED FORMS:  None	EFFECTIVE DATE:  April 10, 2015
	APPROVED: 

### I. AUTHORITY

This policy is issued in compliance with Ohio Revised Code 3748.02, which designates the Ohio Department of Health (ODH) to be the Ohio radiation control agency.

### II. PURPOSE

The purpose of this directive is to provide guidance on the use of potassium iodide (KI) to reduce radiological doses to members of the public and emergency responders within the 10-mile emergency planning zone (EPZ) during a nuclear accident and release of radioactive material at the Davis Besse Nuclear Power Station (Davis-Besse) near Oak Harbor, Ohio; the Perry Nuclear Power Plant (Perry) near North Perry, Ohio; or the Beaver Valley Power Station (Beaver Valley) near Shippingport, Pennsylvania.

### III. APPLICABILITY

This directive is intended for State, county, and local elected officials; State, county, and local health agencies; State, county, and local emergency preparedness and response organizations; and members of the public, large employers, and special population facilities and organizations within the 10-mile EPZ around Davis-Besse, Perry, and the portion of Columbiana County within the Beaver Valley EPZ.

### IV. DEFINITIONS

**10-Mile Emergency Planning Zone (EPZ):** An area within an approximate 10-mile radius of a nuclear power station that is divided into sub-areas which are set-up along easily identifiable boundaries. This is an area for which planning is needed to ensure that prompt and effective actions can be taken to protect the public in the event of an incident at a commercial nuclear power facility that results, or could result in a radiological release.

**Care Center:** Location (usually a school) set aside for the mass care and feeding of members of the public evacuated from the EPZ during an emergency at a nuclear power station. In some counties, radiation monitoring and decontamination of the public, if needed, also occurs at care centers (see Reception Centers).

**Committed Dose Equivalent (CDE):** The dose equivalent to organs or tissues of reference that will be received from an intake of radioactive material by an individual during the 50 year period following the intake.

**Decontamination:** The reduction or removal of radioactive material clinging to or around a person, object, or area.

**Emergency Responder:** An individual who has an essential mission within the plume exposure pathway EPZ to protect the health and safety of the public who could be exposed to ionizing radiation from the plume or from its deposition. An emergency responder may also be referred to as an Emergency Worker (EW).

**Exposure:** The condition of being made subject to a radiation hazard. In this document, exposure may be used as a generic term to refer to the absorbed dose or dose equivalent of radiation affecting an individual or population.

**Fast-Breaking Event:** A nuclear power plant event or incident that, either instantaneously or in a very short time period, progresses to a General Emergency classification, with or without a release of radioactive materials, which requires immediate (prompt) notification of the public, and requires urgent and immediate actions on the part of the general public. Urgent and immediate actions by the public could include any action, such as evacuation sheltering-in-place, or monitoring news or emergency information updates for further action, as determined necessary by the situation.

**General Emergency:** Fourth of four emergency classification levels, meaning that events are in progress or have occurred which involve actual or imminent substantial core degradation with a potential for loss of containment integrity, or security events that result in an actual loss of physical control of the facility. Releases can reasonably be expected to exceed U.S. EPA Protective Action Guideline (PAG) exposure levels offsite for more than the immediate site area.

**Institutionalized Persons:** Persons who reside in institutions such as nursing homes or prisons and may need to depend on others for assistance with protective actions.

**Monitoring:** The act of detecting the presence of radiation and the measurement of contamination or radiation levels. Monitoring may also be referred to as “surveying.”

**Plume:** Generally an atmospheric release from a nuclear power plant, in an accident or emergency, which may contain radioactive noble gases and volatile solids. This cloud is not visible to the eye, but can be detected and measured with radiation measurement equipment.

**Potassium Iodide (KI):** A stable compound of iodine in the form of a salt, taken orally to saturate the thyroid gland, thereby blocking the absorption of radioactive iodine released during a nuclear reactor accident.

**Preparedness Organizations:** The groups that provide interagency coordination for domestic incident management activities in a non-emergency context. Preparedness organizations can include all agencies with a role in incident management, for prevention, preparedness, response, or recovery activities. They

represent a wide variety of committees, planning groups, and other organizations that meet and coordinate to ensure the proper level of planning, training, equipping, and other preparedness requirements within a jurisdiction or area.

**Rad (Radiation Absorbed Dose):** The name for the conventional unit for absorbed dose of ionizing radiation. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram; the corresponding International System (SI) unit is the gray (Gy); 1 rad = 0.01 Gy = 0.01 Joule/kg.

**Reception Center:** A pre-designated facility outside the EPZ (minimum is 15 miles from the nuclear power facility) at which the evacuated public can register, receive radiation monitoring and decontamination, assistance in contacting others, directions to Care Centers, receive general information, and reunite with others. (Note: also called a relocation center, registration center)

**Release:** A radiological release (airborne or liquid) to the outside environment attributable to an emergency event.

**Shelter In-Place:** (referred to as “Sheltering” in U.S. EPA 400-R-92-001) A protective action for the public, meaning to stay indoors with ventilation systems turned off, doors and windows closed, and listening to Emergency Alert System (EAS) broadcast. Shelter In-Place is a protective action, not to be confused with providing temporary shelter (living quarters) for the public.

**Transient Population:** Non-residents and persons who do not permanently reside in the EPZ, but may be present during an emergency.

## V. POLICY

It is the policy of the ODH that:

- Evacuation remains the primary protective action for a nuclear power reactor accident involving a release of radioactive material to the environment. In the event evacuation is not possible (e.g., adverse weather conditions or Hostile Action) the public will shelter in place until instructed otherwise. The public may also be instructed to take KI as an adjunct to the above protective actions.
- The administration of KI is meant to be a supplement to evacuation or sheltering in place, and not a replacement for these actions. The public should not delay evacuation or leave shelter in order to obtain KI. KI protects only against exposure to radioactive iodine. By leaving shelter to seek KI, the public risks unnecessary exposure to radionuclides other than radioactive iodine that may pose a greater health risk.
- The distribution of KI to the public within the 10-mile EPZ by the individual local health departments is in accordance with a distribution plan developed by the local county emergency management agencies (EMA) and local health departments.
- Local county EMAs consider development and distribution of educational outreach pamphlets to inform the public about the use of KI as a supplement to evacuation or sheltering in place. This should include locations of designated monitoring/decontamination and reception centers where the public can obtain KI during evacuation.

- The administration of KI to the public, emergency workers and institutionalized individuals within the 10-mile EPZ is in accordance with U.S. Food and Drug Administration (FDA) approved-dosage guidance provided by the manufacturer during the declaration of a nuclear power plant General Emergency with a release or a significant probability of a release of radioactive material.
- That KI be stockpiled at predetermined monitoring, decontamination, and reception centers established by the individual county EMA's and local health districts along predesignated evacuation routes to help ensure effective and efficient distribution to evacuated populations.
- There should not be a delay in the administration of KI because it will reduce or eliminate its effectiveness in blocking the uptake of radioactive iodine by the thyroid.

## VI. PROCEDURES

### A. BACKGROUND

Epidemiological data from near the Chernobyl nuclear facility following the 1986 explosion and fire provides the most reliable information available to date on the relationship between thyroid radioactive uptake and cancer risk. The information suggests the risk of thyroid cancer is inversely related to age, which puts young children at greater risk of thyroid cancer than older individuals, relative to lower levels of radioactive exposure. The majority of thyroid cancer cases following the Chernobyl accident occurred in children who likely received a committed dose equivalent (CDE) of less than 30 rad to the thyroid.

#### 1. Affected Areas

For the Davis-Besse Nuclear Power Station, the 10-mile EPZ includes parts of Ottawa and Lucas counties. Monitoring/decontamination centers for evacuees from Ottawa and Lucas Counties are located in Sandusky, Lucas and Erie Counties.

For the Perry Nuclear Power Plant, the 10-mile EPZ includes parts of Lake, Ashtabula and Geauga counties. Evacuee monitoring/decontamination centers are also located in these counties.

For the Beaver Valley Power Station in Shippingport, Pennsylvania, the 10-mile EPZ includes part of Columbiana County. Evacuee monitoring/decontamination centers are also located in this county.

#### 2. 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 radioactive iodine. Populations of concern include full-time residents, part-time residents, transients, institutionalized groups, people with special needs and emergency workers.

## **B. POTASSIUM IODIDE (KI)**

The human thyroid gland has an affinity for iodine. 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 United States Nuclear Regulatory Commission (NRC) has offered to fund the purchase of KI for states who request KI for the public located within the 10-mile EPZs around nuclear power plants.

### **1. Effectiveness**

A delay in taking KI will reduce or eliminate its effectiveness in blocking the uptake of radioactive iodine by the thyroid. Ingestion of radioactive iodine increases the radiation dose to the thyroid, which increases the risk of thyroid cancer.

KI is about 95 percent effective in blocking radioiodine deposition in the thyroid if taken several hours before, during or immediately after inhalation or ingestion of radioactive iodine. The effectiveness of KI drops to about 50 percent when taken about four hours after exposure. After about eight hours after exposure, the ability to block radioiodine is essentially nonexistent.

KI is effective only against radioiodine and provides no protection from the other inhaled or ingested mixed fission products that may also be 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 and deposited on the ground. Prolonged external radiation exposure dose can cause serious health consequences.

Evacuation is the primary protective action in the event of a release of radioactive material to the environment. Sheltering in place may be an option based on short releases, adverse weather conditions, or hostile action. The public should not delay evacuation or leave shelter in order to obtain KI. KI only protects against exposure to radioactive iodine. By leaving shelter to seek KI, the public risks unnecessary exposure to radionuclides other than radioactive iodine that may pose a greater health risk.

### **2. Sensitivity**

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. The potential for side effects from KI are small; however, people with known iodine-sensitive conditions should avoid KI. Guidance from the 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 a low thyroid reserve) and inflammation of the blood vessels due to lack of an immune response mechanism in the blood ([hypocomplementemic vasculitis](#)).

The FDA has determined that pregnant or breast feeding women should be given KI, but should avoid repeat dosing.

The FDA has concluded the benefits of KI outweigh the risks to babies, but they should be medically monitored for transient hypothyroidism. Without immediate treatment, transient hypothyroidism may cause mental retardation.

The FDA has determined KI in breast milk can pose a risk of hypothyroidism in nursing infants; nursing babies should be medically monitored for transient hypothyroidism.

### **C. ADMINISTRATION OF POTASIU M IODIDE (KI)**

During a nuclear power plant emergency with a release or where there is a significant probability of a release of radioactive material, ODH will make recommendations to local authorities to direct people within the 10-mile EPZ to begin taking KI. The KI must be taken in accordance with the FDA approved-dosage guidance provided by the manufacturer.

This recommendation for KI administration may be applied to any or all of the following categories of people: the public, emergency workers and institutionalized individuals. The decision to take KI by any individual is a voluntary one.

#### **1. Administration of KI to the Public**

Members of the public who are capable of evacuation should evacuate when instructed. Evacuation must not be delayed in order to locate a supply of KI within the evacuation area. Similarly, if the public has been instructed to shelter in place, members of the public should not leave shelter in order to obtain KI. KI protects only against exposure to radioactive iodine. By leaving shelter to seek KI, the public risks unnecessary exposure to radionuclides other than radioactive iodine that may pose a greater health risk.

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 will personally administer KI to their children. Adults will administer KI to themselves. The decision to take KI by any individual is a voluntary one.

If a nuclear power plant accident occurs during school hours, parents or guardians are not expected to be present to administer KI to their children. In that event, administration of KI to children by school or day-care officials is allowed, in accordance with the guidance provided by the KI tablet manufacturer. Exceptions are made for parents or guardians, who have an “opt out” form filed beforehand with the local school or day-care official.

#### **2. Administration of KI to Institutionalized Populations and Emergency Workers**

Institutionalized populations (e.g., incarcerated, nursing home residents) and those emergency workers who are either working inside of designated sub-areas of the 10-mile EPZ, or need to enter a designated sub-area through which the plume passes, will be advised to take KI in accordance with FDA approved-dosage guidance provided by the manufacturer at the declaration of a nuclear power plant General Emergency with a radioactive material release or significant probability of a

radioactive material release. The decision to take KI by any individual is voluntary; however, the decision by an emergency worker to not take KI may limit work assignments to work outside of the 10-mile EPZ.

### **3. KI Dosage Recommendations**

KI dosage recommendations are adopted from the FDA-approved guidance.

To minimize the risk of potential side effects, only the recommended dosage should be taken. One KI dose (two 65 milligram (mg) tablets) protects against thyroid uptake of radioiodine for about 24 hours. Taking more than a single dose at any one time or taking doses more than two days after exposure has ended increases the risk of side effects without providing additional benefit.

If circumstances prevent an individual from evacuating and he or she is exposed to the airborne radioactive release plume, ODH recommends 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.

The KI available from the NRC is a dosage of 65 mg per tablet. ODH recommends following the manufacturer's guidance on the daily dosage for the public. The table below represents the FDA approved manufacturer's guidance.

**Table 1.** Recommended Daily KI Dosage Guidance

Population	Recommended KI Dosage	Number of 65 mg Tablets (whole or crushed)
Over 18 years	130 mg	2
Over 12 years to 18 years (who weigh at least 150 pounds)	130 mg	2
Over 12 years to 18 years (who weigh less than 150 pounds)	65 mg	1
Over 3 years to 12 years	65 mg	1
Over 1 month to 3 years	32 mg	1/2
Birth to 1 month	16 mg	1/4
<p>* <b><u>Pregnant or breastfeeding women or babies under 1 month of age</u></b> should take as directed above and call a doctor as soon as possible. Repeat dosing should be avoided. It is recommended that thyroid function be checked in babies less than 1 month of age that take KI. Women who are pregnant or breastfeeding should also be checked by a doctor if repeat dosing is necessary. Although these precautions should be taken, the benefits of short-term use of KI to block uptake of radioactive iodine by the thyroid gland far exceed its chances of side effects.</p>		

#### D. PROCUREMENT, DISTRIBUTION AND STORAGE

ODH requested replacement KI from the NRC which was received in May and September, 2014. The new KI, distributed under the brand name ThyroSafe<sup>®</sup>, is in the form of 65 mg tablets, 10 tables per blister pack, two blister packs per individual consumer box and bears one of two lot numbers: TU401A (exp. date 12/31/19) or TU404A (exp. date 4/30/20).

KI should be stored in accordance with the manufacturer's instructions. Old, expired KI should be withdrawn from service and may be disposed of as normal solid waste.

ODH coordinates with the NRC, the Ohio Emergency Management Agency (Ohio EMA), affected county EMAs, and the local health departments to ensure an adequate supply of KI is available in Ohio for affected populations inside the 10-mile EPZs of commercial nuclear power plants. One consumer box of twenty tablets provides enough KI for five people for a period of two days.

##### 1. Cost and Availability

KI supplied by the NRC shall be provided at no cost to the public.

## **2. Pre-Accident Planning**

ODH will procure KI through the NRC for counties to provide to the public residing within the 10-mile EPZ. ODH will work with local health departments to support their plans for distribution of KI to the public. Plans may include the use of other organizations to distribute KI.

People who receive KI should be provided with copies of the KI manufacturer package insert or other similarly prepared information.

ODH recommends stockpiling supplies of KI at designated monitoring/ decontamination and reception centers. However, after an emergency alert notification is made, ODH recommends that KI be made available only at designated facilities outside of the 10-mile EPZ, such as the monitoring/decontamination and reception centers for evacuees, and on a priority basis to people contaminated by the plume, children and pregnant women. Counties should consider providing KI to individuals demonstrating exposure to the radioactive plume upon entrance to a monitoring/decontamination center. Distribution plans should include provisions for distribution of KI to people with special needs.

## **3. Transient Population Distribution**

KI made available for use by transient populations may be stockpiled locally. Transient populations include individuals who do not reside in, but spend considerable amount of time in the 10-mile EPZ either by work, function, or leisure. In cases where participants or workers travel inside the 10-mile EPZ to their place of work, organization, or recreational facility, distribution of KI should be considered for these locations.

KI for transient populations was included in the batch received in September, 2014, from the NRC. Appropriate amounts of KI for transient populations were included in the supply of KI distributed to the local health departments. In the event of a nuclear power plant emergency, transient populations may obtain KI from the local health department's designated monitoring/decontamination and reception centers.

## **E. POLICY IMPLEMENTATION**

ODH recognizes that evacuation is the most effective means of ensuring protection of the public in the unlikely event of an accident at a nuclear power plant which results in the release of radioactive material. ODH also recognizes that a program of providing KI to the public is an effective supplemental protection measure to evacuation. Local efforts at the county level should focus on public education and distribution strategies. Locally stockpiled KI for easy access for evacuated populations should be utilized.

**Table of Effective Changes**

Version	Effective Date	Superseded/Modified	Significant Changes
0	4/29/2002	NA	First Issuance
1	4/21/2004	0	All categories of individuals take KI at the same time for the same areas.
2	1/8/2007	1	Removed voluntary pre-distribution. Added stockpile at Monitoring, Decon, and Reception Centers.  A two year extension on the expiration date was granted by the FDA on the 2007 dated KI.
3	6/19/2009	2	Added Sheltering in Place as a protective action.  Updated with new lot numbers and expiration dates.
4	2014	3	Removed relocation of school children. Added take KI when there is a release or significant probability of a release of radioactive material. Updated with the new lot numbers/expiration date for the replacement KI.