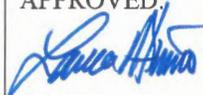




SUBJECT: Distribution and Use of Potassium Iodide (KI) for the 10-Mile Emergency Planning Zone Population	PAGE 1 OF 6
RELATED RULE/CODE: ORC 3748.02	NUMBER: 10-BEHRP-01
RELATED PHAB STANDARDS: None	SUPERSEDES: 10-BEHRP-01, Rev 6, December 2017
RELATED FORMS: None	EFFECTIVE DATE: June 5, 2018
	APPROVED:  6-5-18

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 and delegates the Director of Health the authority to issue recommendations concerning potassium iodide (KI).

II. PURPOSE

The purpose of this policy is to provide guidance on the use of KI to reduce radiological doses to members of the public including institutionalized individuals, and also emergency workers within the emergency planning zone (EPZ) during a nuclear accident and release of radioactive iodine 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.

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 power plant accident.

III. APPLICABILITY

This policy is intended to give guidance for state, county, and local elected officials; state, county, and local health agencies; state, county, and local emergency workers and members of the public, large employers, special population facilities and other organizations within the EPZ around Davis-Besse, Perry, and the portion of Columbiana County within the Beaver Valley EPZ.

IV. DEFINITIONS

Emergency Planning Zone (EPZ): A geographic area surrounding a commercial nuclear power plant for which emergency planning is needed to ensure that prompt and effective actions can be taken by offsite response organizations to protect the public health and safety in the event of a radiological incident. The plume pathway EPZ is approximately 10 miles in radius.

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 ingestion.

Emergency Worker (EW): An individual who has an essential mission within the plume exposure pathway to protect the health and safety of the public who could be exposed to ionizing radiation from the plume or from its deposition.

Exposure: Being exposed to sources of ionizing radiation.

General Emergency (GE): Licensee emergency classification level indicating that events are in process or have occurred that involve actual or imminent substantial core degradation or melting, with 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 Environmental Protection Agency protective action guide exposure levels offsite for more than the immediate site area.

Institutionalized: Individuals who reside in institutions, such as nursing homes or correctional facilities, who may need to depend on others for assistance with protective actions.

Medically Fragile: Institutionalized individuals, who because of their medical condition cannot be moved.

Plume: Generally, a gaseous 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 (i.e., non-radioactive) form of iodine that can be used effectively to block the uptake of radioactive iodine by the thyroid gland of a human being.

Reception Center: A pre-designated facility outside the EPZ (minimum is 15 miles from the nuclear power plant) at which the evacuated public can register, receive radiation monitoring and decontamination, assistance in contacting others, directions to shelters, reunite with others, and receive general information.

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

Shelter-In-Place: A protective action that includes going indoors listening to an Emergency Alert System radio or television station, closing all windows and doors, closing exterior vents, and turning off heating and air conditioning equipment using outside air.

Special Population Facilities: Facilities housing institutionalized individuals.

V. POLICY

It is the policy of the Ohio Department of Health that:

- Evacuation remains the primary protective action for a nuclear power plant accident involving a release of radioactive iodine to the environment. In the event evacuation is not possible (e.g., adverse weather conditions, hostile action, or medically fragile) the public will shelter-in-place until instructed otherwise.

- KI will be recommended for the affected public including institutionalized individuals, and emergency workers within the EPZ at the declaration of General Emergency with a release or a significant probability of a release of radioactive iodine that results in a Committed Dose Equivalent (CDE) of 5 rem child thyroid.
- KI should be taken in accordance with U.S. Food and Drug Administration (FDA) approved dosage guidance provided by the KI manufacturer as identified in Table 1.
- Priority for administration of KI should be given to vulnerable populations, such as infants, children and pregnant females, then anyone under 40 years, then 40+ years. Per FDA recommendation, do not recommend repeat dosing in pregnant females.
- The administration of KI is meant to be a supplement to evacuation or sheltering in place.
- KI does not have to be administered by or in the presence of medical workers. Parents/guardians will administer to their children. Adults will administer to themselves. School officials will administer to students, except for parents/guardians who have an “opt out” form filed beforehand with the local school/daycare.
- The decision to take KI is voluntary; however, the decision by an Emergency Worker to not take KI may limit work assignments.
- There should not be a delay in the administration of KI because any delay will reduce or eliminate its effectiveness in blocking the uptake of radioactive iodine by the thyroid.
- The distribution of KI to the public including institutionalized individuals, and emergency workers within the EPZ 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, those who care for institutionalized individuals, and emergency workers. This should include locations of designated reception centers where KI can be obtained during evacuation.
- KI is stockpiled at locations within the EPZ to help ensure effective and efficient distribution to evacuated populations in accordance with local plans.
- KI should be stored according to manufacturer recommendations.

VI. KI DOSAGE RECOMMENDATIONS

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

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. However, there are risks and benefits associated with taking KI.

Individuals should consider the benefit of taking KI versus the risk of an adverse reaction that may occur for people with known iodine-sensitive conditions:

- Dermatitis associated with complications of celiac disease ([dermatitis herpetiformis](#)), and inflammation of the blood vessels due to lack of an immune response mechanism in the blood ([hypocomplementemic vasculitis](#)) should avoid KI.
- Individuals with [Graves' disease](#), enlargement of the thyroid (multinodular goiter), [auto-immune thyroiditis](#) (which causes a low thyroid reserve) should be treated with caution.
- People with nodular thyroid and heart disease should not take KI.

If you are not sure whether to take KI, consult your healthcare professional ahead of time about the specific risks and benefits of taking KI with the above medical conditions.

Potential side effects include skin rashes; swelling of the salivary glands; metallic taste, burning mouth and throat; sore teeth and gums; symptoms of a head cold; upset stomach and diarrhea. An allergic reaction can have more serious symptoms. These include fever and joint pain; swelling of parts of the body (face, lips, tongue, throat, hands or feet); trouble breathing, speaking, or swallowing; wheezing or shortness of breath. Severe shortness of breath requires immediate medical attention.

Following the Chernobyl radiation accident, one in 270 of the newborns receiving 15 mg of KI showed a short-term hypothyroidism. The effects observed in adults and children were generally minor. Because some newborns may develop this short-term or transient hypothyroidism, newborns given KI should be medically monitored for hypothyroidism symptoms. Your provider will determine if treatment is necessary.

To minimize the risk of potential side effects, only the recommended dosage should be taken. One KI dose protects against thyroid uptake of radioactive iodine 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 plume, ODH recommends the appropriate KI dose be taken once each day for the duration of the radioactive plume exposure period as denoted through public broadcasts or notification from local officials. 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 distributed has a dosage of 65 mg per tablet. 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>* Pregnant or breast-feeding women or babies under 1 month of age 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 who take KI. Women who are pregnant or breast-feeding should also be checked by a doctor [to determine] 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>		

VII. MISCELLANEOUS

A. Disposal

For disposal instructions see website listed below.

- <http://www.odh.ohio.gov/odhPrograms/rp/techs/kipolicy.aspx>

B. Shelf Life Extension

For shelf life extension, please see the following guidance.

- <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM080549.pdf>

C. For additional information click on the links below:

- <https://www.nrc.gov/about-nrc/emerg-preparedness/about-emerg-preparedness/potassium-iodide-use.html>
- <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM080542.pdf>

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.
5	8/12/2016	4	Added criteria for recommending KI at 5 rem child thyroid. Updated new logo plus minor corrections throughout.
6	12/31/2017	5	Removed sections about background, effectiveness, procurement, and distribution.
7	6/5/2018	6	Added and updated definitions, added Miscellaneous section and added storage to the policy statement.