What is potassium iodide and what is it used for?
Potassium iodide (KI) is a chemical compound that can be used to protect the thyroid gland from possible radiation injury caused by radioactive iodine (radioiodine). Some radiological emergencies may release large amounts of radioiodine to the environment. Since iodine concentrates in the thyroid gland, inhalation or ingestion of food contaminated with radioiodine can lead to radiation injury to the thyroid, including increased risk of thyroid cancer and other thyroid diseases.

How does KI work?
Taking KI saturates the thyroid gland with stable (non-radioactive) iodine. This prevents or reduces the amount of radioiodine that will be taken up by the thyroid.

What are the risks to the thyroid from radioiodine?
The radiation dose to the thyroid that results from the uptake of radioiodine increases the risk of thyroid cancer, especially among children. Observations in Europe following the Chernobyl reactor accident in 1986 suggest that the younger the child at the time of exposure, the greater the risk of thyroid cancer. Risk may accrue at very low levels of radioiodine exposure, especially in young children. High radiation doses to the thyroid can also induce hypothyroidism, both in children and adults.

How effective is the use of KI?
Potassium iodide when taken before, or shortly after exposure to radioiodine is effective in reducing radioiodine uptake by the thyroid gland. Reducing this uptake decreases the risk of thyroid cancer in individuals or populations at risk for inhalation or ingestion of radioiodine. KI does not protect against radiation doses received from external sources of radiation or from other radionuclides (except radioactive isotopes of iodine) that may be ingested or inhaled. It also does not protect body organs or tissues, other than the thyroid.

What are the side effects of KI?
Adverse reactions to KI are rare. The risks of stable iodine administration include sialadenitis (inflammation of the salivary gland), gastrointestinal disturbances, allergic reactions and minor rashes. In addition, persons with known iodine sensitivity should avoid KI, as should individuals with dermatitis herpetiformis and hypocomplementemic vasculitis, extremely rare conditions associated with an increased risk of iodine hypersensitivity.

Thyroidal side effects of stable iodine include iodine-induced thyrotoxicosis. This is more common in older people and in iodine deficient areas, and usually requires repeated doses of stable iodine. Iodide goiter and hypothyroidism are potential side effects more common in iodine sufficient areas, but they require chronic high doses of stable iodine. Therefore, individuals with multinodular goiter, Graves' disease, and autoimmune thyroiditis (most likely to be adults) should be treated with caution, especially if dosing extends beyond a few days.

Transient biochemical hypothyroidism was observed in 0.37% (12 of 3214) of neonates treated with KI in Poland after the Chernobyl reactor accident in 1986, with no reported sequelae to date. The U.S. Food and Drug Administration (FDA) has determined that short-term administration of KI at thyroid blocking doses is safe and, in general, more so in children than adults.

What precautions are recommended if KI is issued to neonates?
The FDA determined that the benefits of KI treatment to reduce the risk of thyroid cancer outweigh the risks of such treatment in neonates. However, in light of the potential consequences of transient hypothyroidism for intellectual development, FDA recommends that neonates treated with KI be monitored for this effect by measurement of TSH (and FT4, if indicated). Thyroid hormone therapy should be instituted in cases in which hypothyroidism develops.
What are the recommended prophylactic doses of KI?
FDA provides recommendations for administration of KI based on age/weight, and pregnancy and lactation status. KI is currently FDA-approved and available over the counter in 65 mg and 130 mg tablets and liquid form. MHHS recommends 65 mg tablets because they are larger than the 130 mg tablets and scored in quarters. For children or babies who cannot take pills, parents and caregivers can cut or crush the pill to make lower doses. Efforts should be made to dose at the FDA-recommended level, especially for neonates. The blocking effect of iodide on the thyroid lasts for approximately 24 hours. Any suppressive effect of KI on thyroid function has been shown to be minimal, even in young children. Dosing using the 65 mg tablets is provided below.

<table>
<thead>
<tr>
<th>Threshold Thyroid Radioactive Exposures and Recommended Doses of KI for Different Risk Groups</th>
<th>Predicted Thyroid exposure(cGy)</th>
<th>KI dose (mg)</th>
<th># of 130 mg tablets</th>
<th># of 65 mg tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults over 40 yrs</td>
<td>≥500</td>
<td>130</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Adults over 18 through 40 yrs</td>
<td>≥10</td>
<td>130</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Pregnant or lactating women</td>
<td>≥5</td>
<td>65</td>
<td>1/2</td>
<td>1</td>
</tr>
<tr>
<td>Adoles. over 12 through 18 yrs*</td>
<td>65</td>
<td>1/2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Children over 3 through 12 yrs</td>
<td>32</td>
<td>1/4</td>
<td>1/2</td>
<td></td>
</tr>
<tr>
<td>Over 1 month through 3 years</td>
<td>16</td>
<td>1/8</td>
<td>1/4</td>
<td></td>
</tr>
<tr>
<td>Birth through 1 month</td>
<td>16</td>
<td>1/8</td>
<td>1/4</td>
<td></td>
</tr>
</tbody>
</table>

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

For persons who cannot swallow KI tablets, instructions on how to make liquid KI from the tablets can be found at the end of this document.

How often should KI be administered?
The protective effect of KI lasts approximately 24 hours. For optimal prophylaxis, KI should be dosed within one to three hours prior to an anticipated exposure or after exposure has occurred. KI should be dosed daily, until a risk of significant exposure to radioiodines by either inhalation or ingestion no longer exists. FDA indicates that across populations at risk for radioiodine exposure, the overall benefits of KI far exceed the risks of overdosing, especially in children, although it continues to emphasize particular attention to dose in infants. Pregnant women should be given KI for their own protection and for that of the fetus, as iodine (whether stable or radioactive) readily crosses the placenta. However, because of the risk of blocking fetal thyroid function with excess stable iodine, repeat dosing with KI of pregnant women should be avoided. Lactating females should be administered KI for their own protection. KI to the mother is not a means to deliver KI to infants, who should get their KI directly. As with direct administration of KI, stable iodine as a component of breast milk may also pose a risk of hypothyroidism in nursing neonates. Therefore, repeat dosing with KI should be avoided in the lactating mother, except during continuing severe contamination. If repeat dosing of the mother is necessary, the nursing neonate should be monitored as recommended above.

Why is the Michigan Department of Health and Human Services issuing these recommendations?
The Michigan Department of Health and Human Services (MDHHS) is making KI available at no cost to people living and working in and around Michigan’s three nuclear power plants at local pharmacies. This allows individuals, families, businesses and institutions to have KI readily available, along with their other emergency supplies, in case of a nuclear power plant accident involving release of radioiodines. MDHHS is providing KI only in the 65 mg tablets.
It should be noted that, unlike dosing guidelines provided in the FDA 2001 guidance document (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080542.pdf), the FDA-approved dosing guidelines provided by the manufacturer in the package insert and in MDHHS guidance documents are not based on predicted thyroid exposure. The manufacturer’s dosage guidelines represent the “minimal effective dosage” that would safely protect individuals in their age groups. They provide a conservative and simple protective action during a nuclear incident.

For additional information please contact:
the Michigan Department of Health and Human Services at
1-800-648-6942 or e-mail MDHHS-KI@michigan.gov

Other resources:
www.michigan.gov/KI
www.bt.cdc.gov/radiation/ki.asp
www.who.int/ionizing_radiation/pub_meet/Iodine_Prophylaxis_guide.pdf
Potassium Iodide ("KI") Preparation and Dosing Instructions for Use During a Nuclear Emergency

To Make KI Solution (Liquid Form), using two 65 mg KI Tablets

If government authorities declare that a radiation emergency has occurred, you may have been exposed to radioactive iodine. Potassium iodide can prevent thyroid cancer in people who have been exposed to radioactive iodine. Potassium iodide is also known as “KI.” Children who have been exposed to radioactive iodine have a greater risk of thyroid cancer than adults do. You may need to make a KI solution (liquid form) for anyone who cannot swallow tablets. This sheet explains how to make and give the KI solution. FDA-approved KI tablets come in 65 mg and 130 mg strengths.

Instructions for preparing the KI solution using two 65 mg tablets are given below.

To Make the Potassium Iodide ("KI") Solution You Will Need:

- Two 65 mg KI tablets
- Teaspoon
- Small bowl
- Four teaspoons of water
- Four teaspoons of a drink. We recommend any one of the following:
  - White milk
  - Chocolate milk
  - Orange juice
  - Soda (For example, cola)
  - Infant formula
  - Raspberry syrup
  - Water

Directions for Making the Potassium Iodide ("KI") Solution:

Step 1. Soften the KI tablets:
- Put two 65 mg KI tablets into a small bowl. Add four teaspoons of water. Soak the tablets for one minute.

Step 2. Crush the softened KI tablets:
- Use the back of the teaspoon to crush the tablets in the water. At the end of this step, there should not be any large pieces of KI. This makes the KI and water mixture.

Step 3. Add a drink to the KI and water mixture:
- Choose a drink from the list above. Mix four teaspoons of the desired drink with the KI and water mixture made in Step 2. Adding the desired drink makes the final KI solution.

Step 4. Give the right amount of the final KI solution, using the chart below.

How Much of the Final Potassium Iodide ("KI") Solution to Give Each Day

The chart below tells you how many teaspoons of the final KI solution to give each day. The amount is based on the person’s age. Give this amount once a day until your healthcare provider or public health official says you may stop.

<table>
<thead>
<tr>
<th>Age</th>
<th>Once Daily Dose of KI Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>19 years and older</td>
<td>8 teaspoons</td>
</tr>
<tr>
<td>13 to 18 years (150 pounds or more)</td>
<td>8 teaspoons</td>
</tr>
<tr>
<td>13 to 18 years (149 pounds or less)</td>
<td>4 teaspoons</td>
</tr>
<tr>
<td>4 to 12 years</td>
<td>4 teaspoons</td>
</tr>
<tr>
<td>Older than 1 month to 3 years</td>
<td>2 teaspoons</td>
</tr>
<tr>
<td>Birth to 1 month</td>
<td>1 teaspoon</td>
</tr>
</tbody>
</table>

Storing Any Extra Prepared Potassium Iodide ("KI") Solution:

Store any extra final KI solution mixed in Step 3 in a refrigerator. Any extra KI solution can be used another day. After 7 days, throw out any unused KI solution.

For more information regarding potassium iodide go to CDER’s Bioterrorism Page at the following web address:

www.fda.gov/kiprepare

August 22, 2012