

Lesson 8: KI as a Supplemental Public Protective Action

Lesson Overview

The purpose of this lesson is to provide an overview of the use of potassium iodide (KI) as a supplemental public protective action.

Upon completion of this lesson, you will be able to:

- Describe Federal policy regarding the use of KI as a thyroidal blocking agent by emergency workers, institutionalized persons, and the general public.
- Describe FDA recommendation for administration of KI based on age, predicted thyroid exposure, and pregnancy and lactation status.
- Explain Federal guidelines associated with the decision making process concerning KI as a supplemental public protective action.

Remember you can access the glossary in one of two ways throughout this course. You can select the glossary button in the top right hand corner of each main content screen. In addition, on content screens you can select underlined words to access their definitions in the online glossary. Selecting an underlined word will take you directly to its definition in the glossary.

This lesson should take approximately **45 minutes** to complete.

Implementation of KI References

NRC amended 10 CFR 50.47 (10)

NRC amended 10 CFR 50.47 (10) (1 of 2)

On January 19, 2001, the Nuclear Regulatory Commission (NRC) published an amendment to its regulations, 10 CFR 50.47 (10), requiring that consideration be given to including KI as a protective measure for the general public that would supplement sheltering and evacuation.

NRC amended 10 CFR 50.47 (10) (2 of 2)

Any licensee (plant operator) has an obligation to ensure that states have considered the use of KI as a supplemental protective action for the public. Licensees are required to use this information in developing protective action recommendations for off-site agencies.

If states make the decision to make KI available for the public, the NRC will fund supplies for two tablets per individual within the 10-mile EPZ. The NRC will not fund ancillary costs, including storage or distribution.

Implementation References

Current references on implementation include: FRPCC Federal Policy.

Federal Radiological Preparedness Coordinating Committee (FRPCC) Policy

The FRPCC has revised the 1985 Federal policy regarding the use of KI as a thyroidal blocking agent by emergency workers, institutionalized persons, and the general public in the vicinity of nuclear power plants. This policy is for use by state, Native American tribal nations, and local agencies responsible for radiological emergency planning and preparedness in the unlikely event of a major radiological emergency at a commercial nuclear power plant.

Federal position on Use of KI - The Federal position is that KI should be stockpiled and distributed to emergency workers and institutionalized persons for radiological emergencies at a nuclear power plant and its use should be considered for the general public within the 10-mile EPZ of a nuclear power plant. However, the decision on whether to use KI for the general public is left to the discretion of states and, in some cases, local governments.

In making the decision whether to stockpile KI, the states should be aware that the Federal government believes that the use of KI is reasonable and prudent measure as a supplemental protective action for the public. While there may be logistical difficulties in providing KI to the general public, any distribution scheme should take care to ensure that KI distribution does not impede or delay orderly evacuation.

Chernobyl accident's Impact on FRPCC policy - Revision of the policy to include members of the public reflects lessons learned from the Chernobyl Nuclear power plant accident of 1986, both about the consequences of an accident and about the safety and efficacy of KI.

The Chernobyl accident demonstrated that thyroid cancer can indeed be a major result of a large reactor accident. Based on the experiences from Chernobyl, young children are at greatest risk of thyroid cancer from radioactive iodine exposure. The critical exposure pathway was consumption of contaminated milk as previous lessons have stated.

There may be a few medical side effects in administering the drug to potentially affected individuals or in administering the drug to the general public in a radiological emergency. Although the post-Chernobyl data from Poland revealed few serious medical side effects associated with this drug, this possibility cannot be discounted, especially in certain groups of people. For example, people who are allergic to iodine should not take KI.

Implementation References

Current references on implementation include: FEMA, *Guidance on the Use of KI by the General Public for Commercial Nuclear Power Plant Accidents*.

FEMA Guidelines for KI Implementation

The decision to include KI in the range of public protective actions rests with the states. FEMA is available to assist states with the decision making process and has developed a decision matrix to aid in that process. There are two basic methods of distribution:

- Pre-distribution to the public
- Stockpiles in facilities such as reception or mass care centers

Based on the distribution method adopted by a state, the capability to implement the decision will be evaluated by FEMA as part of its "Reasonable Assurance Finding" recommendation to the NRC. The evaluation of a states' capability to distribute KI to the general public can be achieved through the Annual Letter of Certification, when KI is pre-distributed, and/or a combination of Staff Assistance Visits and biennial exercise demonstrations, when KI is in a fixed facility.

Implementation References

Current references on implementation include: *Guidance on the Use of KI as a Thyroid Blocking Agent in Radiation Emergencies*.

FDA, Guidance on the Use of KI as a Thyroid Blocking Agent in Radiation Emergencies

FDA guidance on the use of KI as a thyroid blocking agent in radiation emergencies has been updated from its original content in 1978.

The latest guidance was revised based upon a comprehensive review of the data relating radioiodine exposure to thyroid cancer risk accumulated in the aftermath of the 1986 Chernobyl reactor accident.

The studies support the etiologic role of relatively small doses of radioiodine in the dramatic increase in thyroid cancer among exposed children. Furthermore, it appears that the increased risk occurs with a relatively short latency. Finally, the Polish experience supports the use of KI as a safe and effective means by which to protect against thyroid cancer caused by internal thyroid irradiation from inhalation of contaminated air or ingestion of contaminated food and drink when exposure cannot be prevented by evacuation, sheltering, or food, and milk control.

Latest Guidance: Risks of Stable Iodine Administration

Short-term administration of KI at thyroid blocking doses is safe and, in general, more so in children than adults. The risks of stable iodine administration include sialadenitis (an 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, which is more common in older people and in iodine deficient areas but usually requires repeated doses of stable iodine. In addition, iodide goiter and hypothyroidism are potential side effects more common in iodine sufficient areas, but they require chronic higher doses of stable iodine. In light of the preceding, individuals with multinodular goiter, Graves' disease, and autoimmune thyroiditis should be treated with caution, especially if dosing extends beyond a few days. The vast majority of such individuals will be adults.

The transient hypothyroidism observed in 0.37% (12 of 3214) of neonates (newborn child) treated with KI in Poland after Chernobyl has been without reported sequelae to date (pathological conditions following the initial effect). There is no question that the benefits of KI treatment to reduce the risk of thyroid cancer outweigh the risks of such treatment in neonates. Nevertheless, in light of the potential consequences of even transient hypothyroidism for intellectual development, the FDA recommends that neonates (within the first month of life) treated with KI be monitored for this effect by measurement of TSH (and FT4, if indicated) and that thyroid hormone therapy be instituted in cases in which hypothyroidism develops.

Latest Guidance: FDA Recommendation for Administration of KI

Recommendations of KI administration for different risk groups are meant to provide states and local authorities as well as other agencies with the best current guidance on safe and effective use of KI to reduce thyroidal radioiodine exposure and thus the risk of thyroid cancer. The FDA recognizes that, in the event of an emergency, some or all of the specific dosing recommendations may be very difficult to carry out given their complexity and the logistics of implementation of a program of KI distribution. The recommendations should therefore be interpreted with flexibility as necessary to allow optimally effective and safe dosing given the exigencies of any particular emergency situation.

- **Adults over 40 years** - Adults over 40 need take KI only in the case of a projected large internal radiation dose to the thyroid (> 500 rem) to prevent hypothyroidism. The downward KI dose adjustment by age group, based on body size considerations, adheres to the principle of minimum effective dose.
- **Adults over 18 through 40 years** - The recommended standard dose of KI for adults through age 40 is same as adults over 40 and adolescents (130 mg).
- **Adolescents over 12 through 18 years** - Adolescents approaching adult size (i.e., >70 kg) should receive the full adult dose (130 mg).
- **Children over 3 through 12 years** - The recommended standard dose of KI for all school-age children is the same (65 mg).
- **Children over 1 month through 3 years** - The standard dose of KI for children over 1 month through 3 years is 32 mg.
- **Birth through 1 month** - Neonates should receive the lowest dose (16 mg). Repeat dosing of neonates should be avoided.
- **Pregnant or lactating women** - Pregnant women should be given KI for their own protection and for that of the fetus, as iodine readily crosses the placenta. However, because of the risk of blocking fetal thyroid function with excess iodine, repeat dosing with KI of pregnant women should be avoided.

Lactating females should be administered KI for their own protection, as for other young adults, and potentially to reduce the radioiodine content of the breast milk, but not as a means to deliver KI to infants, who should get their KI directly. As for 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.

Latest Guidance: Dosage of KI Administration

The protective effect of KI lasts approximately 24 hours. For optimal prophylaxis, KI should therefore be dosed daily, until a risk of significant exposure to radioiodines by either inhalation or ingestion no longer exists.

The following people should be given priority with regard to other protective measures (i.e., sheltering, evacuation, and control of the food supply):

- Individuals intolerant of KI at protective doses
- Neonates
- Pregnant women
- Lactating women

Latest Guidance: Timing of KI Administration

For optimal protection against inhaled radioiodines, KI should be administered before or immediately coincident with passage of the radioactive cloud, though KI may still have a substantial protective effect even if taken 3 or 4 hours after exposure. Furthermore, if the release of radioiodines into the atmosphere is protracted, then, of course, even delayed administration may reap benefits by reducing, if incompletely, the total radiation dose to the thyroid.

Prevention of thyroid uptake of ingested radioiodines, once the plume has passed and radiation protection measures (including KI) are in place, is best accomplished by food control measures and not by repeated administration of KI. Because of radioactive decay, grain products, and canned milk or vegetables from sources affected by radioactive fallout, if stored for weeks to months after production, pose no radiation risk from radioiodine. Thus, late KI prophylaxis at the time of consumption is not required.

Implementation References

Current references on implementation include: *Home Preparation Procedure for Emergency Administration of KI Tablets to Infants and Small Children*.

FDA, Home Preparation Procedure for Emergency Administration of KI Tablets to Infants and Small Children (1 of 2)

KI is stockpiled as tablets because tablets are easy to store; however, infants and small children cannot swallow tablets. In an emergency, KI may need to be given to infants and small children by their parents or caregivers. Since KI dissolved in water may be too salty to drink, the FDA is providing instructions on how to mix the KI tablets with food or drink to disguise the taste.

Taste tests were conducted with six mixtures of KI and drinks:

- Water
- Low fat milk
- Low fat chocolate milk
- Flat soda (e.g. cola)
- Raspberry syrup
- Orange juice

The mixture of KI and **raspberry syrup** disguised the taste best. Low fat chocolate milk, orange juice, and flat soda generally had an acceptable taste. Low fat white milk and water did not hide the salty taste.

FDA, Home Preparation Procedure for Emergency Administration of KI Tablets to Infants and Small Children (2 of 2)

To administer KI tablets to infants and small children at home, you will need the appropriate ingredients and supplies.

Ingredients and supplies needed:

- 130 mg KI tablet
- Metal spoon
- Small bowl
- One of the drinks from the list or infant formula

Mixture preparation:

- Grind one 130 mg tablet into a fine powder in bowl with metal spoon.
- Add four teaspoonfuls of water. Mix with spoon until dissolved.
- Add four teaspoonfuls of drink to the mixture.

The amount of KI in the drink is 16.25 mg per teaspoon. The number of teaspoons administered depends on the age of the child. The mixture will keep for up to seven days in the refrigerator. The FDA recommends that KI drink mixtures be prepared weekly; unused portions should be discarded.

Implementation References

Current references on implementation include: FDA, *DRAFT Guidance for Federal Agencies and State and Local Governments*, KI Tablets Shelf Life Extension.

FDA, DRAFT Guidance: KI Tablets Shelf Life Extension (1 of 3)

This document is intended to provide guidance to Federal agencies and to state and local governments on testing to extend the shelf life of stockpiled KI tablets. The FDA developed this document in response to several state inquiries on this topic.

This guidance discusses the FDA recommendations on:

- The requisite testing for such shelf life extensions
- The qualifications of laboratories suitable to conduct the tests
- The issues regarding notification of holders of stockpiled KI tablets as well as end users (consumers who have purchased KI, or intermediate holders of KI such as fire departments, health departments, hospitals, or other entities who store KI for use in emergencies) about changes to batch shelf life once testing has been successfully conducted.

This guidance is applicable for KI that is stockpiled under controlled conditions.

FDA, DRAFT Guidance: KI Tablets Shelf Life Extension (2 of 3)

KI tablets, USP, is a compendial drug product that is manufactured to meet the recommended tests and specifications listed in the USP monograph. Assay and dissolution are the two specifications with potential relevance to stability, assuming identification and content uniformity testing were performed at release.

Identification and content uniformity are performed by the quality control division of the manufacturer before the product can be released for sale. Stability studies over many years have confirmed that none of the components of KI tablets, including the active ingredient, has any significant potential for chemical degradation or interaction with other components or with the components of the container closure system when stored per labeled directions.

FDA, DRAFT Guidance: KI Tablets Shelf Life Extension (3 of 3)

To date, the only observed changes during stability testing have been the failure of some batches of KI tablets to meet the USP S1 dissolution specification, Q=75 percent in 15 minutes. Some tablets tested required slightly longer than the specified time to achieve dissolution. Even in the case of a failure of this sort, the product would remain stable. In such cases, instructions can be provided to crush the tablets and mix them with juice or other liquid prior to administration as suggested for emergency pediatric dosing.

In any long-term stability evaluation, appearance should be monitored as a matter of course. In the specific case of KI tablets, a yellowish discoloration would be indicative of stability problems. Since pure KI is known to be very stable (as long as it is protected from moist air), ongoing evaluation and testing of each batch is probably unnecessary as long as the market package remains intact and continues to be stored under controlled conditions as described in the labeling.

Implementation References

Current references on implementation include: FEMA, *REP Program Manual*.

FEMA, REP Program Manual, August 2002

According to FEMA policy, criterion 2.b.2. a decision-making process involving consideration of appropriate factors and necessary coordination is used to make protective action decisions (PADs) for the general public (including the recommendation for the use of KI, if it is the Off-site Response Organization's [ORO] policy).

If the ORO has determined that KI will be used as a protective measure for the general public under off-site plans, then the ORO should demonstrate the capability to make decisions on the distribution and administration of KI as a protective measure for the general public to supplement sheltering and evacuation. This decision should be based on the ORO's plan and procedures or projected thyroid dose compared with the established PAG for KI administration. The KI decisionmaking process should involve close coordination with appropriate assessment and decision-making staff.

Implementation References

Current references on implementation include:

- NRC Amended 10 CFR 50.47(10) 1/19/01
- FRPCC Federal Policy, 1/10/02
- FEMA. Guidance on the Use of KI by the General Public for Commercial Nuclear Power Plant Accidents, 12/20/01
- FDA Guidance on the Use of KI as a Thyroid Blocking Agent in Radiation Emergencies, 12/11/01
- FDA Home Preparation Procedure for Emergency Administration of KI Tablets to Infants and Small Children 7/3/02
- FDA DRAFT Guidance for Federal Agencies and State and Local Governments, KI Tablets Shelf Life Extension, 3/03
- FEMA, REP Program Manual, 4.12

You have reviewed all current references on implementation of KI as supplemental public protective action.

Lesson Summary

In this lesson you learned about the following references that provide guidance on using KI as a supplemental public protective action:

- NRC Amended 10 CFR 50.47 (10)
- FRPCC policy
- FEMA, Guidance on the Use of KI by the General Public for Commercial Nuclear Power Plant Accidents
- FDA, Guidance on the Use of KI as a Thyroid Blocking Agent in Radiation Emergencies
- FDA, Home Preparation Procedure for Emergency Administration of KI Tablets to Infants and Small Children
- FDA, Draft Guidance for Federal Agencies and State and Local Governments, KI Tablets Shelf Life Extension

- FEMA, REP Program Manual

The next lesson will cover FDA protective action guides (PAGs).