U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Frequently Asked Questions About Potassium Iodide

On this page:

What is potassium iodide?

Potassium iodide is a salt, similar to table salt. Its chemical symbol is KI. It is routinely added to table salt to make it "iodized." Potassium iodide, if taken in time and at the appropriate dosage, blocks the thyroid gland's uptake of radioactive iodine and thus could reduce the risk of thyroid cancers and other diseases that might otherwise be caused by exposure to radioactive iodine that could be dispersed in a severe nuclear accident.

What is the role of potassium iodide in radiological emergency preparedness?

Potassium iodide is a special kind of protective measure in that it offers very specialized protection. Potassium iodide protects the thyroid gland against internal uptake of radioiodines that may be released in the unlikely event of a nuclear reactor accident.

The purpose of radiological emergency preparedness is to protect people from the effects of radiation exposure after an accident at a nuclear power plant. Evacuation is the most effective protective measure in the event of a radiological emergency because it protects the whole body (including the thyroid gland and other organs) from all radionuclides and all exposure pathways. Administering KI can be a reasonable, prudent, and inexpensive supplement to in-place sheltering and evacuation.

What is the benefit of taking potassium iodide during a radiological accident?

When potassium iodide is ingested, it is taken up by the thyroid gland. In the proper dosage, and taken at the appropriate time, it will effectively saturate the thyroid gland in such a way that inhaled or ingested radioactive iodines will not be accumulated in the thyroid gland. The risk of thyroid effects is reduced. Such thyroid effects resulting from radioiodine uptakes due to inhalation or ingestion, or both, could result in acute, chronic, and delayed effects. Acute effects from high doses include thyroiditis, while chronic and delayed effects include hypothyroidism, thyroid nodules, and thyroid cancer.

Does this rule imply that America's nuclear reactors are less safe?

In 2001, the NRC revised of its emergency preparedness regulation that requires that States with a population within the 10-mile emergency planning zone of commercial nuclear power plants consider including potassium iodide as a protective measure for the general public to supplement sheltering and evacuation in the unlikely event of a severe nuclear power plant accident.

The rule does not imply that the present generation of nuclear power plants are less safe than previously thought. On the contrary, present indications are that nuclear power plant safety has significantly improved since the existing emergency preparedness requirements became effective after the Three Mile Island-2 accident in 1979.

Why does the rule require States to consider the use of potassium iodide instead of mandating its use?

The NRC will not require use of potassium iodide by the general public because the NRC believes that current emergency planning and protective measures--evacuation and sheltering--are adequate and protective of public health and safety. However, the NRC recognizes the supplemental value of potassium iodide and the prerogative of the States to decide the appropriateness of the use of potassium iodide by its citizens.

The NRC believes the final rule together with the decision to provide funding for the purchase of a State's supply of potassium iodide strikes a proper balance between encouraging (but not requiring) State authorities to take advantage of the benefits of potassium iodide.

By requiring consideration of the use of potassium iodide, the Commission recognizes the important role of States and local governments in matters of emergency planning.

This rule applies to States and Tribal governments that have a nuclear power plant within their borders and populations within the 10-mile emergency planning zone and to local governments designated by States to request funding for potassium iodide.

What does it mean for a State to consider the use of potassium iodide?

A State considering the use of potassium iodide would at least review the regulation (66 FR 5427; January 19, 2001), the Federal Policy on the Use of Potassium Iodide, Food and Drug Administration (FDA) guidelines "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies," the FEMA guidelines, and the NRC disclaimer and would briefly deliberate the State's position on the use of potassium iodide by the general public in the unlikely event of a severe nuclear reactor accident.

In NRC's experience, States periodically review their emergency preparedness plans to ensure that the plans are up-to-date and account for the possibility of changed circumstances in any locality. NRC expects that States that routinely schedule periodic reviews of their emergency preparedness plans would consider use of potassium iodide during their first scheduled review. NRC expects that States that do not routinely conduct such reviews would consider the use of potassium iodide whenever they schedule periodic emergency preparedness exercises.

What kinds of things should States consider in deciding whether to incorporate the use of potassium iodide in their emergency planning?

Considerations to be evaluated by State and local authorities in deciding whether to institute a program for the use of potassium iodide by the general public include the following:

- Whether potassium iodide should be distributed to the general population before an accident occurs or as soon as possible after an accident occurs.
- Whether the risks of exposure to radioactivity will be lower if the evacuation of the general population is initiated (with or without the use of potassium iodide) or if the general population is sheltered and the administration of potassium iodide initiated.
- How potassium iodide will be distributed during an emergency.
- What assumptions should be made about its actual availability and use in the event of an incident if potassium iodide is predistributed?
- What medical assistance will be available for individuals who may have some adverse reaction to potassium iodide?
- How medical authorities will advise the population to take potassium iodide and under what circumstances this advice will be given (i.e., methods for public education, information, and instruction).
- How the authorities will provide potassium iodide to transient populations.

What are the recommended dosages of potassium iodide?

FDA is the Federal agency responsible for decisions about appropriate thresholds and dosages for use of potassium iodide. FDA published their final guidelines on the use of potassium iodide and included revised dosages and intervention levels: "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies." Additionally, FDA has published guidance on Home Preparation Procedure for Emergency Administration of Potassium Iodide Tablets to Infants and Small Childrenand also answered Frequently Asked Questions on Potassium Iodide (KI). To facilitate use of KI in emergency situations, on December 23, 2002, FDA published Guidance for Industry KI in Radiation Emergencies - Questions and Answers.

Can individual members of the public obtain potassium iodide?

FDA has approved potassium iodide as an over-the-counter medication. As with any medication, individuals should check with their doctor or pharmacist before using it.

Why is KI only being provided to the 10-mile EPZ around nuclear power plants?

The population closest (within the 10 mile EPZ) to the nuclear power plant are at greatest risk of exposure to radiation and radioactive materials. The purpose of radiological emergency preparedness is to protect people from the effects of radiation exposure after an accident at a nuclear power plant. Evacuation is the most effective protective measure in the event of a radiological emergency because it protects the whole body (including the thyroid gland and other organs) from all radionuclides and all exposure pathways. However, in situations when evacuation is not feasible, in-place sheltering is substituted as an effective protective action. In addition, administering potassium iodide is a reasonable, prudent, and inexpensive supplement to both evacuation and sheltering. When the population is evacuated out of the area, and potentially contaminated foodstuffs are interdicted, the risk from further radioactive iodine exposure to the thyroid gland is essentially eliminated.

Why is the NRC only providing two KI tablets per person?

The tablets are to be used, if necessary, to supplement evacuation or sheltering. After individuals have evacuated the area, then they will no longer be exposed to significant quantities of radioiodines. The KI tablets, if taken at the appropriate dosage and time, block the thyroid gland, preventing uptake of radioactive iodine. Any radioactive iodine taken into the body after consumption of KI will be rapidly removed from the body. The two tablets will protect the thyroid gland for approximately 48 hours.

Will KI be effective in case of a terrorist attack or dirty bomb?

If terrorists attack either at a nuclear power plant or with a "dirty" bomb, radioactive iodine would have to be released in order for potassium iodide (KI) to be needed. Potassium iodide protects the thyroid gland only against the internal uptake of radioiodines.

A nuclear power plant will make protective action recommendations based on current emergency plans, which may

include the recommendation to take KI as a supplement to evacuation and/or sheltering. In the case of a dirty bomb, protective actions will be made according to the threat presented. If the bomb contained radioactive iodine, then the use of KI may be appropriate. However, radioactive iodine is not considered to be a viable component of a dirty bomb due to its relatively short half-life and the difficulties in obtaining significant quantities. More information on dirty bombs and response to terrorist activities can be found on the Nuclear Security and Safeguards Web page. Other information can be found at the Department of Homeland Security.

Have other Federal agencies included potassium iodide in their emergency planning considerations?

The Food and Drug Administration as well as the Centers for Disease Control and Prevention have posted KI information on their Web sites.

What is the shelf life of KI tablets?

As with all drug products, the manufacturer must specify an expiration date of the drug on either the package or the individually wrapped tablet. The NRC distributes two tablet strengths of potassium iodide, 130 and 65 mg tablets. The shelf life of IOSAT 130 mg tablets is 7 years and the shelf life of ThyroSafe 65 mg tablets is 6 years.

For States interested in extending the shelf life of KI, the FDA has published guidance on shelf life extension for the tablet form of potassium iodide. Extending the shelf life of KI tablets is possible due to the inherent stability of the chemical form. However, the tablets must be stored under the conditions specified by the manufacturer to be considered for shelf life extension. In addition, this guidance only is intended for Federal agencies and State and local governments that maintain KI stockpiles under the conditions specified by the manufacturer.

The liquid formulation of KI also has a shelf-life of 5 years. The extension guidance does not apply to this product form.

Is it safe to take KI tablets with an expired shelf-life?

Yes, potassium iodide tablets are inherently stable and do not lose their effectiveness over time. Manufacturers must label their products with a shelf-life to ensure that consumers purchase safe and useful products.

According to FDA guidance on Shelf-life Extension, 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 components of the container closure system when stored according to labeled directions. To date, the only observed changes during stability (shelf-life) testing have been the failure of some batches of KI tablets to meet dissolution specifications. 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 remains usable. In such cases, instructions can be provided to crush the tablets and mix them with a juice or other liquid prior to administration as suggested for emergency pediatric dosing.*

What are the requirements if a State chooses to extend the shelf-life of their KI stockpiles?

The decision to extend the shelf-life of potassium iodide tablets relies on the States. The FDA, in a February 15, 2007 letter to the NRC stated that the FDA does not have any regulation or policy regarding application of an extended expiration dating period to lots that were manufactured prior to the implementation of the extended expiration period. However, the FDA does not object to such a practice as long as adequate records are kept and doing so is scientifically sound. It would be considered to be scientifically sound ?if the lots having the expiration date extended had no significant difference in formulation, manufacturing process or packaging materials from current lots. The letter ...to NRC from counsel to Anbex, Inc. dated January 23, 2007 indicates that this is the case.? RECIP, the manufacturer of the 65 mg tablets, supplied lot numbers along with extended expiration dates.

States must maintain records of current stockpiled lot number(s) and expiration date(s) as well as new expiration date(s) along with the basis documents for their decision (letter from Anbex, RECIP, and FDA). Stockpiled products must be stored in accordance with manufacturers? recommendations.

If a State chooses to extend the shelf life of its KI stockpiles, will they still be eligible for replenishment of KI stockpiles in the future?

Yes, the NRC will resupply KI, at the appropriate time, to those States that choose to extend current KI stockpiles.

What are the results of the National Academy of Sciences study on the distribution and administration of potassium iodide?

The National Academy of Sciences report can be accessed at http://books.nap.edu/openbook.php?isbn=0309090989&page=1

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