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

Consideration of Potassium Iodide in Emergency Planning

On this page:

For more information, see Potassium Iodide Frequently Asked Questions.

The Nuclear Regulatory Commission has revised a section of its emergency preparedness regulations. The revised rule requires that States* with a population within the 10-mile emergency planning zone (EPZ) 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 final rule amends 10 CFR 50.47(b)(10). The NRC published the rule change in the *Federal Register* (Volume 66, Number 13, page 5427) on January 19, 2001. The change became effective April 19, 2001.

Along with this rule change, the NRC is providing funding for a supply of potassium iodide for a State that chooses to incorporate potassium iodide for the general public into their emergency plans. After funding the initial supply of potassium iodide, the Commission decided to fund the replenishment on a one-time basis.

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 within the appropriate time and at the appropriate dosage, blocks the thyroid gland's uptake of radioactive iodine and thus reduces the risk of thyroid cancers and other diseases that might otherwise be caused by thyroid uptake of radioactive iodine that could be dispersed in a severe reactor accident.

The NRC and the Federal Emergency Management Agency (FEMA) are the two Federal agencies responsible for evaluating emergency preparedness at and around nuclear power plants. The NRC is responsible for assessing the adequacy of onsite emergency plans developed by the utility, while FEMA is responsible for assessing the adequacy of offsite emergency planning. The NRC relies on FEMA’s findings in determining that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

The Food and Drug Administration (FDA) is the definitive medical authority in the United States on the use of potassium iodide.

*When used in this Web site, State includes Native American governments.

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Eligibility for Obtaining Potassium Iodide

This rule applies to States and Tribal governments with nuclear power plants within their borders, with populations within the 10-mile EPZ, and local governments designated by States to request potassium iodide funding.

The Commission believes the final rule, together with the Commission's decision to provide funding for the purchase of a State's supply of potassium iodide, strikes a proper balance between encouraging (but not requiring) the offsite authorities to take advantage of the benefits of potassium iodide and acknowledging the offsite authorities' role in such matters. 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.

TOP

Process for Obtaining Potassium Iodide

On December 20, 2001, the NRC sent letters to the 34 States with populations within the 10-mile EPZ of nuclear reactors. This letter discusses the NRC program to provide potassium iodide to States and includes, as attachments: the NRC Statement of Consideration in support of the final rule; the FDA final guidelines EXIT on use of potassium iodide; and FEMA guidelines on incorporating potassium iodide into emergency response plans, as well as the NRC disclaimer .

The revised Federal Policy on Use of Potassium Iodide (FR Volume 67, Number 7, page 1355) was also provided to the States.

The Office of Public Affairs issued a press release on December 20, 2001, to announce the NRC's potassium iodide program.

TOP

Process for Replenishment of Existing Potassium Iodide Stockpiles

On October 26, 2006, the NRC sent letters to the 21 States that have received 130 and/or 65 mg potassium iodide tablets through the NRC’s initial KI offer. This letter discusses the NRC’s decision to replace expiring stockpiles of potassium iodide on a one-time basis as well as instructions for obtaining replacement KI stockpiles. The letter includes, as attachments, the FDA final guidelines on use of potassium iodide EXIT; the NRC Statement of Consideration in support of the final rule; the NRC disclaimer; and Staff Requirements - SECY-06-0142 - Options and Recommendations for Replenishing Expired Potassium Iodide (KI).

TOP

Shelf Life Extension and Replenishment of Existing Potassium Iodide Stockpiles

NRC received numerous inquiries from States regarding the possibility of extending the shelf-life of the KI tablets in light of the approval by FDA to the manufacturers for product shelf-life extension. The manufacturer (RECIP) of the 65-mg tablet issued an extension of the product by lot number. The manufacturer (Anbex) of the 130 mg tablets in a correspondence from its legal counsel to the NRC indicated that there are no significant differences in the formulation, manufacturing process, or packaging materials for the existing lots as compared to current lots. The FDA in a letter to NRC stated that "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." In a letter to the States, the NRC transmitted the FDA correspondence on shelf-life extension and Commission direction to Staff (SRM-COMSECY-07002) on full and partial replenishment of KI, and announced the availability of additional pediatric liquid KI.

States that choose to extend their stockpiles must document the lot number(s) of the KI product, the current expiration date, and the extended expiration date. This document should be available for review by representatives from DHS/FEMA Radiological Preparedness Program during the routine evaluations of offsite emergency preparedness.

TOP

Distribution of Liquid Pediatric KI

On January 12, 2005, the FDA approved the oral solution of 65mg/mL dose for use in children. On November 10, 2005, the NRC, in cooperation with the Department of Health and Human Services (HHS), sent letters to the States announcing the availability of liquid pediatric KI for States with populations within the 10 mile EPZ.

On March 7, 2007, the NRC, in cooperation with HHS, sent letters to the States announcing the availability of additional liquid pediatric KI for States with populations within the 10-mile EPZ. This letter expanded the offer to one bottle per household within the EPZ as well as stockpiled supplies at schools, day care centers, hospitals and other areas where populations may gather.

TOP

Regulations and Guidance

The NRC final rule on the Consideration of Potassium Iodide in Emergency Plans was published in the *Federal Register* on January 19, 2001. This rule became effective April 19, 2001. The FDA final guidance on Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies EXIT was published in December 2001. The Federal Emergency Management Agency published the revised Federal Policy on the Use of Potassium Iodide in January 2002.

TOP

Current Status on KI Distribution

Twenty-three states (Alabama, Arizona, California, Connecticut, Delaware, Florida, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee, Vermont, Virginia, West Virginia and Wisconsin) have requested and/or received potassium iodide tablets. Arizona, Connecticut, Delaware, Florida, New Jersey, New York, Louisiana, Maryland, Massachusetts, Minnesota, Mississippi, North

Carolina, South Carolina, Vermont, Virginia, and West Virginia have requested and/or received liquid pediatric potassium iodide.

TOP

Role of Reactor Licensees

The Commission notes that this rule will introduce another element in the context of emergency planning requirements for which licensees are ultimately responsible. Licensees have the obligation to confirm that offsite authorities have considered the use of potassium iodide as a supplemental protective action for the general public. It will also require the licensees to use this information in developing Protective Action Recommendations for offsite agencies.

TOP

Distribution of KI Within 20-Mile Radius of Nuclear Power Plants

Section 127 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act EXIT) requires State and local governments through the national KI stockpile to distribute KI tablets to population within 20 miles of a nuclear power plant. The Bioterrorism Act also directed the National Academy of Sciences (NAS) to study the expanded distribution of potassium iodide and report back to the President on the best distribution methods to accomplish such an expanded distribution. The NAS published this study EXIT in January 2004.

On August 29, 2005, the Department of Health and Human Services (HHS) published draft guidelines for State, local, and tribal governments, for the expanded distribution, stockpiling, and utilization of KI in the event of a radioactive iodine release from a commercial nuclear power plant incident. On September 2, 2005, HHS issued a correction to add deadline for receiving public comments. The NRC provided comments to the draft guidelines on November 1, 2005.

On July 3, 2007, President Bush delegated his authority to invoke the waiver provision in Section 127 to his science advisor, Dr. Marbuger, Director of the Office of Science and Technology Policy at the White House. In a January 22, 2008 EXIT memo, Dr. Marburger announced his decision to invoke the Section 127(f) waiver. A technical paper EXIT on the issue of KI was prepared by the Federal Radiological Protection Coordinating Committee KI Sub-Committee at the request of Dr. Marburger as part of his determination process.

TOP

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