

DRAFT FOR PUBLIC COMMENT

Tier 3 – SECY-11-0137 Additional Recommendation 4 (AR4)

SECY-11-0137 identified a number of additional issues with a clear nexus to the Fukushima Daiichi event that may warrant regulatory action, but which were not included with the NTTF recommendations. One of the additional recommendations that warranted further consideration and potential prioritization was:

AR4 Evaluate whether Potassium Iodide (KI) should be pre-staged beyond the current 10 mile zone.

Regulations and Guidance

1. 10 CFR 50.47(b)(10) “Emergency plans,” states the onsite and offsite emergency response plans for nuclear power reactors must meet specified standards, one of which is a range of protective actions developed for the plume exposure pathway EPZ for emergency workers and the public. In developing this range of actions, consideration is given to evacuation, sheltering, and, as a supplement to these, the prophylactic use of potassium iodide (KI), as appropriate. Guidelines for the choice of protective actions during an emergency, consistent with Federal guidance, are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed.

Staff Assessment and Basis for Prioritization

Following the event at Fukushima, stakeholders have submitted comments to the NRC requesting the pre-staging of KI beyond the current 10 mile zone to be reevaluated.

The NRC revised emergency preparedness regulations to address requirements for KI, which was effective April 19, 2001. 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 2001 revision to the rule was based on early health effects data from the Chernobyl nuclear power plant accident which showed an increase in thyroid cancer among children.

The Commission at that time, believed the final rule, together with the Commission's decision to provide funding for the purchase of a State's supply of KI, strikes a proper balance between encouraging (but not requiring) the offsite authorities to take advantage of the benefits of KI and acknowledging the offsite authorities' role in such matters. By requiring consideration of the use of KI, the Commission recognizes the important role of States and local governments in matters of emergency planning.

Section 127 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) requires State and local governments through the national KI stockpile to distribute KI tablets to populations within 20 miles of a nuclear power plant. In a January 22, 2008 memo, Dr. Marburger, Director of the Office of Science and Technology Policy at the White House, announced his decision to invoke the Section 127(f) waiver thus keeping the current 10 mile KI distribution zone. The rationale for waiving this requirement is there is a more effective preventive measure currently existing for the extended zone covered by the Act, namely avoidance of exposure altogether through evacuation of the potentially affected population and interdiction of contaminated food. Analysis of radiological release

events that could lead to adverse thyroid conditions beyond the current 10 mile zone shows that such limiting or avoiding exposure to radiation through these mechanisms is practical and much more effective than the administration of KI in the proposed extended zone.

Based on the recommendation of the Potassium Iodide Working Group (FDA, CDER, CDRH, and NIH), the FDA set the protective action guide of 5 rem projected dose to the child thyroid for the administration of KI. The staff has concluded that based on available data to date, it is unlikely that the FDA thyroid dose PAGs were exceeded beyond 10 miles as a result of the accident at Fukushima. The staff will continue to monitor and evaluate the results of the findings as studies are conducted in and around the Fukushima site.

Staff Recommendation

The staff will continue to study health effects on populations around nuclear power plants. The issue of whether KI should be distributed beyond the 10-mile EPZ will be evaluated within ongoing efforts to address issues surrounding the use of KI. The staff plans to review information obtained from studies proposed by the Japanese government and will propose any changes to policy issues regarding KI.

Unique Implementation Challenges

The staff has not identified any unique challenges which would preclude moving forward.

Schedule and Milestones

The staff will continue to monitor and evaluate the results of the population health studies that have been proposed by the Japanese government.