November 1, 2005

Dr. Robert Claypool
Office of Mass Casualty Planning
Office of Public Health Emergency Preparedness
U.S. Department of Health and Human Services
200 Independence Avenue SW., Room 638G
Washington, D.C. 20201

Dear Dr. Claypool:

On behalf of the Nuclear Regulatory Commission (NRC), I am providing the following comments on the draft Federal guidelines to make potassium iodide (KI) available to jurisdictions within a 20-mile radius of nuclear power plants. The Federal Register notice (FRN) that promulgated the draft guidelines also requested comments on whether the expanded distribution of KI was necessary, considering existing preventive measures and/or other thyroid prophylaxis.

The draft guidelines provide a good discussion of potassium iodide, the radiological emergency planning efforts for commercial nuclear power plants, the potential consequences of terrorism on nuclear power plants, and the impacts of the 1986 Chernobyl accident. The guidelines would provide to State, local, and tribal governments a framework for considering whether to expand distribution of KI out to 20 miles around nuclear power plants. While Section 127 of P.L. 107-188, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), refers to distribution of KI *tablets*, the proposed guidance generally refers to distribution of KI.

The NRC staff does not have specific comments on the draft guidelines. However, the NRC staff concludes that the predetermined protective actions in place for the populations within the 10 and 50 mile Emergency Planning Zones provide the necessary protection for the thyroid gland from radioactive iodine and that expanded distribution of KI is unnecessary.

Expanded distribution of KI could negatively impact the current, well-established, and scientifically sound framework of the NRC's emergency preparedness regulations. The NRC and the Federal Emergency Management Agency regulatory framework for emergency preparedness was put into place after the 1979 accident at Three Mile Island Unit 2. Each nuclear power plant operator was required to submit the radiological emergency response plans of State and local governments that are within the 10-mile plume exposure pathway emergency planning zones (EPZ), as well as the plans of State governments within the 50-mile ingestion pathway EPZs. These emergency planning zones facilitate the implementation of a preplanned strategy for protective actions during an emergency.

As the draft guidelines point out, NRC analyses indicate that, in the event of an emergency at a nuclear power plant that causes a release of radioactive materials in excess of routine low-level effluents, exposure to these materials poses the greatest risk for people closest to the plant. The risks to these people would arise from the exposure pathways of direct shine, immersion in a plume, inhalation and ingestion of radioactive materials, and ground shine. The objectives of the predetermined protective actions within the 10-mile EPZ, which include sheltering, evacuation, and, where appropriate, the use of potassium iodide, are to mitigate these risks in the event of an emergency.

The population at greater distances from the plant may be at risk of exposure to radioactive materials by way of ingestion of these materials. Predetermined protective actions for the 50-mile ingestion exposure pathway EPZ include interdiction of contaminated milk, food, and water as well as protective measures for livestock.

Section 127 of the Bioterrorism Act 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 in January 2004. Although the NAS did not identify any one particular "best method" of distribution, the Academy raised questions regarding the usefulness of expanded distribution of KI. Specifically, Chapter 5 of the report states (on page 81): "Exposure to radioactive iodine is possible through the ingestion pathway, so it is important that plans address this situation. Monitoring of the environment and food products controls this route of exposure. Removing contaminated products from the market and isolating contaminated products until the radioactive iodine decays to safe levels are the most effective way to eliminate radiation exposure and damage to the thyroid. That also eliminates the need for the use of KI by the general public as a protective action." In the conclusions and recommendations of the NAS report (on page 159), the Academy summarized this finding as follows: "KI is also effective for protection against the harmful thyroid effects of radioiodine ingested in contaminated milk and other foods, but food testing and interdiction programs in place throughout the United States are more effective preventive strategies for ingestion pathways."

These NAS findings have been buttressed by the most recent report of the International Atomic Energy Agency's (IAEA's) Chernobyl Forum on the health effects of the Chernobyl accident, which was issued in August 2005. This report included a finding that ingestion of contaminated milk products was the primary cause of the thyroid cancers found in children living in the surrounding regions. Consequently, interdiction of contaminated milk and use of stored feed would have prevented most of the thyroid cancers found in these children.

Therefore, we have concluded that other, more effective, protective measures are in place to protect the thyroid gland in the event of a release of radioactive iodine, and that expanded distribution of KI is unnecessary. Thus, the NRC recommends that the Secretary of Health and Human Services, as delegated by the President, apply subsection 127(f) of the Bioterrorism Act.

Thank you for the opportunity to comment on these important guidelines. If you have any questions or would like to discuss our comments, please do not hesitate to contact Eric Leeds, the NRC's Director of Preparedness and Response, at 301-415-2334.

Sincerely,

***/RA/***

William F. Kane
Deputy Executive Director for Reactor
and Preparedness Programs
Office of the Executive Director for Operations

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