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A Duke Energy Company

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February 2, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
1061 Fishers Lane, rm. 1061
Rockville, MD 20852

ATTENTION: Docket No. 00D - 1681

SUBJECT: Draft Guidance on Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies; Availability 66 Fed. Reg. 801, January 4, 2001)

Duke Energy Corporation has reviewed the "Draft Guidance on Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies; Availability," (66 Fed. Reg. 801, January 4, 2001), and offers the following comments.

The United States has developed the most effective and sophisticated emergency preparedness plans in the world. The U.S. model recognizes that evacuating an area is the most effective response for protecting the health and safety of the public. In other countries, stockpiling potassium iodide or predistributing tablets for residents near a nuclear power plant is done as a last resort because they have not developed or planned for evacuations of the public. Where evacuations are performed, potassium iodide would not add any extra measure of safety, and could actually complicate and hinder emergency response. Any large release, which is highly improbable, from a nuclear power plant would also include other radioactive elements for which KI would not offer protection. Risk due to thyroid dose is of significantly less concern relative to the risk associated with external radiation from noble gases.

Duke Energy Corporation will recommend evacuation of the general public if dose is projected to exceed 1 REM TEDE -OR- 5 REM Thyroid CDE in any sector, or will make a default protective action recommendation to evacuate the 2 mile radius and five mile downwind sectors for any plant condition that warrants a General Emergency declaration, whether there is a radiological

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release or not. The states and counties have the responsibility to implement protective actions. These action should result in evacuation of the general public before doses reach the level where KI is indicated.

Consequences of thyroid uptakes following Chernobyl are cited as a reason the U.S. should distribute potassium iodide. We believe that the FDA position should be evaluated based on an NRC report (An Analysis of Potassium Iodide (KI) Prophylaxis for the general Public in the Event of a Nuclear Accident, April 1992) reviewing the Chernobyl experience. The report concluded that while KI was distributed to the public, the bulk of iodide prophylaxis was restricted to the avoidance of thyroid burdens from the ingestion of contaminated food products. This emphasizes the importance of existing emergency planning for the ingestion pathway, rather than KI.

The FDA draft guidance notes that the population most at risk is children through adolescence, and pregnant or lactating women. One of the major impediments with distribution of KI to day care and school children is coordination and administration of the program. This includes the actual decision making process to administer KI or evacuate, parental approval and record keeping, identification and documenting allergic reactions, and the availability of a qualified medical professional to administer the potassium iodide.

If there are any questions regarding the comments provided, please contact Tina Kuhr by telephone at (704) 382-3151.

Yours truly,

M. S. Tuckman

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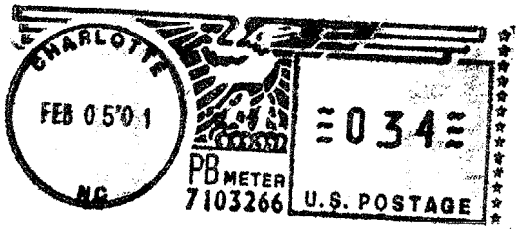

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