March 7, 2007

Kirksey E. Whatley, Director
Office of Radiation Control Alabama Department of Public Health
P.O. Box 303017-3017
Montgomery, AL 36130-3017

Dear Mr. Whatley:
(See attached identical letters list)

The purpose of this letter is threefold: (1) to announce the availability of an additional dosage form of liquid potassium iodide (KI) to protect the thyroid gland from uptake of radioactive iodine; (2) to transmit correspondence from the Food and Drug Administration (FDA) regarding shelf-life extension of existing KI stockpiles; and (3) to provide updated NRC Commission guidance to staff on replenishment of KI stockpiles (SRM ML070590742).

On January 12, 2005, the FDA approved ThyroShield™ (KI Oral Solution, USP) 65 mg/mL oral solution. The oral solution is the first to be developed specifically for children, although it is suitable for adult use. One milliliter (mL) of the solution contains 65 mg of KI in a palatable black raspberry-flavored solution providing easy, emergency-ready dosing for individuals ranging from infants to adults. ThyroShield™ is designed for easy administration of the liquid KI utilizing a graduated eyedropper. ThyroShield™ is provided in one ounce (30 mL) bottles that provide up to 30 pediatric doses of KI per bottle or 15 adult doses. Specific dosing instructions for children, based on the child’s age and weight, are included in the consumer product information sheet that accompanies the bottles. All ThyroShield™ bottles are packaged in such a way as to provide “child proof” access to the product.

The Nuclear Regulatory Commission (NRC) in cooperation with the Department of Health and Human Services (HHS), Office of Public Health Emergency, offered a supply of liquid KI to States in 2005 for use by the pediatric population. The NRC and HHS are again making available ThyroShield™ to all eligible States and Federally-recognized Tribal Governments. This offer is expanded in scope from the previous offer. States may request sufficient supply of ThyroShield™ for each household, hospital(s), school(s), daycare center(s), and other pertinent facilities in the 10-mile Emergency Planning Zone(s).

If you are interested in this offer and would like to either add to your current KI stockpiles or to request KI for the first time, please provide your request in writing to Nader Mamish, Deputy Director, Division of Preparedness and Response, Mail Stop O6H2, U.S. NRC, Washington, D.C. 20555. Your letter must include the following information: The nuclear power plant (NPP) site(s); the number of 30 mL (30 cc) bottles of ThyroShield™ requested; the contact person authorized to receive the KI; and the ‘Ship to’ address for KI delivery. Upon receipt of this information, the NRC will make arrangements for HHS’s contractor to ship KI directly to your designated contact/address. You may also fax your request to 301-415-2968.
We request that a single submittal for KI be provided by each State and Federally-recognized Tribal Government. If decisions about emergency planning and the use of KI are the responsibility of local, rather than State authorities, we request that the State consolidate the local requests and forward the consolidated request covering all NPPs within the State to the NRC.

NRC has recently received inquiries from States regarding shelf-life extension of existing stockpiles. Some States have contacted FDA directly to extend the shelf-life of existing stockpiles. To assist States in their decision process, NRC contacted FDA for guidance on shelf-life extension. As a result, FDA forwarded a letter to NRC for dissemination to States regarding extension of KI stockpiles. The FDA letter provides the basis upon which the State may extend the shelf-life of its stockpiles and the information that must be maintained to support the extension decision. However, the final decision to apply shelf-life extension to KI stockpiles remains a State decision. This letter is enclosed for your consideration and use. Additional information about NRC’s KI policy can be found on NRC’s web site at: http://www.nrc.gov/what-we-do/emerg-preparedness/protect-public/potassium-iodide-use.html.

In a Staff Requirements Memorandum (SRM - COMSECY-07-0002 - POTASSIUM IODIDE REPLENISHMENT) the Commissioners directed the staff to continue its efforts to replenish KI for those States that have expressed a need for either complete or partial replenishment. This memorandum is enclosed for your information.

If you have any questions about shelf-life extension or the liquid KI offer, please contact Patricia Milligan, Office of Nuclear Security and Incident Response, Division of Preparedness and Response, by telephone at 301-415-2223 or by e-mail at pxm@nrc.gov.

Thank you for your consideration of this important issue.

Sincerely,

/RA/

Roy P. Zimmerman, Director
Office of Nuclear Security and Incident Response

Enclosures:
As stated
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Sincerely,

/RA/

Roy P. Zimmerman, Director
Office of Nuclear Security and Incident Response

Enclosures:
As stated

DISTRIBUTION: (NSIR-07-0128)

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Package #: ML070660216
* see previous concurrence
Identical Letters Sent to:

Kirksey E. Whatley, Director
Office of Radiation Control Alabama Department of Public Health
P.O. Box 303017-3017
Montgomery, AL 36130-3017

Bernard Bevill,
Arkansas Department of Health and Human Services
Division of Radiation Control
P.O. Box 1437, Mail Slot H-30
Little Rock, AR 72203-1437

Aubrey Godwin, Director
Arizona Radiation Regulatory Agency
4814 South 40th Street
Phoenix, AZ 85040

James D. Boyd, Commissioner
California Energy Commission
1516 Ninth Street, MS-34
Sacramento, CA 95814

Edward L. Wilds, Jr., Ph.D., Director
Department of Environmental Protection Division of Radiation
79 Elm Street-5th Floor
Hartford, CT 06106-5127

Harry W. Otto, Ph.D., FAIC
Department of Natural Resources & Environmental Control
Division of Water Resources
89 Kings Highway
Dover, DE 19901

William A. Passetti, Chief
Florida Bureau of Radiation Control Department of Health
4052 Bald Cypress Way, SE, Bin C21
Tallahassee, FL 32399-1741

Jim Sommerville, Acting Chief
Department of Natural Resources Environmental Protection Division
Program Coordination Branch
2 Martin Luther King Jr., Street, Suite 1452 East Tower
Atlanta, GA 30334
Daniel K. McGhee,
Iowa Department of Public Health
Bureau of Radiological Health
Lucas State Office Bldg.
321 East 12th Street
Des Moines, IA 50319

Joseph G. Klinger, Acting Assistant Director
Illinois Emergency Management Agency
Division of Nuclear Safety
1035 Outer Park Drive, 5th Floor
Springfield, IL 62704

Thomas A. Conley, CHP, RRPT, Chief
Radiation & Asbestos Control Section
Kansas Dept. of Health & Environment
Bureau of Air and Radiation
1000 SW Jackson, Suite 310
Topeka, KS 66612-1366

Richard Penrod, Senior Environmental Scientist
Emergency & Radiological Services Division
Office of Environmental Services
Northwestern State University-Russell Hall, Room 201
Natchitoches, LA 71497

John Giarrusso, Jr., Nuclear Preparedness Mgr.
Massachusetts Emergency Management Agency
400 Worcester Road
Framingham, MA 01702-5399

George Aburn, Jr., Director
Maryland Department of the Environment Air and Radiation
Management Administration
1800 Washington Blvd.-Suite 705
Baltimore, MD 21230

Thor Strong, Chief
Rad. Protection & Medical Waste Section
Waste & Hazardous Materials Division
Michigan Department of Environmental Quality
Post Office Box 30241
Lansing, MI 48909-7741

John L. Stine, Division Director
Minnesota Dept.of Health
Environmental Health Division
P. O. Box 64975
St. Paul, MN 55164-0975
H. Floyd Gilzow, Deputy Director for Policy
Missouri Department of Natural Resources
P.O. Box 176
Jefferson City, MO 65102

Robert W. Goff, Director
Division of Radiological Health
State Department of Health
P.O. Box 1700
Jackson, MS 39215-1700

Beverly O. Hall, Chief
Radiation Protection Section Health
Department of Environment & Natural Resources
3825 Barrett Drive
Raleigh, NC 27609-7221

Robert E. Leopold, Administrator
Nebraska Health and Human Services Systems
P.O. Box 95007
Lincoln, NE 68509-5007

Christopher Pope, Director
Homeland Security & Emergency Management
Bureau of Emergency Management
New Hampshire Department of Safety
33 Hazen Drive
Concord, NH 03305

Lisa P. Jackson, Commissioner
New Jersey Dept. of Environmental Protection
P.O. Box 402
Trenton, NJ 08625-0402

CC: Paul Baldauf, Assistant Director
Radiation Protection & Release Prevention Dept.
Division of Environmental Safety & Health
Dept. of Environmental Protection
P.O. 415
Trenton, NJ 08625-0415

Peter Smith, President
New York State Energy Research and Development Authority
17 Columbia Circle
Albany, NY 12203-6399

CC: John P. Spath, Program Manager
Radioactive Waste Policy and Nuclear Coordination
New York State Energy Research and Development Authority
17 Columbia Circle
Albany, NY 12203-6399
Carol A. O’Claire, Branch Chief
Radiological Branch
Ohio Emergency Management Agency
2855 West Dublin-Granville Road
Columbus, OH 43235-2206

David J. Allard, Director
Bureau of Radiation Protection
Pennsylvania Department of Environmental Protection
Rachel Carson State Office Building- P.O. Box 8469
Harrisburg, PA 17105-8469

Michael Moore, Assistant Director
Division of Waste Management
Bureau of Land and Waste Management
South Carolina Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201

L. Edward Nanney, Director
Division of Radiological Health
Tennessee Department of Environment & Conservation
L & C Annex,401 Church Street 3rd Floor,
Nashville, TN 37243-1532

Roger Mulder, Director,
Pantex Program
State Energy Conservation Office
Comptroller of Public Accounts
P.O. Box 13528
Austin, TX 78701

Michael M. Cline, Director
Virginia Department of Emergency Services Management
10501 Trade Court
Richmond, VA 23236-3713

David O’Brien, Commissioner of Public Service
Department of Public Service
112 State Street-Drawer 20
Montpelier, VT 05620-2601

Matt Steuerwalt
Office of the Governor
Executive Policy Division
P.O. Box 43113
Olympia, WA 98504-3113
Paul S. Schmidt, Manager  
Division of Public Health  
Radiation Protection Section  
Department of Health and Family Services  
P.O. Box 2659  
Madison, WI 53701-2659

Dan Hill, Chief  
Radiological Health Program  
Office of Environmental Health Services  
DHHR Bureau for Public Health  
Capitol & Washington Streets  
1 Davis Square, Suite 200  
Charleston, WV 25301-1798

Mr. T. Pearce O’Kelley, Chairperson  
Conference of Radiation Control Program Directors, Inc.  
Office of Executive Director  
205 Capitol Avenue  
Frankfort, KY 40601

Ms. Audrey Bennett, Tribal Council President  
Prairie Island Indian Community  
5636 Sturgeon Lake Road  
Welch, MN 55089