



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

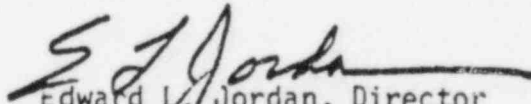
JUN 24 1985

MEMORANDUM FOR: Richard W. Krimm, Chairman
Federal Radiological Preparedness
Coordinating Committee
Federal Emergency Management Agency

FROM: Edward L. Jordan, Director
Division of Emergency Preparedness
and Engineering Response
Office of Inspection and Enforcement

SUBJECT: DRAFT FEDERAL POLICY STATEMENT ON THE DISTRIBUTION
AND USE OF POTASSIUM IODIDE

This responds to your request of November 15, 1984 regarding the proposed draft Federal policy statement on the distribution and use of potassium iodide. The Commission has reviewed the draft policy statement that was distributed to the FRPCC on March 26, 1985 and finds that it is consistent with its views and opinions on this protective action. Accordingly, the NRC agrees with the acceptability of the draft policy statement and concurs with its distribution to state and local governments as Federal guidance with the minor editorial changes annotated on the enclosed copy.


Edward L. Jordan, Director
Division of Emergency Preparedness
and Engineering Response
Office of Inspection and Enforcement

Enclosure:
Draft Federal Policy Statement

cc: See page 2

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JUN 24 1985

Richard W. Krimm

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cc: W. J. Dircks, EDO
J. M. Taylor, IE
R. H. Vollmer, IE
J. G. Partlow, IE
B. K. Grimes, IE
S. A. Schwartz, IE
D. B. Matthews, IE
K. E. Perkins, IE
C. R. Van Niel, IE
F. Kantor, IE
E. F. Williams, IE

Policy on Distribution of Potassium Iodide Around Nuclear Power Sites
for Use as a Thyroidal Blocking Agent

The purpose of this document is to provide Federal policy and guidance with regard to distribution of potassium iodide (KI) and its usage as a thyroid blocking agent around operating nuclear power sites. The issue has been addressed in terms of two components of the population that might require or desire potassium iodide use: (1) Emergency workers and institutionalized individuals, and (2) general population. This guidance is advisory to State and local governments who, within the limits of their authority, should consider these recommendations in the development of emergency plans and in determining appropriate actions to protect the general public. In summary, the policy recommends the stockpiling or distribution of KI during emergencies for emergency workers and institutionalized persons, but does not recommend requiring predistribution or stockpiling for the general public. The bases for these recommendations are given below. It is recognized, however, that options on the distribution and use of KI rests with the States, and hence, the policy statement permits State and local governments, within the limits of their authority, to take measures beyond those recommended or required nationally.

The U.S. Nuclear Regulatory Commission (NRC) and the Federal Emergency Management Agency (FEMA) have already issued guidance to State and local authorities as well as licensees of operating commercial nuclear power plants in NUREG-0654/FEMA-REP-1, v. 1, recommending the stockpiling and distribution during emergencies of KI for thyroidal blocking to emergency workers and to institutionalized individuals. That recommendation is endorsed as an available protective action in the event of an incident at a nuclear power plant. Thyroid blocking for emergency workers and institutionalized individuals was recommended because:

- (1) These individuals would be more likely to be exposed to the radioiodine in an airborne radioactive release from the plant in the event of an accident;
- (2) The number of individuals involved at any site is relatively small and requires a limited supply of KI that can be readily distributed;
- (3) The storage, distribution, and administration of KI can be readily controlled;
- (4) The known sensitivity to potassium iodide of this limited number of individuals can be reviewed; and,
- (5) These individuals can be readily monitored for adverse side effects by medical personnel.

The Federal position with regard to the predistribution or stockpiling of potassium iodide for use by the general public is that it should not be required. While valid arguments may be made for the use of KI, the preponderance of information indicates that a nationwide requirement for the predistribution or stockpiling for use by the general public would not be worthwhile. This is based on the ability to evacuate the general population and the cost effectiveness of a nationwide program which has been analyzed by the NRC and DOE National Laboratories (NUREG/CR-1433, March 1984). While the use of KI can clearly provide additional protection in certain circumstances, the assessment of the effectiveness of KI and other protective actions and their implementation problems indicate that the decision to use KI should be left to the State and local authorities.

Important to stress that the use of potassium iodide in a radiation emergency is not a panacea in that it does not block the uptake of other radionuclides and does not protect against external radiation. Furthermore, its use needs to be balanced against the cost and effectiveness of other protective measures such as sheltering and evacuation. This recommendation is made in full recognition of the potential positive effects of the drug, action by the FDA permitting KI over-the-counter sales, and the authority of State and local health officials to elect to distribute and use the drug based on the specific needs of individual sites.

The use of KI is effective as a thyroidal blocking agent in reducing accumulation by the thyroid gland of radioiodine which has entered the body through inhalation or ingestion. Radioiodine accumulation in the thyroid can be reduced to less than 10 percent of what it would be without a blocking agent by a daily oral intake of (130 milligrams for adults, 65 milligrams for infants) KI providing administration is started before or immediately after the exposure to the radioiodine, and treatment continues for at least 48 hours beyond the time of the last exposure. This effectiveness decreases to less than 50 percent blocking of the radioiodine uptake, if administration of the KI is delayed until 4 hours after an acute ingestion or inhalation.

It is recognized that the options on distribution and use of KI for thyroidal blocking to protect the public health and safety resides with the State and, in some cases, local health authorities. Therefore, with the exception of Federal and utility personnel, the decision for use of KI during an actual emergency for the general public is the responsibility of these authorities. In deciding whether to distribute and use KI for the general population, these authorities must consider a number of factors.

One of the considerations in deciding whether to implement the distribution and use of KI for the general population is that KI blocking effectively reduces the radiation exposure of only the thyroid gland. While this is an important contribution to the health and safety of the individual, it is not nearly as effective as measures which protect the total body of the individual from radioactivity. Both in-place sheltering and precautionary evacuations can reduce the exposure to the thyroid and total body. The use of KI for thyroidal blocking is not an effective means by itself for protecting individuals from the radioactivity in an airborne release resulting from a nuclear power plant accident and, therefore, should only be considered in conjunction with sheltering, evacuation, or other protective methods.

The Food and Drug Administration (FDA) has evaluated the medical and radiological risks of administering KI for thyroidal blocking under these emergency conditions and has concluded that it is safe and effective and has approved over-the-counter sale of the drug for this purpose. FDA guidance states that risks from the short term use of relatively low doses of KI for thyroidal blocking in a radiation emergency are outweighed by the risks of radioiodine induced thyroid nodules or cancer at a projected dose to the thyroid gland of 25 rem or greater. Since FDA has authorized the non-prescription sale of KI, it is legally available to individuals who, based on their own personal analysis, choose to have the drug immediately available.

considerations and problems to be evaluated by the State and local authorities deciding whether to institute this program include: (1) Whether the KI should be distributed to the population before an accident occurs or as soon as possible after an accident occurs; (2) whether the risks of exposure to radioactivity will be lower if the evacuation of the general population is initiated or if the general population is sheltered and the administration of KI initiated; (3) how the KI will be distributed during the emergency; (4) what medical assistance will be available to assist the individuals who may have some adverse reaction to KI; (5) how medical authorities will advise the population to take KI and under what circumstances this advice will be given; (6) if KI is predistributed, what assumptions should be made about its actual availability and use in the event of an incident. (7) how the authorities will provide KI to transient populations; and (8) whether use of other respiratory protection (e.g., dust masks, or breathing through wet towels) may be equally effective, especially in conjunction with sheltering.

In summary, the use of KI to prevent radioiodine from accumulating in the thyroid gland can be an effective ancillary protective action during a nuclear power plant accident. However, many factors make stockpiling and/or pre-distribution to the general public questionable. Whether KI should be stockpiled and distributed to the general public around a particular site depends on local conditions. Additionally, decisions on its use or the use of alternative protective measures during an emergency depends on accident and environmental conditions that may prevail at the time. Any decision by State and local authorities to use KI should be based on the conditions of the environment for the specific operating commercial nuclear power plant and should include detailed plans for distribution, administration, and medical assistance. The following references are intended to assist State and local authorities in decisions related to use of KI.

1. National Council on Radiation Protection and Measures (NCRP), Protection of the Thyroid Gland in the Event of Releases of Radioiodine. NCRP Report No. 55, August 1, 1977.
2. Food and Drug Administration (HEW), Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency. 43 FR 58798, December 15, 1978.
3. Halperin, J. A., B. Shleien, S. E. Kahana, and J. M. Bilstad, Background Material for the Development of the Food and Drug Administration's Recommendations on Thyroid-Blocking with Potassium Iodide, FDA 81-8158, U.S. Dept. of Health and Human Services (March 1981).
4. Food and Drug Administration, Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Final Recommendations on Use. (Notice of Availability) 47 FR 28158, June 29, 1982..
5. Food and Drug Administration, Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Recommendations on Use. (April 1982) Prepared by the Bureau of Radiological Health and Bureau of Drugs, Food and Drug Administration, Department of Health and Human Services.
6. Nuclear Regulatory Commission, Examination of the Use of Potassium Iodide (KI) As an Emergency Protective Measure for Nuclear Reactor Accidents (March 1980). Prepared by Sandia National Laboratories for the NRC.

that day. New applications involving this project site, to the extent provided for under 18 CFR Part 4, may be filed on the next business day.

Kenneth F. Plumb,

Secretary.

[FR Doc. 85-14846 Filed 6-19-85; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP85-162-000]

Southern Natural Gas Co.; Proposed Changes in FERC Gas Tariff

June 17, 1985.

Take notice that Southern Natural Gas Company (Southern) on June 12, 1985, tendered for filing the following revised tariff sheets to its FERC Gas Tariff, Sixth Revised Volume No. 1: First Revised Sheet No. 40; Fourth Revised Sheet No. 41; Original Sheet No. 41A.

The proposed effective date of the sheets is July 15, 1985.

Southern's present Section 13 of the General Terms and Conditions provides that a purchaser may, within any 12 month period, decrease its contract demand at any delivery point if that purchaser or another purchaser or other purchasers increase their contract demands at other delivery points in total amount equal to the decrease, provided that the increased contract demand can be delivered without investment in new facilities (except minor measurement or delivery facilities) by Southern. As proposed, revised Section 13 of the General Terms and Conditions would allow each of Southern's resale customers, subject to Southern's ability to deliver the gas, an opportunity to receive a pro rata share of the contract demand made available when one of Southern's resale customers requests a reduction in its total contract demand in an amount greater than 1,000 Mcf. In addition, all customers desiring to increase their total contract demands would be entitled, subject to the ability of Southern to deliver the gas, to receive 5 Mcf as a minimum share of the contract demand made available.

Copies of this filing have been served upon Southern's jurisdictional customers and interested state public service commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before June 22, 1985. Protests will

be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 85-14847 Filed 6-19-85; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP85-156-001]

Valero Interstate Transmission Co.; Corrected Filing

June 14, 1985.

Take notice that on June 12, 1985, Valero Interstate Transmission Company (Vitco) tendered for filing the following substitute tariff sheets correcting its previous filing of May 31, 1985 in Docket No. RP85-156-000:

FERC Gas Tariff, Original Volume No. 1

Substitute 8th Revised Sheet No. 14

superseding 7th Revised Sheet No. 14

FERC Gas Tariff, Original Volume No. 2

Substitute 2nd Revised Sheet No. 6

superseding 1st Revised Sheet No. 6

Vitco's filing of May 31, 1985 for the purpose of reinstating its base tariff rates did not correctly reflect gas costs consistent with Vitco's PGA effective June 1, 1985.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before June 21, 1985. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 85-14848 Filed 6-19-85; 8:45 am]

BILLING CODE 6716-01-B

[Docket No. ID-2181-000]

Virgil C. Summer; Application

June 13, 1985.

Take notice that on May 17, 1985, Virgil C. Summer (applicant) filed an application pursuant to Section 305(b) of the Federal Power Act to hold the following positions:

Director, South Carolina Electric & Gas Company

Chief Executive Officer, South Carolina Electric & Gas Company

Chairman of Board, South Carolina Electric & Gas Company

Director, South Carolina Generating Company, Inc.

Chairman, South Carolina Generating Company, Inc.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before June 24, 1985. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 85-14849 Filed 6-19-85; 8:45 am]

BILLING CODE 6717-01-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent

AGENCY: Federal Emergency Management Agency.

ACTION: Notice of Issuance of Federal Policy.

SUMMARY: The Federal Radiological Preparedness Coordinating Committee (FRPCC) is publishing this notice to provide guidance to State and local agencies responsible for radiological emergency planning and preparedness regarding the distribution of potassium iodide for use as a thyroidal blocking agent by the general public in the vicinity of nuclear power plants. The

Federal Emergency Management Agency (FEMA) chairs the FRPCC, thereby assuming the responsibility for this publication.

FOR FURTHER INFORMATION CONTACT:

Gerard W. Smith, Technological Hazards Division, Office of Natural and Technological Hazards Programs, State and Local Programs and Support, Federal Emergency Management Agency, 500 C Street SW., Washington, D.C. 20472, 202-646-2869.

SUPPLEMENTARY INFORMATION:

Background

This guidance on distribution of potassium iodide as a thyroidal blocking agent to the general public in the vicinity of nuclear power plants is part of a Federal interagency effort coordinated by the Federal Emergency Management Agency (FEMA) for the Federal Radiological Preparedness Coordinating Committee (FRPCC). FEMA issued a final regulation in the Federal Register of March 11, 1982, (47 FR 10758), which reflected governmental reorganizations and reassigned agency responsibilities for radiological incident emergency response planning. A responsibility assigned to the Department of Health and Human Services (HHS) and in turn delegate to the Food and Drug Administration (FDA) is the responsibility to provide guidance to State and local governments on the use of radioprotective substances and prophylactic use of drugs (e.g. potassium iodide) to reduce radiation dose to specific organs including dosage and projected radiation exposures at which such drugs should be used.

In the Federal Register of June 29, 1982 (47 FR 28158), FDA published recommendations for State and local agencies regarding the projected radiation dose to the thyroid gland at which State and local health officials should consider the use of potassium iodide. The recommendations stated that: (1) Potassium iodide be used during radiation emergencies by people who are likely to receive more than 10 to 20 rads to the thyroid. (2) The drug at the recommended doses could block at least 90 percent of radioiodine absorption if the first dose is given shortly before or immediately after exposure to radioiodine. The drug could still block 50 percent of radioiodine uptake if the first dose is administered within 4 hours after exposure. (3) State and local officials should establish a system for informing the public how to use potassium iodide, how to report side effects of the drug, and how to get treatment for any adverse reactions.

The guidance published here contains the rationale on the use of potassium iodide for emergency workers and institutionalized individuals. It also incorporates the considerations that should be made in deciding to implement the distribution and use of potassium iodide for the general population. The decisions on distribution and use of potassium iodide for thyroidal blocking to protect the public health and safety resides with the State and, in some cases, local health authorities. It suggests that any decision by State and local authorities to use potassium iodide should be based on the site environment and conditions at the time of an emergency for the specific operating commercial nuclear power plant and should include detailed plans for distribution, administration, and medical assistance.

The Federal position with regard to the predistribution or stockpiling of potassium iodide for use by the general public is that it should not be required.

Richard W. Krimm,

Chairman, Federal Radiological Preparedness Coordinating Committee.

[FR Doc. 85-14810 Filed 6-19-85; 8:45 am]

BILLING CODE 6718-01-M

[Docket No. FEMA-REP-5-WI-2 and FEMA-REP-5-WI-3]

The Wisconsin Radiological Emergency Response Plans Site-Specific for the Kewaunee and Point Beach Nuclear Power Plants

ACTION: Certification of FEMA Findings and Determinations.

In accordance with the Federal Emergency Management Agency (FEMA) rule 44 CFR Part 350, the State of Wisconsin submitted its plans relating to the Kewaunee and Point Beach Nuclear Power Plants to the Director of FEMA Region V on April 6, 1981, for FEMA review and approval. On August 30, 1984, the Regional Director forwarded his evaluations to the Associate Director for State and Local Programs and Support in accordance with § 350.11 of the FEMA rule. Included in the evaluations are reviews of the State and local plans around the Kewaunee and Point Beach facilities, and evaluations of the joint exercises conducted on January 21, 1981, March 9, 1982, November 1, 1983, and June 19, 1984, in accordance with § 350.9 of the FEMA rule. A report of the public meeting held on January 22, 1981, to discuss the site-specific aspects of the State and local plans in accordance with § 350.10 of the FEMA rule was also included.

Based on the evaluations by the Regional Director and the review by the FEMA Headquarters staff, I find and determine that, subject to the condition stated below, the State and local plans and preparedness for the Kewaunee and Point Beach Nuclear Power Plants are adequate to protect the health and safety of the public living in the vicinity of the plants. These offsite plans and preparedness are assessed as adequate in that they provide reasonable assurance that appropriate protective actions can be taken offsite in the event of a radiological emergency and are capable of being implemented. The condition for the above approvals is that the adequacy of the public alert and notification system already installed and operational must be verified as meeting the standards set forth in Appendix 3 of the Nuclear Regulatory Commission (NRC)/FEMA criteria of NUREG-0654/FEMA-REP-1, Revision 1 and FEMA-43, "Standard Guide for the Evaluation of Alert and Notification Systems for Nuclear Power Plants."

FEMA will continue to review the status of offsite plans and preparedness associated with the Kewaunee and Point Beach Nuclear Power Plants in accordance with § 350.13 of the FEMA rule.

For further details with respect to this action, refer to Docket Files FEMA-REP-WI-2 and FEMA-REP-5-WI-3 maintained by the Regional Director, FEMA Region V, Federal Center, Battle Creek, Michigan 49016.

Dated: June 14, 1985.

For the Federal Emergency Management Agency.

Samuel W. Speck,

Associate Director, State and Local Programs and Support.

[FR Doc. 85-14809 Filed 6-19-85; 8:45 am]

BILLING CODE 6718-01-M

FEDERAL RESERVE SYSTEM

First Railroad & Banking Company of Georgia and First Financial Management Corp.; Acquisition of Company Engaged in Permissible Nonbanking Activities

The organization listed in this notice has applied under § 225.23 (a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23 (a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to

FEDERAL EMERGENCY MANAGEMENT AGENCY

Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent

AGENCY: Federal Emergency
Management Agency.

ACTION: Notice of Issuance of Federal
Policy—correction.

SUMMARY: The Federal Radiological Preparedness Coordinating Committee (FRPCC) is publishing this notice to provide guidance to State and local agencies responsible for radiological emergency planning and preparedness regarding the distribution of potassium iodide for use as a thyroidal blocking agent by the general public in the vicinity of nuclear power plants. The Federal Emergency Management Agency (FEMA) chairs the FRPCC, thereby assuming the responsibility for this publication.

In FR Doc. 85-14810 beginning on page 25624 in the issue of Thursday June 20, 1985, the statement of Federal Policy was inadvertently not included. The complete policy is stated herein. In addition, a portion of the Supplementary Information has been deleted because it was inconsistent with previously published Food and Drug Administration policy.

FOR FURTHER INFORMATION CONTACT:
Gerard W. Smith, Technological
Hazards Division, Office of National
and Technological Hazards Programs,
State and Local Programs and Support,
Federal Emergency Management
Agency, 500 C Street SW., Washington,
D.C. 20472 202-646-2869.

SUPPLEMENTARY INFORMATION:

Background

This guidance on distribution of potassium iodide as a thyroidal blocking agent to the general public in the vicinity of nuclear power plants is part of a Federal interagency effort coordinated by the Federal Emergency Management Agency (FEMA) for the Federal Radiological Preparedness Coordinating Committee (FRPCC). FEMA issued a final regulation in the Federal Register of March 11, 1982, (47 FR 10758), which reflected governmental reorganizations and reassigned agency responsibilities for radiological incident emergency response planning. 44 CFR 351 A responsibility assigned to the Department of Health and Human Services (HHS) and in turn delegated to the Food and Drug Administration (FDA) is the responsibility to provide guidance to State and local governments

on the use of radioprotective substances and prophylactic use of drugs (e.g., potassium iodide) to reduce radiation dose to specific organs including dosage and projected radiation exposures at which such drugs should be used.

In the Federal Register of June 29, 1982 (47 FR 28158), FDA published recommendations for State and local agencies regarding the projected radiation dose to the thyroid gland at which State and local health officials should consider the use of potassium iodide.

The guidance published here contains the rationale on the use of potassium iodide for emergency workers and institutionalized individuals. It also incorporates the considerations that should be made in deciding to implement the distribution and use of potassium iodide for the general population. The decisions on distribution and use of potassium iodide for thyroidal blocking to protect the public health and safety resides with the State and, in some cases, local health authorities. It suggests that any decision by State and local authorities to use potassium iodide should be based on the site environment and conditions at the time of an emergency for the specific operating commercial nuclear power plant and should include detailed plans for distribution, administration, and medical assistance.

The Federal position with regard to the predistribution or stockpiling of potassium iodide for use by the general public is that it should not be required.

Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agency

The purpose of this document is to provide Federal policy and guidance with regard to distribution of potassium iodide (KI) and its usage as a thyroid blocking agent around operating nuclear power sites. The issue has been addressed in terms of two components of the population that might require or desire potassium iodide use: (1) Emergency workers and institutionalized individuals, and (2) general population. This guidance is advisory to State and local governments who, within the limits of their authority, should consider these recommendations in the development of emergency plans and in determining appropriate actions to protect the general public. In summary, the policy recommends the stockpiling or distribution of KI during emergencies for emergency workers and institutionalized persons, but does not recommend requiring predistribution or stockpiling for the general public. The bases for these recommendations are

given below. It is recognized, however, that options on the distribution and use of KI rests with the States, and hence, the policy statement permits State and local governments, within the limits of their authority, to take measures beyond those recommended or required nationally.

The U.S. Nuclear Regulatory Commission (NRC) and the Federal Emergency Management Agency (FEMA) have already issued guidance to State and local authorities as well as licensees of operating commercial nuclear power plants in NUREG-0654/FEMA-REP-1, Rev. 1, recommending the stockpiling and distribution during emergencies of KI for thyroidal blocking to emergency workers and to institutionalized individuals. That recommendation is endorsed as an available protective action in the event of an incident at a nuclear power plant. Thyroid blocking for emergency workers and institutionalized individuals was recommended because:

(1) These individuals would be more likely to be exposed to the radioiodine in an airborne radioactive release from the plant in the event of an accident;

(2) The number of individuals involved at any site is relatively small and requires a limited supply of KI that can be readily distributed;

(3) The storage, distribution, and administration of KI can be readily controlled;

(4) The known sensitivity to potassium iodide of this limited number of individuals can be reviewed, and

(5) These individuals can be readily monitored for adverse side effects by medical personnel.

The Federal position with regard to the predistribution or stockpiling of potassium iodide for use by the general public is that it should not be required. While valid arguments may be made for the use of KI, the preponderance of information indicates that a nationwide requirement for the predistribution or stockpiling for use by the general public would not be worthwhile. This is based on the ability to evacuate the general population and the cost effectiveness of a nationwide program which has been analyzed by the NRC and DOE National Laboratories (NUREG/CR-1433). While the use of KI can clearly provide additional protection in certain circumstances, the assessment of the effectiveness of KI and other protective actions and their implementation problems indicates that the decision to use KI (and/or other protective actions) should be made by the States and, if appropriate, local authorities on a site specific basis.

It is important to stress that the use of potassium iodide in a radiation emergency is not a panacea in that it does not block the uptake of other radionuclides and does not protect against external radiation. Furthermore, its use needs to be balanced against the cost and effectiveness of other protective measures such as sheltering and evacuation. This recommendation is made in full recognition of the potential positive effects of the drug, action by the FDA permitting KI over-the-counter sales, and the authority of State and local health officials to elect to distribute and use the drug based on the specific needs of individual sites.

The use of KI is effective as a thyroidal blocking agent in reducing accumulation by the thyroid gland of radioiodine which has entered the body through inhalation or ingestion. Radioiodine accumulation in the thyroid can be reduced to less than 10 percent of what it would be without a blocking agent by a daily oral intake of (130 milligrams for adults, 65 milligrams for infants) KI providing administration is started before or immediately after the exposure to the radioiodine, and treatment continues for at least 48 hours beyond the time of the last exposure. This effectiveness decreases to less than 50 percent blocking of the radioiodine uptake, if administration of the KI is delayed until 4 hours after an acute ingestion or inhalation.

It is recognized that the *options on distribution and use of KI for thyroidal blocking to protect the public health and safety resides with the State and, in some cases, local health authorities.* Therefore, with the exception of Federal agency and utility personnel, the decision for use of KI during an actual emergency by the general public is the responsibility of these authorities. In deciding whether to distribute and use KI for the general population, *these authorities must consider a number of factors.*

One of the considerations in deciding whether to implement the distribution and use of KI for the general population is that KI blocking effectively reduces the radiation exposure of only the thyroid gland. While this is an important contribution to the health and safety of the individual, it is not nearly as effective as measures which protect the total body of the individual from radioactivity. Both in-place sheltering and precautionary evacuations can reduce the exposure to the thyroid and

total body. The use of KI for thyroidal blocking is not an effective means by itself for protecting individuals from the radioactivity in an airborne release resulting from a nuclear power plant accident and, therefore, should only be considered in conjunction with sheltering, evacuation, or other protective methods.

The Food and Drug Administration (FDA) has evaluated the medical and radiological risks of administering KI for thyroidal blocking under these emergency conditions and has concluded that it is safe and effective and has approved over-the-counter sale of the drug for this purpose. FDA guidance states that risks from the short term use of relatively low doses of KI for thyroidal blocking in a radiation emergency are outweighed by the risks of radioiodine induced thyroid nodules or cancer at a projected dose to the thyroid gland of 25 rem or greater. Since FDA has authorized the nonprescription sale of KI, *it is legally available to individuals who, based on their own personal analysis, choose to have the drug immediately available.*

Other considerations and problems to be evaluated by the State and local authorities in deciding whether to institute this program include: (1) Whether the KI should be distributed to the population before an accident occurs or as soon as possible after an accident occurs; (2) whether the risks of exposure to radioactivity will be lower if the evacuation of the general population is initiated or if the general population is sheltered and the administration of KI initiated; (3) how the KI will be distributed during the emergency; (4) what medical assistance will be available to assist the individuals who may have some adverse reaction to KI; (5) how medical authorities will advise the population to take KI and under what circumstances this advice will be given; (6) if KI is predistributed, what assumptions should be made about its actual availability and use in the event of an incident; (7) how the authorities will provide KI to transient populations; and (8) whether use of other respiratory protection (e.g., dust masks, or breathing through wet towels) may be equally effective, especially in conjunction with sheltering.

In summary, the use of KI to prevent radioiodine from accumulating in the thyroid gland can be an effective ancillary protective action during a nuclear power plant accident. However,

many factors make stockpiling and/or pre-distribution to the general public questionable. Whether KI should be stockpiled and distributed to the general public around a particular site depends on local conditions. Additionally, decisions on its use or the use of alternative protective measures during an emergency depends on accident and environmental conditions that may prevail at the time. Any decision by State and local authorities to use KI should be based on the conditions and site environment for the specific operating commercial nuclear power plant and should include detailed plans for distribution, administration, and medical assistance. The following reference are intended to assist State and local authorities in decisions related to use of KI.

1. National Council on Radiation Protection and Measures (NCRP), Protection of the Thyroid Gland in the Event of Releases of Radioiodine. NCRP Report No. 55, August 1, 1977.

2. Food and Drug Administration (HEW), Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency. 43 FR 58798, December 15, 1978.

3. Halperin, J.A., B. Shleien, S.E. Kahana, and J. M. Bilstad, Background Material for the Development of the Food and Drug Administration's Recommendations on Thyroid-Blocking with Potassium Iodide, FDA 81-8158, U.S. Dept. of Health and Human Services (March 1981).

4. Food and Drug Administration, Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Final Recommendations on Use. (Notice of Availability) 47 FR 28158, June 29, 1982.

5. Food and Drug Administration, Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Recommendations on Use. (April 1982) Prepared by the Bureau of Radiological Health and Bureau of Drugs, Food and Drug Administration, Department of Health and Human Services.

6. Nuclear Regulatory Commission, Examination of the Use of Potassium Iodide (KI) As an Emergency Protective Measure for Nuclear Reactor Accidents (NUREG/CR-1433, March 1980). Prepared by Sandia National Laboratories for the NRC.

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