UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

DOCKETED
USNRC

In the Matter of)
)
UNION ELECTRIC COMPANY) Docket No. STN 50-483
)
(Callaway Plant, Unit 1))

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FINDINGS OF FACT AND CONCLUSIONS OF LAW

I. INTRODUCTION

Pursuant to Board Order, dated 11 August 1983, a hearing was held in Fulton, Missouri on 13 September 1983 for the purpose of adjudication of Reed Contentions 6 and 16. The Applicant and the NRC Staff presented witnesses; Mr. Reed did not offer witnesses. The following findings of fact and conclusions of law are forwarded in compliance with the Board Order issued at that hearing.

II. OPINIONS

Intervenor Reed's Contentions 6 and 16 relate to the need for predistribution of potassium iodide (KI) to emergency workers and the general public that resides within the Plume Exposure Pathway Emergency Planning Zone (PEP EPZ) and the absence of adequate instructions relating to protective actions to be taken by said residents in the event of a release of radio-nuclides during a nuclear power plant accident.

The State of Missouri has, since this issue has been raised, reversed its original stand and ordered issuance of KI to emergency workers. This portion of Reed's contention has been satisfactorily resolved and is no longer considered at issue.

The State of Missouri has not ordered issuance of KI to the public

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residing within the PEP EPZ, nor provided effective means for respiratory protection against radionuclides released to the atmosphere in the event of a serious accident at the Callaway Plant No. 1; to include protective measures to off-set thyroid damage from radio-iodines.

The Food and Drug Administration has concluded that the risks from short-time use of relatively low doses of KI for thyroid blocking in a radiological emergency are outweighed by the risks of radioiodine induced thyroid nodules or cancer at the projected dose to the thyroid of 25 Rems and recommended doses of KI at 130 milligrams (mg) a day for adults and children above 1 year of age and 65 mg per day for infants below the age of 1 year be administered in a radiation emergency. The Food and Drug Administration (FDA) has further concluded that at such doses, KI is safe and effective and has authorized KI, in the above doses, to be manufactured and distributed as a non-prescription drug. The "non-prescription" status places said drug outside the needs for medical control or supervision. It is sold with instructions for use clearly printed on the packaging or duly enclosed within said packaging. Such usage instructions meet FDA criteria or the drug will not be authorized for sale.

Applicant witnesses repeatidly cited the facts above during the hearing on 13 September 1983, and repeated same in its Proposed Findings of Fact and Conclusions of Law; however, it has attacked said FDA findings with testimony relating to "risks", "use for non-intended purposes, "inducing a false sense of security in the public", "uncontrolled administration of KI without medical supervision", "a greater risk of the likelihood of, and a diminished ability to respond to adverse reactions". Such attacks on FDA

rules, regulations, or any provision thereof should not be permitted by the Nuclear Regulatory Commission or any other Federal Agency in any adjudicatory proceeding by any party thereto. The Commission does not permit such attacks on its rules, regulations, etc. (see 10 CFR, Part 2, Section 2.758 a).

The parameters for safe use and distribution of KI has been established by the FDA. It has been found to be "safe and effective" as a radioiodine blocking agent at the doses for which manufacture, packaging and over-the-counter sale is authorized.

Mr. Reed used NRC study data (NUREG/CR-0388 SAND78-0269) to determine potential nuclear reactor accidents that could result in major releases of radioactive material and the duration of such releases. Accidents I, III, IV, and VI relate to Pressurized Water Reactors and the Callaway I is a pressurized water reactor. The views expressed in NUREG/CR-0388 SAND78-0269 are necessarily those of the U.S. Nuclear Regulatory Commission; therefore, until said views are modified or otherwise changed by the NRC, they are protected from attack by way of discovery, proof, argument, or other means in any adjudicatory proceeding involving initial licensing subject to 10 CFR, Part 2, Section 2.758(a).

Accident I, cited above, indicates a containment failure at 16 minutes after the start of the accident with airborne concentrations of radioiodines as follows: 16 minutes released cumulative activity in Curies is 1.3×10^6;

1 hour from start of accident activity in Curies is 3.4×10^7;

4 hours from start of accident activity in Curies is 4.3×10^7;

26 hours from start of accident activity in Curies is 4.4×10^7.

The projected dose to the thyroid some 10 hours after the accident has begun and at a distance downwind from the plant of 59 miles is about 10 rems and while below the Protective Action Guides for whole-body and lung, are still in the range for which protective action should be considered for the thyroid. It is reasonable to assume that because of deposition of nuclides while cloud is in transit to the 59 mile marker, the projected dose to the thyroids of those nearer the plant will be larger than that indicated for more distant populations.

Because of the rapidity of this release, and all assumed realistic descriptions of circumstances and radioactive material release progression, it is reasonable to assume that prolonged shelter would be the only option possible for those caught within the PEP EPZ. Thyroid exposures would be expected to exceed 25 Rem within the PEP EPZ and use of KI would be in accordance with FDA useage instructions. Accident descriptions III, IV and VI present similar data.

Use of shelter to reduce exposures from external radiation is reasonable and prudent. Use of respiratory protection, even ad hoc devices, will help ingestion of radionuclides, but to assume that laboratory test results for ad hoc devices will apply under actual residential useage is a false assumption. Mr. Neal Slaten, witness for the Applicant, did not obtain a good face seal on a willing subject during a demonstration at the hearing cited above. Mr. Slaten was even unaware that such "failure to seal" had occurred and had to be advised by the subject of the demonstration that a major leak in the respiratory device had occurred. Had this been a real situation, wherein a parent was holding a device over a child's face, the presumed protection factor would not exist. Mr. Slaten, in his testimony,

stated that combining shelter, respiratory protection and ingestion of KI afforded more protection than did shelter and ad hoc respiratory devices.

The NRC has established the overall objective of emergency plans is to provide dose savings (and in some cases immediate life saving) for a spectrum of accidents that could produce offsite doses in excess of PAGs (NUREG 0654, page 6, lines 10 through 13) and further, that "the ability to best reduce potential exposure under specific conditions during the course of an accident should determine the appropriate response" (NUREG 0654, page 9, lines 17 through 20).

The NRC has, in granting licenses to operate, final authority to protect the public health and safety. Reliance upon input from other Federal agencies such as F.E.M.A., F.D.A., E.P.A. and others is appropriate. The Environmental Protection Agency has determined that homes suitable for winter habitation provide respiratory protection for about 2 hours (see Reed Contentions 6 and 16). The Food and Drug Administration has deemed KI to be safe and effective as a thyroid blocking agent in radiological emergencies, and authorized its manufacture, distribution and sale as a non-prescription drug in designated doses accompanied by specific instructions on use. To accept radical testimony which opposes these governmental findings constitutes an action that the Commission does not permit with regard to its own rules, regulations and related findings.

Potassium iodide (KI) is readily available on the market, today, at a price of $1.00 for a 14 day supply of pills for 1 person. The pills are guaranteed to have a shelf life of 3-5 years by at least one manufacturer (ANBEX), making the cost of predistribution of KI to all families residing in the PEP EPZ for Callaway 1 only $17,094.00 (using population figures in

the Callaway Plant Radiological Emergency Response Plan, Rev 5A, 2/83). Prorated over the 5 year period, the cost is only $3,418.80 per year. Such costs are within the limits of cost/benefit parameters set by the Commission at 40FR19439.

III. SUMMARY

Federal guidance on issuance of KI to the general public and others is non-existant; instead, Federal agencies who are responsible for the protection of the public health and safety in the event of an accident at nuclear power reactors have left such decisions to the several States.

The Nuclear Regulatory Commission, the Federal agency with expertise in nuclear matters and authority to grant operations licenses for nuclear power reactors (production and utilization facilities) have done studies which indicate that serious levels of radioactive iodine can be released from pressurized water reactors during severe accidents (those beyond "design base accidents") and that radiation doses to the thyroid (due to ingestion of radio-iodines) can exceed E.P.A. PAGs for tens of miles down wind from the plant.

The Food and Drug Administration had determined that oral intake of KI is safe and effective as a thyroid blocking agent during radiological emergencies. Further, the FDA has authorized KI to be manufactured, distributed and sold over-the-counter as a "non-prescription drug" (sold to the public without the need for medical control or supervision). In light of such Federal determinations, all testimony in conflict thereto should be considered a radical attack upon a duely constituted and technically qualified government agency, and be rejected by the Board.

Use of shelter as a protective measure against radio-iodines is limited to not more than 2 hours by the Environmental Protection Agency and such

finding should be afforded the same protection that the Commission affords its own findings.

Testimony from Mr. Neal Slaten has shown that use of ad hoc respiratory devices is more difficult in actual practice than it appears, also, that the best protection afforded to individuals exposed to radio-nuclides during an accident is shelter, ingestion of KI, and the use of respiratory protective measures (ad hoc respiratory devices or masks, etc.).

Testimony of Dr. Roger E. Linnemann, M.D. during the hearing showed that citizens who were not in medical facilities, nursing homes, or State institutions should be afforded the protection of KI, if they were attended by medically qualified persons on a regular basis (patients of County Health Nurses). In these cases, the institutions to which the patients were confined were, in fact, their homes.

No serious problem exists in pre-distribution of KI within the PEP EPZ. Residents number less than 18,000 and the cost for a 3-5 year supply (14 day supply) for each person will cost $1.00. The annual cost, prorated over the 5 year period, for the entire PEP EPZ is only $3,4_8.80. This figure is well within the cost/benefit criteria established by the Commission.

Based upon all facts relating to this issue, the determination to order issuance of KI to populations within the PEP EPZ is not hindered by medical or logistical reasons, nor is there a valid cost/benefit issue raised. The only potential hinderance would appear to be political in nature. The question raised is: "How will the public view nuclear power safety if they have KI in front of their faces as they open their medicine cabinets each morning to shave or put on make-up?". Additionally, there may be concern that the nuclear industry's public image may be adversly affected by issuance of KI

since it may be interpreted to refute industry public relations statements that "accidents don't happen at nuclear power plants".

The Applicant has not submitted valid testimony to refute issues raised in Reed's Contention 6, but has, instead, attempted to refute the the findings of the F.D.A. that KI is safe and effective and can be sold (used) without medical supervision. Applicant presented testimony as to the maximum effectiveness of ad hoc respiratory devices, but its expert witness could not apply such ad hoc respiratory devices effectively in actual practice. It's witness, Dr. Linnemann, indicated that exceptions to the standards currently used in State and local RERPs, as relate to issuance of KI to institutionalized persons, are reasonable. As a result, the Applicant's case is filled with contradiction and exception. The public health and safety is best provided when all persons within the PLP EPZ are provided with KI in doses prescribed by the F.D.A. and such KI is ingested in a timely manner as prescribed by instructions contained on the package in which the drug (KI) is enclosed.

IV. CONCLUSIONS OF LAW

The Board has considered all of the evidence submitted on Reed Contentions 6 and 16, as well as proposed findings of fact and conclusions of law filed by the parties. Those proposed findings and conclusions not adopted or otherwise addressed in this decision have been found to be unnecessary to the Board's decision. Based upon a review of the entire record in this proceeding opinion and findings of fact, the Board enters the following conclusions of law.

With respect to matters placed in controversy by Reed Contention 16, there is reasonable assurance that adequate protective measures can and will be taken to properly inform the public of defensive actions needed

to protect the public health and safety.

With respect to matters placed in controversy by Reed Contention 6, there is reasonable doubt that adequate protective measures can be taken in the event of a catastrophic accident (exceeding design based accidents) or all radiological emergencies postulated for pressurized water reactors in NRC studies.

This is a contested proceeding on an application for an operating license for a utilization facility, and the Board has made findings of fact and conclusions of law on all matters in controversy. The Board has determined that a serious safety matter exists. See 10 CFR, Section 2.760a.

Having decided this matter in favor of the Intervenor, the Board withholds its authorization for the facility operations until such time as this safety related matter is satisfactorily resolved.

Respectfully submitted,

John G. Reed

Dated at Kingdom City, Missouri, this 06th day of October 1983.

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CERTIFICATE OF SERVICE

I hereby certify that the document attached hereto was served this 07th day of October, 1983 by deposit in the U.S. mail, first class postage prepaid upon the following:

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