UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

Before the Atomic Safety and Licensing Board

In the Matter of	)	
	)	
THE CLEVELAND ELECTRIC ILLUMINATING COMPANY, ET AL.	)	Docket Nos. 50-440 50-441
	)	
(Perry Nuclear Power Plant, Units 1 and 2)	)	

AFFIDAVIT OF JOHN J. MAURO

City of New York	)	
	:	ss:
State of New York	)	

John J. Mauro, being duly sworn, deposes and says as follows:

1. My name is John J. Mauro. I am the Director of the Radiological Assessment and Health Physics Department of Envirosphere Company, a division of Ebasco Services Incorporated. My business address is Two World Trade Center, New York, New York 10048. Since joining Ebasco in 1973, I have been a consultant to several nuclear utilities and state agencies in the area of emergency planning and radiation protection. I hold a doctorate degree in Biology/Health Physics from New York University Medical Center - Institute of Environmental Medicine. I am certified by the American Board of Health Physics and the Board of Hazard Control Managers. A complete statement of my professional qualifications and experience is attached hereto as Exhibit A. I have personal knowledge of the matters set forth herein and believe them to be true and correct.

INTRODUCTION

2. The purpose of this affidavit is to respond to Sunflower Alliance, Inc., et al.'s ("Sunflower's") Contention G, which states:

> Emergency plans should include the availability of potassium iodide (KI) for emergency workers and the public.

This affidavit demonstrates that the use of KI for offsite emergency workers and the general public is not required by current Federal regulations, and that it is reasonable and appropriate that the Ohio

Department of Health has decided not to provide KI for emergency workers or residents of the plume exposure pathway EPZ for the Perry Nuclear Power Plant.*

3. This affidavit is divided into four main sections. The first section presents a brief overview of the history of the KI issue and is provided in order to establish the historical perspective for the sections which follow. The second section describes the current Federal regulatory guidance regarding the use of KI. The primary purpose of this section is to demonstrate that there are no Federal regulations regarding the use of KI offsite and that all Federal agencies defer to State authorities regarding the use of KI offsite. The third section describes the benefits and limitations of KI. This section demonstrates that the benefits associated with the offsite use of KI are marginal and offset by its deficiencies. The last section specifically addresses KI as a protective measure for offsite emergency workers.

HISTORICAL OVERVIEW OF KI ISSUE

4. Potassium iodide (KI) and other compounds of iodine have been used extensively in the treatment and diagnosis of a variety of illnesses. It has been used as an antibiotic in the treatment of bacterial infections (Stone, 1971), an expectorant in the treatment of asthma (PDR, 1980) and as a thyroid blocking agent to protect the thyroid from radiation during the I-125 fibrinogen test which is used for the detection of venous thrombosis (Denham, 1974). Accordingly, KI and other compounds of iodine have widespread medical use and have long been recognized as an effective means to block the uptake of iodine by the thyroid gland. Because of this medical experience with KI, discussions on the use of KI for protection of the public from radiation accidents are cited in the literature as early as 1963 (Pochin, 1963).

5. With the publication of the Reactor Safety Study (WASH-1400) in 1975, which identified radioactive iodine as a potentially significant contributor to health consequences following a core melt accident, and the growing concern at that time regarding the adequacy of emergency plans (RED-76-73), it was thought that greater attention should be given to the possible use of thyroid blocking agents. In order to provide more complete guidance on this subject, the National Council on Radiation Protection and Measurements (NCRP) published NCRP Report No. 55. In this report, the NCRP reviewed the literature on the effects of exposure of the thyroid gland to I-131 and the effectiveness of various blocking agents

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* Institutionalized persons are considered members of the general public for the purpose of this affidavit, since the County Emergency Plans provide for evacuation of such persons along with the rest of the general population. (SEE "Lake County Emergency Response Plan for the Perry Nuclear Power Plant" (Rev. 3, October, 1984), Section J-06; "Ashtabula County Radiological Emergency Preparedness Plan" (May 10, 1984), Section J.4.1; "Geauga County Radiological Emergency Response Plan" (Change No. 2 dated July, 1984), Section J-4.)

for protection of the thyroid gland. The NCRP concluded and recommended that KI should be considered for use by emergency workers and the general public. It should be noted, however, that the NCRP did not recommend predistribution to individual members of the general public. In addition, it emphasized that the responsible physician for the nuclear facility or state and local officials should make the decisions regarding the administration of the drug (NCRP-55, 1977).

6. At the time this recommendation was made, KI was only available through prescription. Accordingly, no pharmaceutical company would produce it in large quantities since only very limited quantities could be sold via prescription. To remedy this situation, the Food and Drug Administration requested in the Federal Register (43 FR 58798) that new drug applications (NDA) for over the counter (OTC) sale of KI be submitted to FDA. In response to this notice, Carter-Wallace Laboratories submitted an NDA (18-307, May 9, 1979) and received a license for the sale of KI. However, its use was limited to emergency situations and only under the direction of the State and local health authorities.

7. The next milestone in the evolution of the status of KI as a protective agent was the accident at Three Mile Island (TMI). During the accident, the FDA made extensive efforts to obtain large supplies of KI in the event that it was needed. Because of the difficulty encountered by FDA in rapidly obtaining KI, one of the findings of the various TMI study groups was that preplanning for the use of KI is appropriate (Kemeny, 1979).

8. After the TMI findings were issued, the NRC published many regulations and regulatory guidelines pertaining to emergency planning. The most important of these guidelines which address the use of KI as a protective response are contained in NUREG-0654 and state the following:

"Criteria J.6.c

Each licensee shall, for individuals remaining or arriving onsite during the emergency make provisions for:

- Use of radioprotective drugs, (e.g., individual thyroid protection).

Section J.10

The organization's plans to implement protective measures for the plume exposure pathway shall include:

- Provisions for the use of radioprotective drugs, particularly for emergency workers and institutionalized persons within the plume exposure EPZ whose immediate evacuation may be infeasible or very difficult, including quantities, storage, and means of distribution.

- State and local organizations' plans should include the methodology by which decisions by the State

Health Department for administering radioprotective drugs to the general population are made during an emergency and the pre-determined conditions under which such drugs may be used by offsite emergency workers;"

9. In March 1980 the NRC published a study which attempted to further evaluate the merits of KI (Aldrich, 1980). The study concluded that KI is not cost-effective because of the extremely low probability of a large release of radioiodine. Partly as a result of this study, the nuclear industry began to seriously re-evaluate the use of KI. It was also at this time that several other reports were published which revealed that the probability of a release of large quantities of radioiodine following a core melt accident is much less than previously believed (Levenson, 1980; NUREG-0772). In light of these findings, and the general lack of a clear Federal policy on KI, the Nuclear Safety Oversight Committee wrote to President Carter

"that Federal policy should recommend against the use of potassium iodine for the general public until such time as: (1) research has been carried out to clarify the source term for iodine releases thereby demonstrating the need and (2) clear and convincing plans have been formulated to demonstrate how potassium iodide can be effectively distributed and made available for use when needed. We recognize that while potassium iodide is a highly effective thyroid blocking agent, our concern is its misuse by our uninformed public in inappropriate circumstances."

10. In addition, the medical community began to reassess the conclusions of NCRP-55 and the FDA with respect to the safety of KI. This reassessment took the form of position papers by the New York Academy of Medicine (N.Y. Acad. Med, 1981), the American Thyroid Association (Am. Thy. Assoc., 1981) and papers by Nobel Laureate in Medicine Dr R.S. Yalow (Yalow, 1980). In all cases, the primary concern was the uncertain nature of the side effects of KI.

11. Complementing the studies on the side effects and cost-effectiveness of KI were studies performed by the Harvard School of Public Health (Cooper, 1981) on the effectiveness of various expedient methods of respiratory protection. The studies showed that common household items such as wetted towels or sheeting offered a protection factor of 10 or greater for iodine and particulate matter. James Martin of the NRC's Reactor Risk Branch, Division of Risk Analysis, Office of Nuclear Regulatory Research (Martin, 1981) concluded that

"these studies demonstrate that application by the public of ad hoc shelter and respiratory protection could provide inhalation pathway protection factors (PFs) of ten or more and ad hoc respiratory protection providing an additional PF of three to twenty or so. These PFs are very competitive with that of potassium iodide (KI) for the thyroid but the former would protect other organs as well ...."

CURRENT REGULATORY FRAMEWORK

12. There are currently no Federal regulations which require the use of KI as a thyroid blocking agent for offsite emergency workers or members of the general public. As stated by D. McLoughlin, Acting Associate Director State and Local Programs and Support of FEMA:

> "Each State has responsibility for formulating guidance to to define if and when potassium iodide is used as a thyroid blocking agent for emergency workers, institutionalized persons and the general public." (FEMA, 1982)

13. Though the responsibility for decisions regarding the use of KI offsite clearly lies with the State, numerous statements and guidelines have been issued by several Federal agencies. The statements and guidelines have resulted in some confusion as to whether there is a Federal policy on KI, and which agency has the authority to define Federal policy related to KI. In this section, a description is provided of the current position or guidance of the Nuclear Regulatory Commission (NRC), the Federal Emergency Management Agency (FEMA), and the Food and Drug Administration (FDA) on the use of KI.

NRC Guidance

14. The position of the NRC Staff regarding the use of KI offsite has evolved from being supportive of offsite use of KI (NUREG-0654) to recommending against requiring the predistribution or stockpiling of KI as a preplanned emergency protective measure for use by the general public (SECY-83-362).

15. The Staff's position is that there is currently enough information on hand regarding the radioiodine source term following a severe reactor accident to make a definitive statement against the stockpiling or predistribution of KI for general public use. The Staff recommends against stockpiling or predistribution of KI offsite as a condition of an operating license primarily because of the extremely high cost/benefit associated with such programs (Aldrich, 1980). The cost/benefit uncertainty analysis performed by the Staff "conclusively shows that KI offers extremely small benefit in relation to its costs and is not cost-effective as a preplanned emergency protective measure for the general public" (SECY-83-362).

FEMA Guidance

16. As was the case with the NRC, FEMA was originally supportive of KI and recommended its use by offsite emergency workers and institutionalized persons (NUREG-0654). FEMA is currently reviewing its KI guidance in light of its recognition that State health officers have the ultimate responsibility for the health of their citizens, and each State has a responsibility for formulating guidance to define if and when the public and offsite emergency workers should be given potassium iodide and instructed to use it. (Krimm 1982; FEMA, 1982)

17. FEMA has reversed its position regarding the need for Federal stockpiling of KI. In April 1981 and in March 1982, FEMA testified that it was preparing to purchase KI for a national stockpile. However, FEMA subsequently stated that it will no longer have any involvement in the stockpiling of KI. (Krimm, 1982).

18. It is clear that FEMA's position has evolved from very active support for the offsite use of KI to delegating full responsibility for decisions regarding the offsite use of KI to State authorities. FEMA's current role is to review the preparedness planning of State and local governments who wish to exercise the option of KI stockpiling as part of the normal review of State and local preparedness under 44 CFR 350. The reasons for the change in FEMA's positon are the many uncertainties associated with the use of KI and the fact that there are many other methods for protecting the public and emergency workers which could be more effective. (Krimm, 1982; FEMA, 1982)

FDA Guidance

19. Under 44 CFR 351, FDA, as delegated by DHHS, is responsible for assisting State and local authorities in developing plans for preventing adverse effects from exposure to radiation in the event that radioactivity is released. These plans include the prophylactic use of drugs that could reduce the radiation dose to specific organs from the sudden release into the environment of large quantities of radioactivity.

20. In fulfilling these responsibilities, the FDA issued a position paper (47 FR28158) which stated that KI can be safe and effective as a thyroid blocking agent if used as prescribed and under the conditions specified by the FDA. This position, however is worded in a way that has resulted in considerable controversy and some confusion as to whether KI is required for offsite use. Clarification regarding this matter was provided by Dr. G. C. Johnson of FDA. Dr. Johnson emphasized that "the FDA has not recommended the use of KI, rather it has stated that the drug is safe and effective for use in accordance with the labelling instructions." (Johnson, 1982)

21. The FDA has provided this clarification because it recognizes that "each State is responsible for formulating guidance on when, if at all, the public should be supplied with KI along with instructions on how to use it" (47 FR 28158). The role of FDA in this matter is to provide guidance on its proper use, should State officials elect to use it.

22. Based on the above regulatory overview it is clear that differences of opinion exist between the NRC and FEMA regarding the desirability of KI as a protective measure and that the merits of its use at any site are debatable. It is for these reasons that the Federal agencies have left decisions regarding the use of KI to the individual State authorities.

TECHNICAL OVERVIEW

23. The difficulties encountered by Federal agencies in finalizing their policy on KI are due in large part to the complex technical issues associated with its use. In this section, an overview is provided of the technical issues. It is intended to demonstrate that the use of KI has many real and potential limitations which, when viewed in their entirety, support the reasonableness of the State of Ohio's position in deciding against the offsite use of KI.

24. Any decision regarding the use of KI offsite must be based on a balancing of the costs and benefits of such a program. In this section it is shown that the potential benefits of KI are marginal while the real and potential costs are considerable. This observation becomes even more compelling in light of the fact that there are other protective actions which can provide comparable protection to the thyroid gland to KI. (Cooper, 1981)

Benefits

25. On the benefit side of the equation, there is little disagreement that KI, if properly used, would significantly reduce the internal dose to the thyroid gland from inhaled or ingested radioiodine. Specifically, following a severe accident, the use of KI would reduce the dose to the thyroid gland by about a factor of 5 and reduce the number of cancer fatalities about 5% (NUREG-0771). The benefit is only marginal because the exposure of the thyroid gland is not the critical pathway of exposure in terms of cancer fatalities. The critical exposures are to the whole body by radioiodine and other radionuclides. As stated by the NRC Staff in Enclosure A of SECY-83-362, for severe core melt accidents, exposure to the thyroid would be the least of the health problems of concern, especially within about 10 miles, and therefore KI should be given the least consideration as a protective measure.

Costs

26. The costs of the program include both economic costs and potential costs to the public health and safety.

Economic:

27. The economic costs of implementing a KI program include the purchase price of the KI, periodic replacement costs (the KI must be replaced every three years), costs for stockpiling, distributing and monitoring the status of the drug, and administrative expenses associated with the program. Aldrich (1982) has estimated the annualized cost for purchasing KI to be $0.10 per person per year. Even though this is probably an underestimate, it is clear that from a purely economic perspective, even if stockpiling and administrative costs are included, the costs per person are relatively small and are not a critical factor in the decision making process. However, Aldrich has also shown that due to the extremely low probability of a large release of radioiodines, the cost benefit ratio of the offsite use of KI is in excess of 9 million dollars per theoretical death averted. This estimate is based on extremely

conservative assumptions regarding the probability of a large release of radioiodine and conservative assumptions regarding the carcinogenicity of radiation exposure to the thyroid gland. A more realistic estimate is about 200 million dollars per thyroid cancer fatality averted (SECY-83-382). In addition, these estimates do not include any possible adverse health effects associated with the use of KI.

Public Health and Safety:

28. The greatest controversy associated with the use of KI as a blocking agent centers around its possible side effects and its potential for interfering with effective emergency response.

29. Dr. Roslyn S. Yalow has taken a strong position against the administration of KI to the general public without medical supervision, and advocates reliance upon shelter and evacuation. Dr. Yalow agrees with FDA that the side effects are infrequent and generally minor. However, she cites publications which reveal that individuals with rheumatoid arthritis, lupus or hypocomplementic vasculitis could suffer severe, and possibly fatal, side effects from KI administration. (Yalow, 1981).

30. The American Thyroid Association has published a summary of the side effects of KI (Am Thy Assoc, 1981). The paper cites numerous references in the medical literature describing: thyrotoxicosis, edema, nasal polyps, dermatitis and hypocomplementic vasculitis and recommends that a more systematic evaluation of side effects be performed in order to obtain reliable information on the actual risks of KI administration. On March 2, 1981 the Committee on Public Health of the New York Academy of Medicine passed a resolution opposing the stockpiling, at the present time, of KI for the purpose of potentially protecting the population of New York City against an accidental exposure to radioiodine. Among the several reasons for this position were potential adverse side effects and cost-benefit considerations. (NY Acad, 1981).

31. Based on the above studies, FDA acknowledges that uncertainties exist about the incidence and severity of side effects of KI. The side effects cited by the FDA include iodine goiter, hyperthyroidism, hypothyroidism, dermatologic and mucous membrance reactions and allergic reactions. The FDA supports its position by stating that though significant side effects from KI have been reported, they have occurred following chronic administration of daily doses far in excess of those necessary for thyroid blocking in a radiation emergency, and these problems are not expected to occur from the short term use of relatively low doses of potassium iodide. However, the FDA also states that exceptions to this may include persons with unusual sensitivity to iodine, newborn children, the elderly, pregnant women, and the developing fetus. (FDA, 1982). Further, FDA does not consider persons taking more than the recommended dose, either by accident or on the assumption that larger doses would provide greater protection.

32. The FDA also states that KI is not a panacea and that it does not reduce the uptake of other radioactive material, does not provide protection against external radiation and needs to be balanced against other protective measures such as sheltering, evacuation or respiratory

protection. In addition, FDA recommends that, if used, a system of medical reporting and assistance is needed in the event of side effects. (FDA, 1982). Under emergency conditions, medical assistance may be difficult to provide and efforts to provide such assistance could interfere with other protective actions, such as shelter and evacuation.

33. In addition to possible adverse side effects, the use of KI in an emergency can also have detrimental effects on the implementation of other, more effective, protective measures. Since the greatest projected health impacts on the population as the result of passage of a plume would be due to whole body exposures, as opposed to exposure to the thyroid (ACRS 1983), the effectiveness of other, potentially more effective, protective actions could be reduced due to 1) the time taken to locate and take the drug, 2) a false sense of security by the public regarding the effectiveness of the drug, 3) overdoses, (SECY-83-362) and 4) misuse.

34. From another perspective, Malinauskas (1982) calculated that severe reactor accidents with large releases of radioiodine occur with frequencies in the range of 10^{-5} to 10^{-7} per year. With 100 reactors operating in this country, Malinauskas questions the logic of maintaining a continuous supply of KI doses to contend with an event which will occur at a rate of perhaps once every ten centuries. In addition, Malinauskas raises the question whether the number of fatalities projected to occur over this period would be greater due solely to transportation accidents associated with the distribution of KI.

35. In response to this question I have performed the calculation suggested by Malinauskas. Using 10^{-7} to 10^{-5} accidents per reactor per year as the probability of a serious core melt accident, it is estimated that it will take 100,000 to 10,000,000 years before any one reactor will have a serious core melt accident. Assuming that such an accident occurs, the total number of damaged thyroids within 10 miles of the plant is about 500, (Aldrich, 1980) with an estimated maximum of about 15 fatalities due to thyroid cancer. Assuming that 100 vehicle miles must be traveled per year per plant in order to support a KI program, a total of ten million to one billion vehicle miles would be traveled before the KI would need to be used. Using a transportation risk coefficient of 10^{-6} to 10^{-7} fatalities per vehicle mile (WASH-1238), 1 to 1000 fatalities are projected to occur from road accidents required to support the program. Clearly, the potential benefits for KI use are so small that the transportation risks, attendent to its management, may alone be sufficient to offset any benefits.

KI FOR OFFSITE EMERGENCY WORKERS

36. The concerns about side effects and the inability of KI to protect against much more important whole body exposures are equally applicable to offsite emergency workers. In addition, the cost/benefit analysis performed by Aldrich is also applicable to emergency workers because the results of the analysis are independent of the number of people by a given location. These concerns, coupled with increasing evidence that the radioiodine source terms have been grossly overestimated in the past (IDCOR, 1984), provide compelling reasons to look toward other more effective methods for protecting offsite radiation workers. In

addition, given the relatively small number of radiation workers, should conditions exist where significant exposures to radioiodine are likely, procurement and distribution of KI to offsite workers who may receive such exposures can be implemented on an ad hoc basis. For example, all nuclear utilities store relatively large quantities of KI. It is therefore reasonable to assume that these sources of KI could be made available on short notice if needed.

37. As a final point, one may reasonably question why KI is required, and appropriate, for use by on-site emergency workers but not for offsite emergency workers. The primary reason is the very close proximity of the onsite workers to the source of exposure. The onsite response team may need to enter buildings where the levels of radioiodine are elevated, even though the radioiodine source term to the environment is very low.

Conclusion

38. For the reasons stated above, requiring the use of KI for the Perry Nuclear Power Plant, either for offsite emergency workers or the public, would not significantly enhance the public health or safety. The decision by the State of Ohio and the Counties of Lake, Ashtabula and Geauga not to use KI is a reasonable one. Sunflower's Contention G is without merit.

John J. Mauro

Subscribed and sworn to before me
this 1st day of February, 1985

Marie A. Petraitis
NOTARY PUBLIC

MARIE A. PETRAITIS
Notary Public, State of New York
No. 01PE4805003
Qualified in Kings County
Cert. Filed in New York County
Commission Expires March 30, 1985

My Commission Expires:

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EXHIBIT A

Resume

JOHN J MAURO

Education:

BS - Long Island University 1967
MS - New York University 1970
PhD - New York University Medical Center - Institute of Environmental Medicine 1973

Awards:

- Alvin Gruder Memorial Award for Excellence in Biological Sciences
- Member of the Optimates Society for Academic Achievement
- Founder's Day Award for Doctoral Dissertation

Societies:

- Health Physics Society
- American National Standards Committee on Emergency Planning

Certifications:

Certified by the American Board of Health Physics
Certified by the Board of Certified Hazard Control Managers

Current Position:

Director of the Radiological Assessment and Health Physics Department of Envirosphere Company in New York City.

Summary of Professional Experience:

While a graduate student at the Institute of Environmental Medicine of New York University, I was also a full-time Research Assistant from 1970 to 1973. In this position I assisted Principal Investigators on numerous research projects on the ecology and radioecology of the lower Hudson River Estuary.

In addition to my responsibilities as Research Assistant, I was a full-time graduate student, studying environmental health, health physics and radioecology. My doctoral research was on the radioecological behavior of Cs-137 in the lower Hudson River Estuary.

After receiving my doctoral degree in 1973, I joined Ebasco Services as a Radiological Assessment Engineer. Ebasco Services is a major architect-engineer-constructor for power generating facilities. My initial responsibilities at Ebasco were to evaluate the radionuclide release rates from proposed and operating nuclear power facilities under normal plant operation and following postulated accidents, and to determine the radiation exposures and health risks to workers and members of the nearby general population. In this capacity I developed several models for performing radiological impact assessment, and have prepared the radiological impact assessment sections of license applications.

Since joining Ebasco I have held positions of increasing responsibility, and am currently Director of the Radiological Assessment and Health Physics Department in Envirosphere Company, the Nuclear Licensing and

Environmental Health Division of Ebasco Services. In this position, I am responsible for all radiological health and emergency planning services provided by Envirosphere Company. I manage a technical staff of 10 senior level consultants with advanced degrees in nuclear and biological sciences, with a combined 150 years of professional experience in technological risk management.

I continue to personally provide consulting services. These services include the analysis of radiological source terms, environmental transport, radioecology, internal and external dosimetry, health risk assessment, radiological surveillance, emergency planning, regulatory analysis and the preparation and defense of expert testimony on these subjects. Recently I have also become involved in the evaluation of toxic chemical hazards at industrial sites and low-level radioactive waste management. These services have been provided for a large number of clients representing the nuclear power industry and federal and state agencies and their subcontractors.

I have also managed several consulting contracts in the areas of radiological and chemical toxicology, health physics, and emergency planning. Most of these projects have been of a multidisciplined nature and included participation of specialists in the areas of toxicology, nuclear engineering, mathematical modelling, meteorology, hydrology and computer sciences.

Publications and Presentations:

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