

County of San Luis Obispo

COUNTY GOVERNMENT CENTER, RM. 370 ■ SAN LUIS OBISPO, CALIFORNIA 93408 ■ (805) 781-5011



February 5, 1996

Secretary, U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTEN: Docketing and Services Branch

OFFICE OF THE
COUNTY ADMINISTRATOR

RE: Comments on [Docket No. PRM-60-63] Petition for Rulemaking, Peter G. Crane;
Stockpiling of KI

Dear Sirs:

This letter is submitted on behalf of the Office of Emergency Services for the County of San Luis Obispo. San Luis Obispo County is the Responsible Off-site Emergency Organization for an emergency at the Diablo Canyon Nuclear Power Plant. The following are comments on the Petition for Rulemaking to require stockpiling of Potassium Iodide for use by the public at off-site locations around nuclear power plants.

In general, we are not in favor of the proposed rule. The basis for our opposition is as follows:

1. The preferred protective action in nuclear power plant actions are evacuation or sheltering in place. Attempting to distribute KI to the public would likely conflict with the evacuation or sheltering of the public. If emergency conditions warrant the distribution of KI, then they would certainly meet the conditions and guidelines for mandatory evacuation. Trying to get people to go to centralized locations around the County to pick up KI will likely interfere with the intent to rapidly move the public from the designated evacuation area. The public may receive greater exposure by remaining in the area while attempting to pick up KI rather than immediately exiting the area.
2. Although not extremely common, allergic reactions to KI cannot be discounted as insignificant. Anaphylactic shock is one of the possible reactions. The distribution of KI to thousands or tens of thousands people will result in some cases of allergic reaction. Medical response to cases of allergic reaction will be difficult as most medical resources will be allocated to assisting with the evacuation of special care populations in hospitals and nursing homes.
3. The distribution of KI will require that emergency workers that are involved in assisting with evacuation, be reallocated to KI distribution. This may hinder evacuation or other protective actions that are being undertaken. The effect could be to stretch local resources beyond the point of effectiveness.

4. The stockpiling and distribution of KI around the country, and here in San Luis Obispo, will pose potentially significant logistical problems. KI must be changed out as it is a drug that has an expiration date for effectiveness. Tracking each stockpile of KI will require additional efforts being allocated to record keeping, destruction of expired stockpiles and replacement of stockpiles. Examined on a national perspective, there exists the potential for a half dozen to a dozen stockpiles around each nuclear power plant site, with the distribution of several million doses of KI to perhaps hundreds of entities. If adopted, the NRC will likely establish strict guidance for implementation and monitoring of the entities compliance with the proposed rule. As such hundreds or thousands of man hours will be applied annually to comply with this rule.

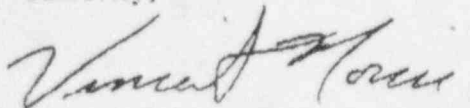
If a stockpile of KI is determined to be a necessity by your agency, a more reasonable approach would be to centralize stockpiles of KI so that they could quickly be delivered to locations where KI is requested. KI could be treated as a federal resource by distributing it to each NRC Region Headquarters. This would minimize the amount of money and time necessary to track, exchange, and certify that KI stockpiles are in place. However, all jurisdictions would be aware of the readily available nature of the KI stockpile and could place a request to access the stockpile if needed. The costs and logistical difficulties associated with the concept of centralized stockpiles will likely be an order of magnitude less than stockpiling resources at each site.

5. California has a policy that stresses other protective actions and does not recognize the use of KI as a protective action for the general populace. The Protective Action Guidelines for the issuance of KI are the same as that for evacuation. Evacuation is the preferred alternative. KI use for emergency workers, whose duties may require them to remain in the plume pathway, is clearly justified and is included in our emergency plans. However, when dose projections indicate that the PAG levels for radioactive will be reached, a protective action decision to evacuate will be made. The California policy is consistent with this concept of operations.

These comments are being forwarded to the California State Office of Emergency Services for inclusion in the comments by the State.

Thank you for the opportunity to comment on this issue.

Sincerely,



Vincent Morici
Emergency Services Coordinator

DEPARTMENT OF HEALTH SERVICES

714/744 P STREET

P.O. BOX 942732

SACRAMENTO, CA 94204-7320



February 7, 1996

Petition for Rulemaking
Docket Number PRM-50-63
Published- Federal Register
Vol 60, No. 227
Monday, November 27, 1995
Proposed Rules

The following comments are submitted by the State of California, Department of Health Services, Environmental Management Branch, Nuclear Emergency Response Program.

1. STATEMENTS: "...the prophylactic use of potassium iodide, which prevents thyroid cancer after nuclear accidents", "...in addition to preventing deaths from thyroid cancer, KI prevents radiation caused illnesses."

RESPONSE: These statements imply that KI is a protection against an individual acquiring cancer of other organs or illnesses following exposure to radioactive iodine from the potential release during a nuclear incident. Where is the supporting data that proves KI prevents other radiation caused illnesses? A list of this data should be made available to all states. The generalized statements do not reflect exposure limits, dose levels at which such effects may occur nor the time limited window for therapeutic administration. There is no mention of side effects, even death for someone who is allergic to iodine. If the FDA has determined that this drug is "safe and effective", why are allergies a controlling factor in issuing KI to Workers, let alone the General Public? Obviously there are only potential estimates for the levels of iodine that could cause a reaction or it would not be classified as a prescription drug. Prior to issuance to Workers, there is a determination of any potential or possibility that the individual may be allergic to iodine which would prohibit that individual from being classified as a worker and these individuals normally receive training in the scope of hazards from KI along with the potential exposure to radiation. The training of the General Public in these same areas has not been addressed. These situations appear to be over looked in the petition. Is the NRC prepared to address the number of legal implications should a member of the General Public be given KI at their directive or recommendation and the individual have an extreme allergic reaction, possibly death? This appears to be a no win situation.

The State of California policies currently prohibit the blanket issuance of KI to the General Public.

This option should be left to the local or State health authorities as currently indicated

in the U.S. Nuclear Regulatory Commission, Response Technical Manual RTM-93 Vol. 1, Rev. 3. In contradiction to the petitioner's opinion of the State and local government's informed judgement, most decisions of this nature would most likely be derived from a multitude of input from all levels of expertise.

2. STATEMENTS: "...potassium iodide for human use, should be available regionally for distribution to the general population and workers." "...the NRC staff declared its support for KI stockpiling." "The Atomic Industrial Forum, a nuclear industry trade association, declared itself against the stockpiling of KI."

RESPONSE: The distribution of KI to the General Public within a short time (1-4 hours) is virtually a logistic impossibility as illustrated in NUREG/CR-6310, even if stockpiled quantities were available locally. "KI should not be distributed to the general population if it will delay other immediate protective actions.", RTM-93, reflects the anticipated problems. Therefore, the next alternate approach is pre-distribution to the General Public. This approach is not prudent due to the potential for misuse of the prescription drug, thus adding to the risk factor. Allegations pertaining to the Cost/Benefit analysis are unfounded and rational reasoning would make it unconscionable to distribute a prescription drug without adequate training, education and controls for the recipient. The State of Tennessee attempted this method and called it a success with only a 66% effectiveness, NUREG 6310. This should not be construed as an expense problem but as an insurmountable task. "The effectiveness of KI in blocking uptake of radioiodine by the thyroid depends strongly on the timing of the dose of KI relative to the exposure to radioactive iodine. KI is most effective when taken just before or within 1-2 hours after exposure..", RTM-93. This time table cannot be met in a realistic approach or even within 3-4 hours for a 50% effectiveness. Proper administration of the drug may not be assured without adequate training for an entire population.

Distribution to the General Public in a timely manner to accomplish the suggested results should not be viewed as a Cost/Benefit initiative but as a Risk vs. Benefit evaluation. Accomplishment of the task is a logistical impossibility and adds risk with minimal benefits.

3. STATEMENTS: Three Mile Island, Potassium Iodide Policy, Effects of Chernobyl, "...petitioner asserts that the changes in medication that go with periodic scans put many patients on a physiological and psychological roller-coaster.", "...that Potassium iodide was safe and effective for thyroid protection..", "The release of radioiodine is

likely to figure prominently in any nuclear power plant disaster and knowledge of its carcinogen potency is inadequate, especially in children."

RESPONSE: Comparison of the results of Three Mile Island (TMI) with the results of Chernobyl appears to go along with the roller-coaster example, only in this situation, it becomes the use of a fear tactic. This tactic is deplorable. There were releases of radioactive iodine at TMI, but to compare the situations of the minimal amounts of release to that of Chernobyl, is once again unconscionable. To imply that the type of reactors and minimal containment barriers like Chernobyl in anyway compare with those in the U.S. is strictly a fear tactic. The results of TMI and Chernobyl should not reasonably be compared since there were no actual effects to the general public from the release at TMI. There has been minimal effort to report or even follow up on events of allergic reaction to KI in either Poland or the previous Soviet Union since there are minimal records and no intent to publish such negative effects by those countries. We may never know of many of those effects, therefore, the petitioner may be very comfortable in the allegations referring to Chernobyl. However, what need was indicated for KI at the TMI incident? Minimal to none. Would it have been distributed to the General Public if available? Not effectively. Had the KI been available for distribution at TMI, could it have been distributed in a timely manner? Probably not. What studies have projected thyroid injury or incidence of increased thyroid cancer in the vicinity of TMI? Basically none.

Evacuation and sheltering are adequate protective measures of choice for U.S. emergency response protective actions as were adequately demonstrated at the TMI incident. The use of KI should remain the responsibility of local and state authorities whether for Workers or General Public. If the NRC wishes to assume full responsibility as the lead Federal agency, and make recommendations, the State and local authorities will openly receive such recommendations. The decision to authorize the use of KI will remain at the direction of the Local Health Officer, when prudent and as the law allows.

4. STATEMENTS: "...nuclear power plant licensees to have adequate supplies of KI available for nuclear power plant workers and the general public.", "...should be available regionally for distribution to the general population and workers...", "...that the United States maintain the option of using the drug potassium iodide for thyroid protection during nuclear accidents.", "...maintaining a KI option ensures that responsible authorities have an additional type of protection at their disposal", "the NRC will provide advice to the state and local governments on ...", "that the States do not have an adequate basis for making informed decisions.", "...that without accurate and current information on KI...States cannot make an informed judgment."

RESPONSE: The petitioner's intent appears to be twofold, (a) assure adequate availability of KI through stockpiling and (b) adding a requirement for the use of KI specifically for the general public.

(a) Availability of KI may well be an issue for the Federal agencies to address. There should be no argument with the fact that stockpiling of KI by the Federal Government may be a sensible and prudent measure to assure its availability since it has been demonstrated that it was not available during a potential need. The Federal Government has made radioactivity monitoring instrumentation available to and maintained by the States for distribution and local stockpiling. This type of program for KI would probably be less expensive than that which has been expended through out the Cold War period, during which, no need for use has developed, and was basically propagated by the fear factor. Stockpiling will not be an answer to the distribution problems and the availability of KI should not be considered in the same scope as actual use by the general public.

(b) If it is the intent of the NRC is to direct the use of KI for the general public, because of assertions made by the petitioner, it appears that the NRC is exceeding its legal authority and confusing advice with a mandate or regulation. The States are quite willing to work hand in hand with all Federal agencies during any incident. Implication to the contrary by the petitioner or that KI is not a viable option within limitations is ludicrous. The current directions indicated in RTM-93 for KI provide adequate guidance with in an acceptable, workable frame work for all levels of government and their legal jurisdictions. The NRC should not have to be reminded that the State of California also provides a number of qualified experts in the field and are available for such decisions.

Stockpiling of KI and distribution may need to be addressed; however, the current protective action issues must remain in proper perspective and not be changed. The existing issues have been previously addressed by a benefit versus risk not a cost versus benefit initiative as indicated by the petitioner.

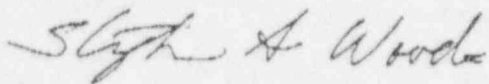
5. STATEMENTS: None

RESPONSE: Without questioning the motives of the petitioner, The NRC must be aware of the eminent expense created by the time and research propagated by this exercise. The entire industry and government as well must once again be penalized for the ineffectiveness demonstrated by the NRC in its failure to resolve this issue early on. It may well be a necessary means to an end, however, in this time of financial restraint, it behooves the NRC to bring this issue to an effective end.

ADDITIONAL NOTES:

1. The Federal Register notice does not address studies on how KI can be realistically administered to large populations in an emergency situation in a sufficient time frame to be effective.
2. The Federal Register Notice does not address the issue of cost effectiveness of training for states who adopt the policy of stockpiling KI.
3. The Federal Register Notice does not address the issue of states who adopt stockpiling KI on how it will affect emergency planning and exercise play.
4. The Federal Register Notice does not address legal issues for states who decide to adopt KI and states who do not decide to adopt or administer KI to the public.

Sincerely,



Stephen A. Woods
Senior Health Physicist
Nuclear Emergency Response Program