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Dennis P. Whalen Executive Deputy Commissioner

September 29, 1998

Aby Mohseni MS T4A43 Nuclear Regulatory Commission 11545 Rockville Pike Rockville, MD 20852-2738

Dear Mr. Mohseni:

Thank you for the opportunity to comment on draft NUREG-1633, "Assessment of the Use of Potassium Iodide as a Public Protective Action During a Severe Reactor Accident" issued on March 30, 1998. In 1997, the New York State Department of Health sought the assistance of its Radiological Health Advisory Committee in reviewing the health aspects of the prophylactic use of potassium iodide (KI) as one of the protective measure options in a severe nuclear power plant emergency. The committee found no health related reasons why KI could not be used for such a purpose and recommended that NY State reexamine its policy which precludes KI use for the public. As a result NY State is in the process of initiating a review to determine if there are logistical and legal reasons for why its current policy should not be changed.

The department had looked forward to NRC's report in the hope that it would assist us in the review. Unfortunately, we find the document to have been prepared to justify a position advocating against the use of KI for public protection, rather than as an objective review of the relevant information. This bias raises doubt as to the value of the document.

Enclosed are general and specific comments on the draft report. No specific comments are made on the Executive Summary since these are covered in the comments on the main report. Please feel free to contact me if you have questions or wish to discuss any of our comments.

Sincerely,

Jey Jackblerg

Karim Rimawi, Ph.D. Director Bureau of Environmental Radiation Protection

Enclosure



NEW YORK STATE DEPARTMENT OF HEALTH COMMENTS ON NRC'S DRAFT NUREG-1633 ASSESSMENT OF THE USE OF POTASSIUM IODIDE AS A PUBLIC PROTECTIVE ACTION DURING A SEVERE REACTOR ACCIDENT

General Comments

- 1. The report appears to have been prepared to justify a position which opposes the prophylactic use of KI for public protection. It selectively references sources that support that point of view and ignores others that tend to justify the use of KI. More balance is needed in presenting factual information that is relevant to this issue. A more complete presentation of the information will make the document more useful to those states that will be examining whether to use KI for public protection.
- 2. The document seems to be based on the premise that protective actions will be **either** evacuation of the affected population **or** the use of KI. It does not consider the implications of using KI as a supplement to other measures which is a more appropriate approach, since no one ever advocated KI use to replace evacuation and sheltering.
- 3. The document limits the discussion to accidents where the acute radiation doses are in the lethal range. The report should include a discussion of the possible role for KI use in accidents where the projected doses are sublethal and where the primary risk is that from doses to the thyroid.
- 4. The report does not address the health implications associated with the possibility that in the absence of the tablets approved by FDA, a portion of the population will seek alternative sources of KI which are not intended for prophylactic use.
- 5. While the report claims not to deal with legal issues, it does not refrain from presenting legal arguments for why KI should not be used in the US. It would be more useful to

include a discussion of the types of legal issues that need to be addressed by a state or local government that is considering the use of KI.

Specific Comments

The following are specific comments on the different sections of the main report. The indicated section numbers and titles are those given in the draft NUREG-1633.

I. Introduction

2nd paragraph - The last sentence states that attention to radioiodines "has led to misunderstandings about their radiological significance." The basis for this statement is not clear. Also, it does not specify who misunderstood the radiological significance of radioiodine nor how. The statement should be clarified and justified, or deleted. Many view the added risk to the thyroid from radioiodine to justify additional protection besides measures such as evacuation and sheltering. For example, the US Environmental Protection Agency (EPA) considers the thyroid to be at disproportionately high risk for induction of nodules and cancer, compared to other organs, to warrant developing specific guidance for thyroid exposure as part of EPA's recommended Protective Action Guides (PAG). Is it NRC's position that such protective guides are not warranted?

4th **paragraph** - This paragraph discusses the criteria and intervention levels that have been developed over the years to aid decision makers in determining the most appropriate protective actions and indicates that such criteria are found in EPA's PAG manual. It goes on to discuss evacuation and sheltering as such measures, but fails to mention that criteria for the prophylactic use of KI are also included in the EPA PAG manual, and that the US Food and Drug Administration (FDA) developed specific criteria for such use. For completeness, FDA and EPA criteria for the use of KI should be added.

5th paragraph and 6th paragraph - The report mounts a strong defense of evacuation as a protective measure. There is no problem with this position. However, it seems the authors view evacuation and use of KI as two mutually exclusive options. We do not believe anyone proposes this position. It is more appropriate for the report to view the use of KI as a protective measure which supplements evacuation and sheltering, rather than supplants them.

7th **paragraph** - The statement that there is just one pathway in which KI provides thyroid protection appears to be in error. KI would protect the thyroid from radioactive iodine that is either inhaled or ingested. The ingestion may come before contaminated food and water is interdicted, or from any contaminated source that is ingested. Also KI is of potential benefit, though at reduced protection levels, if taken several hours before or a few hours after iodine intake, not only if "administered just before" intake.

8th paragraph - Legal factors associated with the use (or non use) of KI are very important issues in decisions on the role of KI for the general public. While some issues may be state specific, a general discussion of potential legal ramifications would have been appropriate for this report, and helpful for states who will need to consider the issue.

II. Severe Accidents

1" paragraph - The statement that in a large break, loss-of-coolant accident (LB-LOCA) there will be a significant delay before there is a large release of radioactive material into the containment is not accurate. For example, the Surry reactor analysis in NUREG-1150 shows that the core can be uncovered in a LB-LOCA within 5 to 10 minutes. Maybe release to the "environment" rather than into "containment" was intended in this statement.

8th (last) paragraph - We agree that due to uncertainties in predicting the source term in an accident, emergency preparedness must accommodate considerable uncertainty. For this reason, we believe that those responsible for making the preparations for protecting public health need to

avail themselves of all possible options. These options should include the potential use of KI to supplement evacuation and sheltering, unless there are compelling logistical or legal reasons indicating otherwise

III. Health Effects

 2^{nd} and 3^{rd} paragraphs - The footnote on page 5 should be moved to this location as both rad and rem are used here. Also, it would be helpful if the radiogenic risk factor is given in the second paragraph.

3rd paragraph - The word "narcosis" of the skin should be replaced with "necrosis".

III. A. Thyroid and Whole Body Doses

2nd paragraph - In this paragraph, the report makes the argument that adverse health effects from the whole body dose are much more severe than the effects to the thyroid. As an example, the report points out that if the thyroid receives an ablation dose, the whole body dose is likely to be fatal. The report fails to address the less severe situations where the whole body dose is well below the lethal dose and where the primary risk to the exposed population is more likely to be due to the radiation dose to the thyroid.

III. B. Doses

1. Whole Body Doses

1st sentence - The basis for this sentence is not clear. Radionuclides that concentrate in a single organ have always been of concern, as in the case of radium ingestion by dial painters in the 30's; early radiation protection criteria have been based on the critical organ concept; EPA PAGs include values for thyroid doses in addition to whole body dose, and current 10 CFR Part 20

regulations include limits for organ doses in addition to the total effective dose equivalent (TEDE).

Last sentence of 1st paragraph, last paragraph and footnote #3 - ICRP-26 and ICRP- 60 concepts and quantities are different. Using ICRP-60's tissue weighing factors to calculate committed dose equivalent (as defined by ICRP-26) is not appropriate. The report should adopt one system or the other, and should not mix the two.

3rd paragraph - The statement that radiation-related carcinogenesis that has been observed to date is "predominantly attributable to irradiation of the whole body" is not correct. While this is the case in the Japanese bomb survivors, it is not true for the many groups studied following medical or occupational exposures where partial body exposure was more the rule than the exception.

The next sentence, (sentence #4 in the same paragraph) is also not correct. Increased thyroid and breast cancer were observed among children irradiated for treatment of tinea capitis in Israel where the average thyroid and breast doses were 9 rad and 1.6 rad, respectively. It appears that this paragraph intends to address external exposure vs. internal, rather than whole body vs. organ irradiation.

III. B. 2. Thyroid Doses

3rd paragraph - This paragraph gives the impression that there is still doubt as to whether radioiodine causes thyroid cancer. The quotation from NCRP-80 that "I-131 has not been shown to be carcinogenic in people", while correct in 1985 when the NCRP report was written, is not correct today. Quoting it in this report is not appropriate since it does not reflect current knowledge. It should be deleted from the report. Also, this paragraph should state that recent evidence has shown that many thyroid cancers observed among children in Europe following the Chernobyl accident are attributable to radioiodine exposure.

III. D. Thyroid Uptake and Thyroid Dose

5th paragraph - The second sentence mentions the ICRP 30 model, however, this is not included in the references.

III E. Risk As a Function of Thyroid Dose

2nd paragraph - Same comment as made on the third paragraph of section III.B.2. Also, the report should give the value of the risk factor for radiogenic thyroid cancer given by NCRP.

III. F. Medical Aspects of Potassium Iodide

This section liberally sites a long list of possible side effects that can be caused by KI and throws doubt at the NCRP's risk estimate of 5×10^{-7} for adverse health effects from 130 mg per day, the relevant KI dose for this discussion. The fact that US FDA found that the risk from the uptake of radioiodine outweighs the risk of side effects from KI in doses of 130 mg per day for adults and 65 mg per day for children below 1 year of age if the projected thyroid dose is 25 rem or greater, should also have been included.

3rd paragraph - The discussion in this paragraph expresses unwarranted doubt as to the findings of the Nauman and Wolff study of adverse effects from use of KI in Poland. The report also contrasts the NCRP's risk estimate with the 0.2% rate of medically significant adverse reactions reported in Poland. The risk of severe adverse effects observed in Poland, 2 cases in 7 million adults and none in 10.5 million children, is of the same order of magnitude as the NCRP's estimate.

The reference to the 0.2% adverse reactions from KI in Poland is not complete without a
description of what those reactions were. From the descriptions given in reference 17,
most appear to be relatively minor.

When severe reactions are considered, there does not appear to be any basis in the report for the last statement in the paragraph that there were scrious differences in outcome when KI is given to a general population rather than prescribed individually.

4th and 5th paragraphs - The report should clarify if these warnings are based on experience and testing (or lack of testing) with specific groups and with prescription strength or stronger medications. Since other organizations, knowledgeable of the information on these side effects, such as FDA, WHO, American Thyroid Association, IAEA, NCRP and ICRP, have concluded that these side effects are not of sufficient level to prevent the use of KI in emergencies, NRC staff needs to review the rationale behind these organizations' position and present it in the report.

6th paragraph - The wording here would lead the reader to the conclusion that the wide range of adverse health effects reported were likely due to KI but not verified, and that there is some evidence, but not solid, that other unreported effects occurred. If this is the intent, staff needs to support these statements by giving references to their sources.

7th **paragraph** - Identifying groups who are at increased risk of reactions to KI is important. Also as important, is the relationship between these reactions and the administered KI dosage. As these reactions can be reduced at the low radiation protection dosages, it is hard to draw the conclusion from the information presented that this is of "sufficient significance" to prevent the general use of KI for public protection.

IV. Emergency Preparedness

5th paragraph - This paragraph gives some situations in which shelter is the appropriate, or only available, protective measure. The report fails to indicate that KI can be used in these situations to supplement the protection provided by the shelter.

8th paragraph - This lists numerous arguments for why KI should not be considered one of the protective measures used in an emergency. The arguments were listed without any discussion of their validity or examination of their implications to emergency planning. For example, one of the arguments for not using KI is that accidents during storms result in a reduction of the overall radiologic hazard. No data were presented to demonstrate that thyroid doses equal to or greater than 25 rem are not possible in an emergency under such conditions. Also, the argument that distribution of KI during seismic or icy conditions is difficult, appears to argue more for giving the public access to KI tablets prior to the emergency, rather than relying on distributing it after the fact or abandoning the idea of its use.

9th paragraph - This appears to imply that the use of KI is appropriate if done as part of the medical evaluation of exposed individuals and states that it is available to the medical community. These are misleading statements. Medical follow up is not likely to occur until days after exposure, when it is too late for KI to be of use. Also, KI is not generally available in the strengths recommended for radiation protection and is not available where needed for use in a timely manner if it is needed.

V. B. Poland Experience

6th paragraph - A description of the "medically significant" reactions should be given.

VI. C. Comparison Between US and International Practice

The relevance of this section to the discussion is not clear. The argument that the public in the US should be denied possible protection because of potential law suits is not valid and should not be advocated by NRC, an agency charged with protecting the public

VII. Sample Calculations

Table 4: The values of the frequency per year need to be entered in the table. Also, the fraction of noble gas core inventory released in scenarios PSUR-1 and PSUR-4 is indicated to be 10. Should this have read 1?

9th **paragraph** - It is stated that thyroid dose coefficients were taken from ICRP-60. Should the reference have been ICRP-53?

VIII. Insights and Conclusions -

Reactor Accident Frequencies and Protective Actions

1st paragraph - This paragraph argues that because of planning criteria used in the US, there could be numerous evacuations when there are no actual releases from the reactors. This gives the impression that a member of the public will be placed at undue risk numerous times more than necessary. The paragraph fails to give the projected time period over which these "numerous evacuations" will take place. Accepting the annual frequency of 1.7 x 10⁻⁴ given in Section VII for accidents leading to core damage, it is projected that an evacuation may be indicated once every 5900 reactor years. At this frequency, we fail to see the significance of the argument made in the report.

VIII. Benefits and Challenges and International Practices

In this section, as in prior sections, the report reemphasizes the US Pharmacopia Drug Information monograph's statements about situations in which KI is contraindicated. No discussion is given of the data and circumstances leading to these warnings. The report also fails to indicate that the FDA approval of the drug did not exclude its use for pregnant women and children.

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