Peter G. Crane 4809 Drummond Avenue Chevy Chase, MD 20815 301-656-3998 pgcrane@erols.com

August 20, 1998

MEMORANDUM FOR: John C. Hoyle, Secretary, USNRC

FROM: Peter Crane *Peter Crane*

SUBJECT: SUPPLEMENTAL COMMENTS ON NRC STAFF TECHNICAL ASSESSMENT OF POTASSIUM IODIDE (DRAFT NUREG-1633)

I. **Introduction**

The NRC staff has published for comment the draft of NUREG-1633, which purports to be a technical assessment of potassium iodide. (The comment period expires September 15, 1998.) In announcing the availability of this document in the July 20, 1998, Federal Register, the staff omitted to mention that the Commission had granted my petition for rulemaking on KI a few weeks earlier. Can the actions of the Commission be of so little import to the NRC staff -- more precisely, to certain elements within the NRC staff -- that they can be ignored or disregarded altogether?[1]

I sincerely regret the need to submit these supplementary comments on NUREG-1633.[2] I am sure that the Commissioners are tired of reading my submissions on KI, but they cannot be half as tired of reading them as I am of having to write them. I had hoped that the KI issue was behind me. I had also hoped, for the NRC's sake, that the contention over KI was largely behind the agency (notwithstanding that a rulemaking would still have to be conducted), and that it would cease to be a distraction from the agency's other pressing responsibilities. It is high time that the NRC moved on to other matters. If all the money that the agency has spent studying and debating the KI issue during this period, including the salaries of all the people in different parts of the organization who have had to devote time to it, had been applied instead to buying KI, this country would probably have an abundance of KI for many years to come.

Nevertheless, I am submitting these comments, principally because, on closer review, I believe that NUREG-1633 has the potential to cause actual harm to the public in the event of an accident, through its discussion of tincture of iodine, as I shall explain below. At the same time, I will also offer some comments on other aspects of the document. As will be seen, my criticisms of NUREG-1633 focus on

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[1] I have already pointed out one remarkable omission from NUREG-1633 in a letter to the docket, dated August 5, 1998, that attached my recent talk on KI in Cambridge, England. The Food and Drug Administration's 1978 approval of KI as "safe and effective" goes unmentioned, as though it never happened, though this should be the starting point of any evaluation of KI's safety by a federal agency. (In other staff documents on KI, we have seen the omission of such other key events as the Kemeny Commission's recommendation in favor of KI stockpiling; the Chernobyl accident and the use of KI by the Poles; the upsurge of thyroid cancer in the former Soviet Union; and so on.) Contrary to the impression that readers of the August 17 issue of *Inside NRC* may have formed, my criticism was not that the NUREG failed to "explicitly acknowledge" the FDA position, it was that the NUREG contained not the slightest hint, explicit or implicit, that the FDA had made a finding on the safety and effectiveness of KI.

[2] As always, these are submitted in my private capacity, and are written at home on my own time.

the way that it represents the facts. You cannot expect a productive public debate on the merits of a policy issue if the public is denied the accurate and complete factual information that is necessary for an informed decision.

I would like to make clear to readers of what follows that I do not regard NUREG-1633 as representative of the NRC as a whole or of its most senior management. If NUREG-1633 were typical of the NRC's overall approach to factual issues relating to public health and safety, there would be reason for the gravest concern, but there is no reason to think that is the case. On the contrary, I believe that NUREG-1633, and the handling of the KI issue by the NRC staff, at levels below that of the staff's most senior management, are an aberration. (To be sure, the NRC's most senior managers bear some responsibility for the fact that the deficiencies in their subordinates' product were not noticed and corrected before NUREG-1633 was allowed to see the light of day, but that is a separate issue.) At the most senior level, the NRC staff is led, I believe, by people of integrity and good will, who do not and would not misrepresent or withhold facts that affect the health and safety of the American people, nor disregard the decisions of the Commission that they work for.

II. **Tincture of Iodine**

Drs. Janusz Nauman and Jan Wolff, in their May 1993 article in the American Journal of Medicine ("Iodine Prophylaxis in Poland After the Chernobyl Reactor Accident: Benefits and Risks", Vol. 94, p. 524), reported that "a surprising 6.14% [of Polish children] were given diluted tincture of iodine by their parents before the start of the [KI] program and then took a single dose of KI," adding, "This was confirmed by the brisk increase in sales of tincture of iodine in pharmacies." (At p. 528.) In their discussion of side effects, they report that "those children receiving diluted tincture of iodine had about twice the incidence of vomiting as the remainder of the group." (At p. 530.)

Dr. Nauman, at the Cambridge symposium, made the point that the fact that parents were willing to administer tincture of iodine to their children from bottles clearly labeled as containing poison suggested that people will not always behave rationally in a radiological accident, and that planners need to take that into account. In a private conversation with me, he said, "We said to these people, 'How could you do this, when it says 'POISON' on the bottle?", and they would say, 'Well, we thought it was a matter of life and death.'"

One moral to be drawn from this is that if you do not have KI available in an accident, some people will medicate their children and themselves with what is at hand, i.e., tincture of iodine.

NUREG-1633, in an apparent effort to discount the value of the Poles' use of KI, has this to say at p. 18: "In addition, about 6 percent of the prophylaxis resulted from self-administered tincture of iodine before the KI program was initiated." At page 37, in the "Glossary" section, it says this of "iodine tincture": "Disinfectant and germicide; 50 percent alcohol, 2 percent iodine, about 45 percent water; 3 drops in a quart of water kills amebas and bacteria in 30 minutes; ***a 4 oz. bottle contains enough iodine to block 22 thyroids.***" [Emphasis added.] There is not the slightest suggestion that there is anything inadvisable about giving tincture of iodine in lieu of KI in an emergency; on the contrary, one reasonable reading of these two passages is that KI stockpiling is unnecessary, because in a pinch, tincture of iodine can be used instead.

I recently telephoned the Georgetown University Hospital Poison Control Center and spoke to Ms. Jane Elshami. She told me that tincture of iodine, if taken by mouth, is rarely fatal. It is more likely to have caustic effects than systemic. The usual scenario for iodine tincture poisoning, she said, is an accidental pediatric ingestion, resulting in corrosive gastroenteritis, followed by vomiting. There can be

cardiac effects and renal toxicity. There is data, she said, on how much is a fatal dose. For adults, the probable mean lethal dose is 2-4 grams of free iodine or 1-2 ounces of a strong tincture. Reported lethal doses vary from a few tenths of a gram to more than 20 grams. She suggested that I could speak to one of their toxicologists if I wanted more detailed information, but it seemed to me that her information was sufficient for present purposes.

If ever there were a serious nuclear accident — unlikely as that is — and a state or local health official, in the excitement of the moment, were to come upon NUREG-1633 and decide, because of the absence of stockpiled KI, to advise parents to give their children tincture of iodine, the NRC would have much to answer for. I do not believe that the agency should take the chance of allowing the document to remain in circulation.

I plan to suggest to the Georgetown University Poison Control Center that it submit its comments on the draft, assuming that it has not already been withdrawn. Maybe if the staff hears directly from the toxicologists, it will pay attention.

III. **The Physician's Desk Reference and the Safety of KI**

With my concerns raised by the iodine tincture issue, it occurred to me to question some of the other factual representations in the document. At page 11, NUREG-1633 says:

> The staff's review of the *Physician's Desk Reference* (45th Edition, published by E.R. Barnhart, 1991) suggested that the safety of KI is far from absolute, especially if the drug is taken without medical supervision. The various reports concerning the medications containing KI are as diverse as the companies that produce the medications; however, these reports ***consistently state that the products are contraindicated for various groups of people (principally pregnant women; nursing mothers***; and people with hyperthyroidism, enlarged thyroids, or sensitivity to iodine."
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> In addition to the ***consistent contraindications***, the reports include a variety of other warnings:
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> - "Potassium iodide can cause fetal harm, abnormal thyroid function and goiter when administered to a pregnant woman. Because of the possible development of fetal goiter, if the drug is used during pregnancy or if the patient becomes pregnant during therapy, apprise the patient of the potential hazard." ....
>
> [Emphasis added.]

I recently consulted the 1997 Physician's Desk Reference and copied the only listing I found for potassium iodide tablets: Thyro-Block, manufactured by Carter-Wallace.[3] The section entitled "Who Should Not Take Potassium Iodide" reads as follows, in its entirety:

> The only people who should not take potassium iodide are people who know they are allergic to iodide. You may take potassium iodide even if you are taking medicines for a thyroid problem (for example, a thyroid hormone or antithyroid drug). ***Pregnant and***

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[3] A copy of this listing, which says that it was last revised in May 1994, is attached.

nursing women and babies and children may also take this drug. [Emphasis added.]

Later on in NUREG-1633, the NRC staff acknowledges (in a commendably full statement of the WHO position) that the World Health Organization and international practice call for administering KI to children and pregnant women in emergencies, but it reiterates the claim that U.S. sources recommend the opposite. The very last paragraph of the document, at p. 28, reads as follows:

> ***International Practices***
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> - Other countries and major international organizations, including the IAEA and WHO, endorse the use of KI. The international policies, in some cases, are significantly different from the U.S. policies. The principal example is the recommendation by the WHO to administer KI to pregnant women and children, ***whereas U.S. references specifically warn against administering KI to that same group.*** Cultural and legal differences between the U.S. and other countries may be the basis for differing perspectives on general drug use. [Emphasis added.]

I have not researched everything that may have been said about KI in every edition of the Physician's Desk Reference, but the quoted excerpt should suffice to refute the proposition that U.S. sources "consistently" advise against giving KI to children and pregnant women.

IV. **Miscellaneous Other Comments**

The following comments I will make only very briefly. Many of them deal with points that I have made at length, often repeatedly, in earlier submissions, and that have been repeatedly been ignored by the NRC staff. I am making them not because I think that at this late date, the same staff members who are responsible for the draft of NUREG-1633 will start responding to them, but for the Commissioners, NRC staff management at the highest levels, the public, and the record.

A. **When must KI be given to be beneficial?** [p. 2]

According to p. 2 of NUREG-1633, "the potential benefits can be realized *only* if the compound is administered just before the inhalation of ingestion of radioiodines." [Emphasis added.]

Let us compare this with what the Food and Drug Administration said in its final recommendations on KI, published in the Federal Register on June 29, 1982 (47 FR 28158):

> FDA concludes in the final recommendations that risks from the short-term use of potassium iodide for thyroid 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. FDA recommends that potassium iodide in doses of 130 milligrams (mg) be considered for thyroid blocking in radiation emergencies in those persons who are likely to receive a projected radiation dose of 25 rem or greater to the thyroid gland from radioiodines released into the environment. To have the greatest effect in decreasing the accumulation of radioiodine in the thyroid gland, these doses of potassium iodide should be administered immediately before or after exposure. If a person is exposed to

radioiodine when circumstances do not permit the immediate administration of potassium iodide, *the initial administration will still have substantial benefit even if it is taken 3 or 4 hours after acute exposure.* [Emphasis added.][4]

Readers can decide for themselves whom they believe: the federal agency with the responsibility for making judgments on the safety and effectiveness or drugs, or the authors of NUREG-1633, who for some reason did not think it appropriate to inform them that the FDA had spoken to the KI issue.

B. **How widespread is the use of KI internationally?** [pp. ix, 19-20]

The NUREG says that "to complete the picture," it includes advice as to the KI policies of the United Kingdom, Sweden, Switzerland, Finland, France, the WHO, and the IAEA. (In fact, it also deals with Germany.) The casual reader might understand this to be a complete list of the countries that stockpile KI, since there is no reference to the fact that many other countries also maintain supplies of the drug. Reference should therefore be made to Norway, Austria, the Czech Republic, Slovakia, Poland, Japan, Russia, Belarus, Ukraine, Armenia, Canada, etc. The reader should be made aware that U.S. policy is the exception rather than the rule.

I would draw particular attention to the case of Canada. (As long ago as April 1994, in a letter to the Commission that was brushed aside at the time, Senators Joseph Lieberman and Alan Simpson pointed out that Canadian provinces with nuclear power plants are among the governmental authorities that stockpile KI.) In view of all the staff's efforts in the NUREG to explain away the use of KI in other countries by pointing to the cultural, legal, and dietary differences between Europe and America, perhaps the staff should address what the differences are between, say, Ontario and Connecticut.

C. **What is the discussion of "ablation" about?** [p. ix]

The NUREG suggests that the "reduction in the risk of thyroid cancer obviously does not apply if the thyroid is ablated (dose greater than about 25,000 rads)." This is an argument that surfaced back in the 1980's: that if the thyroid dose is high enough, the thyroid is ablated (burned out), and thus all the risk of cancer disappears. The NUREG should make clear that even if you were to get an ablating thyroid dose without simultaneously getting enough whole-body dose to kill you, the consequences of being deprived of a functioning thyroid are not insignificant. For this and other medical questions, I suggest that the NRC staff should consult professional thyroidologists. When we have a Public Health Service whose expertise is presumably available to a federal agency, and NIH (which has been studying thyroid cancer for decades) is literally just down the street from NRC, why not call on their expertise?

D. **Evacuation vs. sheltering** [pp. ix, 1]

I have on numerous occasions cited the EPA "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents," EPA 400-R-92-001 (May 1992) for its discussion of sheltering, thyroid dose, etc. It is, I think, a thoughtful and balanced discussion of the pros and cons of evacuation and sheltering. (Rather than characterize what the EPA Manual says, I will attach the relevant pages.) I have tried to persuade the NRC staff to respond to what the Manual has to say; so far it hasn't.

Even if the NRC staff does not like what it says, the EPA Manual should be listed among the

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[4] A copy of the FDA Federal Register Notice is attached.

references. It isn't. As with the FDA "safe and effective" notice, the NRC staff has chosen to ignore what a sister agency has had to say on the very issue now under discussion.

Just to make my position crystal clear, the question as I see it is not whether KI is better than evacuation — it isn't, if complete evacuation is feasible -- but rather, given that emergencies often develop unpredictably, whether you want your emergency authorities to have three arrows in their quiver or only two. I feel strongly that it is better to have three, for greater flexibility in dealing with whatever may arise. If the third arrow were extremely expensive, it might be a harder question, but this one is so cheap that the issue is, or should be, a no-brainer.

E. **How easy is evacuation?** [p. i, 1-2]

The NUREG advises that "evacuation is relatively commonplace" in the U.S., since "people *largely* have their own means of transportation, travel routes are *generally* well suited to the movement of large numbers of people, and people have places to go." [Emphasis added]. The staff contrasts this with administration of a medicine to the general public, which "has no precedence [*sic*] in the United States."

I do not think that this kind of generalization, seemingly plucked out of the air, is a substitute for addressing issues. What does it mean that people "largely" have their own means of transportation? What does it mean that travel routes are "generally" well suited to moving large numbers of people? It would be considerably more useful if the staff addressed actual conditions in the vicinity of U.S. nuclear power plants, rather than offering Pollyannaish observations on the general state of life in the U.S.

F. **Carcinogenicity of I-131** (pp. 7, 9)

The authors of NUREG-1633 twice quote the following 1985 (*i.e.*, pre-Chernobyl) statement in NCRP-80: "Because I-131 has not been shown to be carcinogenic in people, a comparison of the thyroid cancer risk from I-131 with that from x-ray exposure is difficult." (The first time they quote it, they note, however, that the Chernobyl studies "indicate that internal and external dose may be equally effective in producing thyroid cancer.")

The world's leading expert on the long-term effect of I-131 used in medical treatment is Dr. L.E. Holm of Sweden. As he has reported in journal articles, and as he described at the recent conference in England, he has not found any increase in thyroid cancer in persons who received I-131 treatments in a medical setting. In the question period that followed his talk, I asked the following question: "In the United States, iodine prophylaxis with potassium iodide is a contentious issue, and some people are citing your work for the proposition that I-131 is not carcinogenic and that there is therefore no point in stockpiling KI. Would you care to comment?" His response was that his study did not establish whether or not I-131 was carcinogenic, but dealt only with this type of medical exposure to I-131. He added that he himself favored stockpiling of KI.

The crucial fact here is the one that the staff alludes to in the footnote: that in light of the disease appearing since Chernobyl, few experts now doubt the capacity of I-131 to cause cancer, especially in children aged 0-4 at the time of exposure.

G. **"Tendency of papillary cancer to recur in a more aplastic form some 10-20 years later."** [p. 9]

If the same thyroid cancers whose gravity the authors of NUREG-1633 are downplaying, because they "respond favorably to early treatment" [p. 17], tend to "recur in a more aplastic form some 10-20 years later," this puts radiation-caused papillary carcinoma in a new and more ominous light. Again, this is a question for medical experts, and NIH is down the street.

H. **Just two or three deaths**? [p. 17]

The reader could get the impression from this that the radiation-caused thyroid disease in the former Soviet Union is not all that significant. Sadly, that is not the case. Fatality figures alone give a very partial measure of the real significance. You need also to address such issues as the following: How many of the patients are likely to die of the disease at some point in the future? What is the quality of life like for those who have the disease but do not die of it? What is the frequency of metastasis? (At the Cambridge conference, a team from the Thyroid Cancer Center in Minsk, Belarus, reported metastases in more than 70% of cases, with distant metastases (*i.e.*, more extensive) in 14.7% of the patients.) What kinds of treatment are required? What are the health effects and quality of life impacts of those treatments?

If all you are willing to talk about is fatalities, you are giving an incomplete picture of the real significance of the disease, and thereby misleading the reader. One of these years, the NRC must finally begin to address, in a meaningful way, what non-fatal thyroid cancer entails, because this is an essential part of the factual basis for deciding whether it is sensible policy to have KI. Since 1989, I have been trying to explain to the staff that there is more to disease than whether you die of it, and that as a society, we regularly protect our children not only against diseases that are commonly fatal, but also against illnesses that normally are non-fatal, because we are concerned not just with saving life but also with preventing needless suffering. The staff has yet to address that point.

But fatalities are what NUREG-1633 wants to focus on. It says, at p. 9, of the risk of radiogenic thyroid cancer: "Even with external sources, however, the risk is difficult to assess for several reasons. *First, the less-reliable incidence data must be used because thyroid cancer is only infrequently fatal.*" [Emphasis added.] From a scientific agency, this is truly an extraordinary statement. The authors of NUREG-1633 are telling us that the data on radiogenic thyroid cancer is more reliable if it ends in a fatality than if it doesn't. How can such a claim be made with a straight face?

The crux of the policy question is not how many people will ultimately have "thyroid cancer" on their death certificates if there is an accident or act of terrorism and no KI is available, but whether it is worth seven cents to protect American children, especially those four years old and younger, from a disagreeable disease that will mean suffering for all of them and death for a few.[5] I'm sure I'll be accused of emotionalism for saying this, but I've shared a lot of hospital waiting rooms with children who have various types of cancer, and with their parents. I also once had a long telephone conversation with a distraught woman who called me and described the four-year battle of her daughter, then in her early teens, with thyroid cancer: initial surgery, radiation treatment, further surgery to clean out the cancerous lymph nodes from the length of her torso, followed by further radiation treatments. (This young woman will probably survive, but that doesn't mean that she and her mother have not suffered terribly already.) These experiences have helped inform my understanding of what cancer entails for young patients and

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[5] Perhaps the difference in viewpoint was summed up best by an exchange that took place in October, 1997, at the meeting in Painesville, Ohio. I made the point that the cancers in the Belarussian children have tended to be aggressive, with spread to the lymph nodes that leaves the children with surgical scars going from ear to ear. The NRC representative observed that this was in part a result of the limitations of surgical expertise in Belarus, and that in the U.S., the scars would be smaller. But the real issue is not whether American children will have long scars or short scars on their necks, it is whether at minimal cost we can take a step that will help ensure that they need have *no* scars.

their families.[6] The American Thyroid Association's support of KI stockpiling also has a lot to do with the fact that its members are thyroidologists: they see the patients and their families, and they know what thyroid cancer involves. I can't help thinking that if the staff members responsible for NUREG-1633 had had similar experiences, they might be less impressed with the low fatality rates for childhood thyroid cancer and more inclined to agree with the Europeans, Canadians, Japanese, WHO, American Thyroid Association, Senator Lieberman, Senator Harkin, former Senator Simpson, and me that childhood thyroid cancer is a disease well worth preventing.

I. **Seismic events?** [p. 13]

The NUREG says of evacuations, "In addition, seismic events or traffic accidents could block some evacuation routes." Years ago, when intervenors in a California reactor licensing case tried to raise the issue of the complicating effects of earthquakes on emergency planning, the NRC dismissed this possibility, and was upheld in court. This NUREG may prove to be a boon to would-be filers of 2.206 petitions.

J. **"U.S. officials conducted a study"** [p. 21]

The NUREG discusses the TMI accident but fails to mention the President's Commission on the Accident at Three Mile Island (Kemeny Commission) and its recommendation in favor of KI stockpiling — a recommendation that the NRC initially endorsed enthusiastically. However, the NUREG does mention that after Chernobyl, "U.S. officials conducted a study" that determined that no changes in emergency planning were necessary. There is no citation to that study. In fact, it was a staff paper prepared by the NRC staff. (This is a matter of public record, because I criticized that staff paper in my Differing Professional Opinion, which is now a public document.) Here again we see the authors of the NUREG picking and choosing their data, inflating the significance of an ordinary NRC staff paper until it sounds like an authoritative U.S. Government position, while silently tiptoeing around the extensive, detailed, authoritative report of the Presidential Commission.

K. **Fast Food** [p. 8]

NUREG-1633 makes the point that Americans' thyroids are already partially blocked because of the high intake of iodine in the typical American diet. It says: "In recent decades, stable iodine has also become an important additive to bread and fast foods (especially hamburgers)."

In fact, most Americans *do* have a high intake of iodine, certainly as compared with the iodine-poor areas of Eastern Europe. The higher the individual's dietary intake of iodine, the less critical is the need for administration of KI in an emergency. So far, so good. Where I disagree with the authors of the NUREG is their apparent assumption that because millions of Americans have partially blocked thyroids, we can afford to ignore those who don't. Not everyone eats mass-produced bread or fast-food hamburgers.

L. **National Stockpiles** [p. 28]

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[6] I also saw many thyroid cancer patients professionally when I was an administrative judge on the Nuclear Claims Tribunal in the Republic of the Marshall Islands. Many of them had had their lives blighted by radiation-caused thyroid disease.

NUREG-1633 says: "National stockpiles of KI have been recommended along with chemical antidotes, serin vaccines and antibiotics for response to nuclear, biological, and chemical weapons. As an added assurance, these stockpiles are available to State officials, should there be a need for KI on an ad-hoc basis."

The reader should be informed that these stockpiles are supposed to amount to at most 4,000 pills in at most 27 sites. This minuscule amount is not enough to be of significant value to the general public in the event of a nuclear power plant accident or act of terrorism. Moreover, at the November 5, 1997, meeting at the NRC, FEMA officials said that no plans had been made for transferring KI from these stockpiles to the vicinity of nuclear power plants in an emergency.

M. **Legal Aspects** (p. 2)

NUREG-1633 says that it "does not address the ... legal factors associated with the use (or non-use) of KI," but then proceeds to do just that. It informs us, at p. 22, that "[t]he tort system in the U.S. is also quite unique," that in the U.S., "the implementation of a protective action may entail litigation and liability for long after the accident," and that "administration of KI on a mass basis would certainly entail litigation in this country...." It would be helpful to know whether these legal judgments represent the considered view of the NRC's Office of the General Counsel or of the authors of NUREG-1633. If the latter view themselves as better qualified than the FDA to judge drug safety, perhaps they also see themselves as better qualified than the NRC's lawyers to offer legal advice.

V. **Conclusion**

NUREG-1633, as I suggested in my comments filed on August 5, 1998, is a seriously defective document. It is, I submit, an advocacy piece, seemingly written to justify a particular policy position (one that the Commission has since rejected), rather than what was needed, which was a dispassionate analysis of the facts relating to KI. In its discussion of tincture of iodine, NUREG-1633 has sufficient potential to result in harm to the public that the printed copies of the document should be recalled and sent to the recycler. (Electronic versions should be taken off the NRC's website.) But the discussion of iodine tincture is just one of many, many problems with the document.

What the authors of NUREG-1633 may not understand is that a document as slanted as this one — if they recognize it to be slanted, which they may well not — is a reflection not only on them but also on the entire NRC and all the work that the agency does. It is far easier for individuals and organizations to lose their credibility than to regain it once it is lost. Persons intimately familiar with the NRC's work may have (and rightly so) high confidence that the agency would not suppress or manipulate safety data to keep an unsafe plant running; but what is the public at large to think, when it reads a document like this one? One can imagine members of the public asking themselves, "Why should we trust the NRC staff's evaluation of the safety of Millstone if we can't trust its evaluation of KI?" NUREG-1633 is a bad apple, and it should be removed from the barrel quickly.

The next question is whether the document should be rewritten or held in abeyance for now. I believe that the defects in NUREG-1633 are too pervasive to be patched up with an edit here and an edit there. I respectfully suggest to the Commission that the best course of action would be for the staff to proceed expeditiously with the rulemaking that the Commission has directed, and not be distracted from that effort by having simultaneously to try to make a silk purse out of the sow's ear that is NUREG-1633. When the rulemaking is complete, then and only then the staff should prepare a document that explains the basis of the final rule (in whatever form that final rule may take) and provides clear, honest, balanced,

understandable, concise, and user-friendly guidance to help state and local authorities make informed choices regarding KI. Such a document does not need to be anywhere near 40 pages long, as is NUREG-1633. On the contrary, so long as the information in it is sound, a much shorter document would probably be far more helpful to state and local officials, because they are much more likely to read it through. (For the same reason, it is also more likely to get careful review within the NRC.)

In sum, I recommend that NUREG-1633 be shelved. If the information that was developed for it can be useful sometime in the future, when a new guidance document is prepared, well and good; if not, the whole episode nevertheless should have value to the NRC as a learning experience.

Attachments:
1. FDA Federal Register Notice (June 29, 1982)
2. Excerpt from 1997 Physician's Desk Reference
3. Excerpt from EPA Manual of Protective Action Guides and Protective Actions for Nuclear Incidents

cc:
Chairman Jackson
Commissioner Diaz
Commissioner McGaffigan
Senator Joseph Lieberman
Senator Tom Harkin
Georgetown University Poison Control Center
L. Joseph Callan, EDO
Hugh Thompson, Deputy EDO
Karen D. Cyr, General Counsel

18. ANDA 86-925: Isosorbide Dinitrate (sublingual) Tablets containing 10 mg of the drug per tablet; Par.

19. ANDA 86-944: Dipyridamole Tablets containing 25 mg of the drug per tablet; Cord Laboratories, Inc., 2555 West Midway Blvd., Broomfield, CO 80020.

20. ANDA 86-981: Dipyridamole Tablets containing 25 mg of the drug per tablet; Bolar.

21. ANDA 87-006: Dipyridamole Tablets containing 25 mg of the drug per tablet; Zenith.

22. ANDA 87-039: Dipyridamole Tablets containing 25 mg of the drug per tablet; Chelsea.

23. ANDA 87-094: Dipyridamole Tablets containing 25 mg of the drug per tablet; Par.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-1053, as amended (21 U.S.C. 355)), and under authority delegated to the Director of the National Center for Drugs and Biologics (see 21 CFR 5.82 and 47 FR 28913 published in the Federal Register of June 22, 1982).

Dated: June 23, 1982.

Harry M. Meyer, Jr.,

Director, Bureau of Drugs and Biologics.

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BILLING CODE 4110-01-M

[Docket No. 81N-0087]

Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency; Final Recommendations On Use

AGENCY: Food and Drug Administration.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) announces the availability of final recommendations about administering potassium iodide to the general public in a radiation emergency. The final recommendations prepared by FDA's Bureau of Radiological Health and the Bureau of Drugs are being made available to assist State and local authorities in developing emergency-response plans for preventing adverse effects from exposure to radiation in the event that radioactivity is accidentally released into the environment.

ADDRESS: The final recommendations are on display in, and comments may be submitted to, the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and copies may be obtained from Bernard Shleien at the address below.

FOR FURTHER INFORMATION CONTACT: Bernard Shleien, Bureau of Radiological Health (HFX-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6220 or Edwin V. Dutra, Jr., Bureau of Drugs (HFD-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6490.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 22, 1980 (45 FR 69904), the Federal Emergency Management Agency (FEMA) outlined the responsibilities of several Federal agencies concerning emergency-response planning guidance that the agencies should provide to State and local authorities. The October 22, 1980 notice updated an earlier notice on the subject that the General Services Administration (GSA) published in the Federal Register of December 24, 1975 (40 FR 59494). (GSA responsibility for emergency management was transferred to FEMA by Executive Order 12148.)

The Department of Health and Human Services' (HHS) responsibilities for emergency-response planning include assisting State and local authorities in developing plans for preventing adverse effects from exposure to radiation in the event that radioactivity is released into the environment. These plans include the prophylactic use of drugs that would reduce the radiation dose to specific organs from the sudden release into the environment of large quantities of radioactivity that might include several radioactive isotopes of iodine.

As one step toward meeting the Department's responsibilities, FDA issued a notice in the Federal Register of December 15, 1978 (43 FR 58798) announcing its conclusion that potassium iodide is safe and effective for use as a thyroid-blocking agent in a radiation emergency under certain specified conditions of use. The notice also announced, however, that potassium iodide has not been used to such an extent or for such a period of time under radiation emergency conditions to permit the conclusion that the drug may be marketed without an approved new drug application (NDA). Thus, in the interest of public safety, the notice encouraged interested persons to submit to the agency NDA's for potassium iodide in oral dosage forms for use as a thyroid-blocking agent. In the issue for February 22, 1980 (45 FR 11912), FDA announced that potassium iodide as a thyroid-blocking agent is available commercially in both tablet and solution form. (Since that time, FDA has approved an additional NDA for potassium iodide in solution form for use as a thyroid-blocking agent.)

In the Federal Register of June 5, 1981 (46 FR 30199), FDA issued a notice announcing the availability of draft recommendations about administering potassium iodide to the general public in a radiation emergency. The draft recommendations were made available for public comment to provide FDA with views to be considered as it developed its final recommendations on this use of potassium iodide. The comment period closed on October 5, 1981 (see the Federal Register of September 18, 1981; 46 FR 46402).

FDA received comments from individual citizens, professional and consumer advocate groups, State and local health agencies, and other Federal agencies. The issues they raised are discussed in the "Background" section of the final recommendations.

One purpose of FDA's final recommendations is to facilitate a national consensus on the use of potassium iodide during a radiation emergency. Another is to provide information and guidance to Sate and local public health agencies and other persons responsible for formulating emergency-response plans for radiation accidents.

Uncertainties still exist about the dose-response for radioiodine-induced thyroid cancers and the incidence and severity of side effects from potassium iodide. These uncertainties, which are discussed in the final recommendations, are unlikely to be resolved soon.

Based on its consideration of comments received and its analysis of available information, FDA concludes in the final recommendations that risks from the short-term use of relatively low doses of potassium iodide for thyroid 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. FDA recommends that potassium iodide in doses of 130 milligrams (mg) per day for adults and children above 1 year and 65 mg per day for children below 1 year of age be considered for thyroid blocking in radiation emergencies in those persons who are likely to receive a projected radiation dose of 25 rem or greater to the thyroid gland from radioiodines released into the environment. To have the greatest effect in decreasing the accumulation of radioiodine in the thyroid gland, these doses of potassium iodide should be administered immediately before or after exposure. If a person is exposed to radioiodine when circumstances do not permit the immediate administration of potassium iodide, the initial administration will still have substantial benefit even if it is taken 3 or 4 hours after acute exposure.

Taken together, the comments received during the public comment period and the actions of national and foreign radiation protection groups make these recommendations prudent because, although slightly above the range presented in draft recommendations (10 to 20 rem), a 25-rem projected dose to the thyroid is equal numerically to the Environmental Protection Agency's (EPA) upper Protective Action Guidance level for the general public and the United Kingdom's National Radiation Protection Board's upper level proposed for potassium iodide use. (EPA Protective Action Guides call for sheltering, evacuation, and controlled access as protective actions when the total accumulated thyroid doses are projected at 5 to 25 rem for the general population. The EPA guides do not specifically note the use of potassium iodide as a protective action for the general population.) These agencies would expect some protective action to be taken at 25 rem projected dose to the thyroid. Use of a single recommended value also eliminates questioned by State and local public health agencies about whether to use the upper or the lower part of a range of values.

FDA further recommends that officials responsible for radiation emergency response planning include in the emergency response planning a system of public information on the use of potassium iodide and a system of medical contact, reporting, and assistance.

Each State is responsible for formulating guidance on when, if at all, the public should be supplied with potassium iodide along with instructions on how to use it. In preparing guidance and making rules, State and local agencies should inform citizens of the nature of the radiation hazard and of the potential benefits and adverse effects of potassium iodide.

These final recommendations on potassium iodide use must be seen in the context of radiation emergency planning as a whole. The use of potassium iodide in the radiation emergency is not a panacea. It does not reduce the uptake by the body of other radioactive materials or provide protection against external radiation. The cost and effectiveness of other protective measures such as seeking shelter, evacuation, or respiratory protection also need to be considered.

Although FDA received written comments on the draft recommendations and considered them in formulation of these final recommendations, under 21 CFR 10.90 interested persons may submit further written comments on these final recommendations to the Dockets Management Branch (address above).

Dated: June 22, 1982.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

[FR Doc. 82-17688 Filed 6-28-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 82F-0181]

Union Carbide Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Union Carbide Corp. has filed a petition proposing that the food additive regulations be amended to provide for specification changes in polysulfone resins as articles or components of articles intended for repeated use in contact with food.

FOR FURTHER INFORMATION CONTACT: Julia L. Ho, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2B3629) has been filed by Union Carbide Corp., River Road, Bound Brook, NJ 08805, proposing that Part 177 (21 CFR Part 177) of the food additive regulations be amended to provide for a change in the molecular weight specifications and testing requirements for polysulfone resins as articles or components of articles intended for repeated use in contact with food.

The agency has carefully considered the potential environmental effects of this proposed action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 18, 1982.

Sanford A. Miller,

Director, Bureau of Foods.

[FR Doc. 82-17671 Filed 6-28-82; 8:45 am]

BILLING CODE 4160-01-M

National Institutes of Health

Cancer Center Support Review Committee; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Cancer Center Support Review Committee, National Cancer Institute, July 15-16, 1982, Building 31C, Conference Room 6, National Institutes of Health, Bethesda, Maryland 20205. This meeting will be open to the public on July 15 from 8:30 a.m. to 10:00 a.m. to review administrative details, and to present reports by the Division Director and the Branch Chief. Attendance by the public will be limited to space available.

In accordance with provisions set forth in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on July 15, from 10:00 a.m. to adjournment, and on July 16, from 8:30 a.m. to adjournment, for the review, discussion and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentale material and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mrs. Winifred Lumsden, the Committee Management Officer, National Cancer Institute, Building 31, Room 10A06, National Institutes of Health, Bethesda, Maryland 20205 (301/496-5708) will provide summaries of the meeting and rosters of committee members, upon request.

Dr. Robert L. Manning, Executive Secretary, Cancer Center Support Review Committee, National Cancer Institute, Westwood Building, Room 803, National Institutes of Health, Bethesda, Maryland 20205 (301/496-7721) will furnish substantive program information.

Dated: June 17, 1982.

Betty J. Beveridge,

Committee Management Officer, National Institutes of Health.

(Catalog of Federal Domestic Assistance Number 13.397, project grants in cancer center support, National Institutes of Health)

(NIH programs are not covered by OMB Circular A-95 because they fit the description of "programs not considered appropriate" in section 8(b) (4) and (5) of the Circular)

[FR Doc. 82-17664 Filed 6-28-82; 8:45 am]

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ISBN: 1-56363-201-2

Wallace Laboratories—Cont.

Possible side effects include skin rashes, swelling of the salivary glands, and "iodism" (metallic taste, burning mouth and throat, sore teeth and gums, symptoms of a head cold, and sometimes stomach upset and diarrhea).
A few people have an allergic reaction with more serious symptoms. These could be fever and joint pains, or swelling of parts of the face and body and at times severe shortness of breath requiring immediate medical attention.
Taking iodide may rarely cause o-eractivity of the thyroid gland, underactivity of the thyroid gland, or enlargement of the thyroid gland (goiter).

WHAT TO DO IF SIDE EFFECTS OCCUR
If the side effects are severe or if you have an allergic reaction, stop taking potassium iodide. Then, if possible, call a doctor or public health authority for instructions.

HOW SUPPLIED
THYRO-BLOCK® Tablets (Potassium Iodide Tablets, USP) are white, round tablets, one side scored, other side debossed 472 WALLACE, each containing 130 mg potassium iodide. Available in bottles of 14 tablets (NDC 0037-0472-20).

WALLACE LABORATORIES
Division of
CARTER-WALLACE, INC.
Cranbury, New Jersey 08512
IN-0472-03 Rev. 5/94

TUSSI-ORGANIDIN® DM NR*
(*Newly Reformulated) Liquid

TUSSI-ORGAN-DIN® DM-S† NR*
(*Newly Reformulated) Liquid
(guaifenesin, dextromethorphan hydrobromide)

Professional Labeling Information and Directions for Use
This product labeled for sale on prescription only.

DESCRIPTION
TUSSI-ORGANIDIN® DM NR* (*Newly Reformulated) Liquid is a clear yellow liquid with a raspberry flavor.
Each 5 mL (1 teaspoon) contains:

Guaifenesin, USP	100 mg
Dextromethorphan Hydrobromide, USP	10 mg

Other ingredients: Citric acid, D&C Yellow No. 10, FD&C Red No. 40, flavor (artificial), glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol.
Guaifenesin (glyceryl guaiacolate) has the chemical name 3-(2-methoxyphenoxy)-1,2-propanediol. Its molecular formula is $C_{10}H_{14}O_4$, with a molecular weight of 198.21. It is a white, colorless crystalline substance with a slightly bitter aromatic taste. One gram dissolves in 20 mL water at 25°C, freely soluble in ethanol. Guaifenesin is readily absorbed from the GI tract and is rapidly metabolized and excreted in the urine. Guaifenesin has a plasma half-life of one hour. The major urinary metabolite is beta-(2-methoxyphenoxy) lactic acid.

CLINICAL PHARMACOLOGY
TUSSI-ORGANIDIN® DM NR* (*Newly Reformulated) combines the expectorant, guaifenesin and the cough suppressant, dextromethorphan hydrobromide. Guaifenesin is an expectorant the action of which promotes or facilitates the removal of secretions from the respiratory tract. By increasing sputum volume and making sputum less viscous, guaifenesin facilitates expectoration of retained secretions. Dextromethorphan is a synthetic nonopioid cough suppressant, the dextro isomer of the codeine analogue of levorphanol. Dextromethorphan acts centrally to elevate the threshold for coughing, but does not have addictive, analgesic or sedative actions and does not produce respiratory depression with usual doses.

INDICATIONS AND USAGE
Temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants. Calms the cough control center and relieves coughing. Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus, drain bronchial tubes, and make coughs more productive.

CONTRAINDICATIONS
Hypersensitivity to any of the ingredients. The use of dextromethorphan-containing products is contraindicated in patients receiving monoamine oxidase inhibitors (MAOIs) because the effects of dextromethorphan on fetal development has not been established relative to possible adverse effects on fetal development. Therefore, this product should not be used in pregnant patients, unless in the judgment of the physician, the potential benefits outweigh possible hazards.
Nursing Mothers: It is not known whether guaifenesin or dextromethorphan is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when these products are administered to a nursing woman and a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
Laboratory Test Interactions: Guaifenesin or its metabolites may cause color interference with the VMA (vanillylmandelic acid) test for catechols. It may also falsely elevate the level of urinary 5-HIAA (5-hydroxyindoleacetic acid) in certain serotonin metabolite chemical tests because of color interference.
Drug Interactions: Serious toxicity may result if dextromethorphan is coadministered with monoamine oxidase inhibitors (MAOIs). The use of dextromethorphan hydrobromide may result in additive CNS depressant effects when coadministered with alcohol, antihistamines, psychotropics or other drugs which produce CNS depression.
Information for Patients: Patients should be warned not to use this product if they are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If patients are uncertain whether a prescription drug contains an MAOI, they should be instructed to consult a health professional before taking such a product.

ADVERSE REACTIONS
Guaifenesin is well tolerated and has a wide margin of safety. Nausea and vomiting are the side effects that occur most commonly. Other reported adverse reactions have included dizziness, headache and rash (including urticaria). Rare drowsiness or mild gastrointestinal disturbances are the only side effects associated with dextromethorphan in clinical use (see also Drug Interactions).

OVERDOSAGE
Overdosage with guaifenesin is unlikely to produce toxic effects since its toxicity is low. Guaifenesin, when administered by stomach tube to test animals in doses up to 5 grams/kg, produced no signs of toxicity. In severe cases of overdosage, treatment should be aimed at reducing further absorption of the drug. Gastric emptying (emesis and/or gastric lavage) is recommended as soon as possible after ingestion.
Overdosage with dextromethorphan may produce excitement and mental confusion. Very high doses may produce respiratory depression. One case of toxic psychosis (hyperexcitivity, marked visual and auditory hallucinations) after ingestion of a single 300 mg dose of dextromethorphan has been reported.

DOSAGE AND ADMINISTRATION
Adults and children 12 years of age and older: 2 teaspoonfuls (10 mL) every four hours not to exceed 12 teaspoonfuls (60 mL) in 24 hours.
Children 6 years to under 12 years of age: 1 teaspoonful (5 mL) every four hours not to exceed 6 teaspoonfuls (30 mL) in 24 hours.
Children 2 to under 6 years of age: ½ teaspoonful (2.5 mL) every four hours not to exceed 3 teaspoonfuls (15 mL) in 24 hours.
Children 6 mo. to under 2 years of age: A common dosage is ⅛ teaspoonful to ¼ teaspoonful (0.6 mL to 1.25 mL) every 4 hours or ½ teaspoonful (2.5 mL) every 6–8 hours, not to exceed 1.5 teaspoonfuls (7.5 mL) in 24 hours. Individualized dosage should be determined by evaluation of patient.

HOW SUPPLIED
Guaifenesin 100 mg and dextromethorphan hydrobromide 10 mg per 5 mL of clear yellow liquid in bottles of one pint (NDC 0037-4714-10) and one gallon (NDC 0037-4714-20), and 4 fl oz (NDC 0037-4714-01) labeled TUSSI-ORGANIDIN® DM-S† NR*.
Storage—Store at controlled room temperature—15°–30°C (59°–86°F). Protect from light. Keep bottle tightly closed.
†TUSSI-ORGANIDIN® DM-S NR* is TUSSI-ORGANIDIN® DM NR* Liquid either in a 4 fl oz unit of use container with a 10 mL graduated oral syringe and fitment or in a 30 mL sample container.
TUSSI-ORGANIDIN® DM NR* (*Newly Reformulated) Liquid is distributed by:
WALLACE LABORATORIES

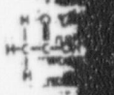
VASCOR®
brand of bepridil hydrochloride
Tablets

Marketed jointly by McNeil Pharmaceutical and Wallace Laboratories. See McNeil Pharmaceutical for information.

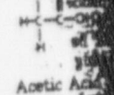
VōSol®
OTIC SOLUTION
(acetic acid otic solution, USP)

VōSol® HC
OTIC SOLUTION
(hydrocortisone and acetic acid otic solution, USP)

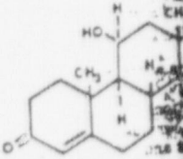
DESCRIPTION
VōSol (acetic acid otic solution, USP) is a 2% solution of acetic acid (2%), in a propylene glycol vehicle with benzethonium chloride, glycol diacetate (3%), benzethonium chloride (0.025%), sodium acetate (0.015%). The empirical formula for acetic acid is CH_3COOH, with a molecular weight of 60.05. Its structural formula is:



VōSol is available as a nonaqueous solution buffered to pH 3 for use in the external ear canal.
VōSol HC (hydrocortisone and acetic acid otic solution, USP) is a solution containing hydrocortisone 1% and acetic acid (2%), in a propylene glycol vehicle with benzethonium chloride, glycol diacetate (3%), benzethonium chloride (0.025%), sodium acetate (0.015%) and citric acid. The empirical formulas for acetic acid and hydrocortisone are $C_2H_4O_2$ and $C_{21}H_{30}O_5$, with a molecular weight of 60.05 and 362.47, respectively. The structural formulas are:



Acetic Acid



Chemically, hydrocortisone is
Pregn-4-ene-3,20-dione,
11,17,21-trihydroxy-,

VōSol HC is available as a nonaqueous solution buffered at pH 3 for use in the external ear canal.

CLINICAL PHARMACOLOGY
VōSol—Acetic acid is antibacterial. Propylene glycol is hydrophilic and provides a vehicle for benzethonium chloride as a surfactant that promotes contact of the solution with the
VōSol HC—Acetic acid is antibacterial. Hydrocortisone is anti-inflammatory, antipruritic; propylene glycol is hydrophilic, reduces surface tension; benzethonium chloride is a surfactant that promotes contact of the solution

INDICATIONS AND USAGE
VōSol—For the treatment of superficial infections of the external auditory canal caused by susceptible bacteria when the action of the antimicrobial is desired.
VōSol HC—For the treatment of superficial infections of the external auditory canal caused by susceptible bacteria when the action of the antimicrobial is desired, and for the relief of inflammation.

...inpyrazone—large doses of aspirin effect of both drugs. Renal excretion ...o be reduced.

...ugs—enhancement of hypoglycemia ...

...ent that they raise urinary pH, antally decrease plasma salicylate con...ely, their withdrawal can result in a ...

...—this and other drugs that acidify a ...rine can elevate plasma salicylate ...

...anced aspirin-induced fecal blood loss ...

...cylate plasma levels may be de...d corticosteroids are given, and may ...tially when they are discontinued.

...ersia, Impairment of Fertility: No ... been done with 'Soma' Compound ...

...ic Effects: **Pregnancy Category C**. ...oduction studies have not been con...mpound with Codeine. It is also not ... Compound with Codeine can cause ...nistered to a pregnant woman or can ...acity. 'Soma' Compound with Codeine ...gnant woman only if clearly needed. ...e shown salicylates to be teratogenic ...station, and embryocidal when given ...ses considerably greater than usual ...umans. Studies in women who took ...ncy have not demonstrated an in...ongenital abnormalities in the off...

...gestion of aspirin near term or prior ...ng delivery or lead to bleeding in ...ate.

...isoprodol is excreted in human milk ...o-four times that in maternal plasma. ...uman milk in moderate amounts and ...tendency in nursing infants. Because ...ous adverse reactions in nursing in...ld be made whether to discontinue ...aking into account the importance of ...r.

... and effectiveness in children below ... not been established.

...ONS

...r, discontinue 'Soma' Compound with ...ppropriate symptomatic and support...

...cts which have occurred with the ad...dividual ingredients alone may also ...ation.

...Nervous System—Drowsiness is the ...nt and along with other CNS effects ...duction. Observed less frequently are ...taxia. Tremor, agitation, irritability, ...eactions, syncope, and insomnia have ...e.

...cratic reactions are very rare. They ...n the period of the first to fourth dose ...no previous contact with the drug (see ...

...ythema multiforme, pruritus, eosino...eruptions with cross-reaction to meprobamate reported. If allergic reactions occur, ...mpound with Codeine and treat symp...ating possible allergic reactions, also ...cipients (information on excipients is ...s on request).

...ycardia, postural hypotension, and ...

...ea, vomiting, epigastric distress and ...

...ous blood dyscrasias have been attrib...alone. Leukopenia and pancytopenia ...ry rarely, in situations in which other ...ns may have been responsible.

...ommon adverse reactions associated ... have been gastrointestinal, including ...itis, occult bleeding, constipation and ...ion, angioedema, asthma, rash, pruri... been reported less commonly. Tinni...serum salicylate levels (see OVER...

...Allergic type reactions in aspirin-sensi... involve the respiratory tract or the ...e former range from rhinorrhea and ...severe asthma, and the latter may ...

Codeine Phosphate: Nausea, vomiting, constipation, miosis, sedation, and dizziness have been reported.

DRUG ABUSE AND DEPENDENCE

Controlled Substance: Schedule C-III (see PRECAUTIONS).

Abuse: In clinical use, abuse has been rare.

Dependence: In clinical use, dependence with 'Soma' Compound with Codeine has been rare and there have been no reports of significant abstinence signs. Nevertheless, the following information on the individual ingredients should be kept in mind.

Carisoprodol—In dogs, no withdrawal symptoms occurred after abrupt cessation of carisoprodol from dosages as high as 1 gm/kg/day. In a study in man, abrupt cessation of 100 mg/kg/day (about five times the recommended daily adult dosage) was followed in some subjects by mild withdrawal symptoms such as abdominal cramps, insomnia, chills, headache, and nausea. Delirium and convulsions did not occur (see PRECAUTIONS).

Codeine Phosphate—Drug dependence of the morphine type may result.

OVERDOSAGE

Signs and Symptoms: Any of the following which have been reported with the individual ingredients may occur and may be modified to a varying degree by the effects of the other ingredients present in 'Soma' Compound with Codeine.

Carisoprodol—Stupor, coma, shock, respiratory depression and, very rarely, death. Overdosage with carisoprodol in combination with alcohol, other CNS depressants, or psychotropic agents can have additive effects, even when one of the agents has been taken in the usually recommended dosage.

Aspirin—Headache, tinnitus, hearing difficulty, dim vision, dizziness, lassitude, hyperpnea, rapid breathing, thirst, nausea, vomiting, sweating and occasionally diarrhea are characteristic of mild to moderate salicylate poisoning. Salicylate poisoning should be considered in children with symptoms of vomiting, hyperpnea, and hyperthermia.

Hyperpnea is an early sign of salicylate poisoning, but dyspnea supervenes at plasma levels above 50 mg/dl. These respiratory changes eventually lead to serious acid-base disturbances. Metabolic acidosis is a constant finding in infants but occurs in older children only with severe poisoning; adults usually exhibit respiratory alkalosis initially and acidosis terminally.

Other symptoms of severe salicylate poisoning include hyperthermia, dehydration, delirium, and mental disturbances. Skin eruptions, GI hemorrhage, or pulmonary edema are less common. Early CNS stimulation is replaced by increasing depression, stupor, and coma. Death is usually due to respiratory failure or cardiovascular collapse.

Codeine Phosphate—pinpoint pupils, CNS depression, coma, respiratory depression, and shock.

Treatment: *General*—Provide symptomatic and supportive treatment, as indicated. Any drug remaining in the stomach should be removed using appropriate procedures and caution to protect the airway and prevent aspiration, especially in the stuporous or comatose patient. Incomplete gastric emptying with delayed absorption of carisoprodol has been reported as a cause for relapse. Should respiration or blood pressure become compromised, respiratory assistance, central nervous system stimulants, and pressor agents should be administered cautiously, as indicated.

Carisoprodol—The following have been used successfully in overdosage with the related drug meprobamate: diuretics, osmotic (mannitol) diuresis, peritoneal dialysis, and hemodialysis (see CLINICAL PHARMACOLOGY). Careful monitoring of urinary output is necessary and caution should be taken to avoid overhydration. Carisoprodol can be measured in biological fluid by gas chromatography (Douglas, J. F., et al: *J Pharm Sci* 56: 145, 1969).

Aspirin—Since there are no specific antidotes for salicylate poisoning, the aim of treatment is to enhance elimination of salicylate and prevent or reduce further absorption; to correct any fluid, electrolyte or metabolic imbalance; and to provide general and cardiorespiratory support. If acidosis is present, intravenous sodium bicarbonate must be given, along with adequate hydration, until salicylate levels decrease to within the therapeutic range. To enhance elimination, forced diuresis and alkalinization of the urine may be beneficial. The need for hemoperfusion or hemodialysis is rare and should be used only when other measures have failed.

Codeine Phosphate—Narcotic antagonists, such as nalorphine and levallorphan, may be indicated.

DOSAGE AND ADMINISTRATION

Usual Adult Dosage: 1 or 2 tablets, four times daily. Not recommended for use in children under age twelve.

HOW SUPPLIED

'Soma' Compound with Codeine Tablets (carisoprodol, USP 200 mg, aspirin 325 mg, and codeine phosphate, USP 16 mg) are oval, convex, two-layered and inscribed on the white layer with SOMA CC and on the yellow layer with [illegible] are available in bottles of [illegible]

Storage: Store at controlled room temperature 15°-30°C (59°-86°F). Protect from moisture.

Dispense in a tight container.

WALLACE LABORATORIES
Division of CARTER-WALLACE, INC.
Cranbury, New Jersey 08512

Rev. 9/93

Shown in Product Identification Guide, page 339

THYRO-BLOCK® OTC
TABLETS
(POTASSIUM IODIDE TABLETS, USP)
(pronounced poe-TASS-e-um EYE-oh-dyed)
(abbreviated: KI)

TAKE POTASSIUM IODIDE ONLY WHEN PUBLIC HEALTH OFFICIALS TELL YOU. IN A RADIATION EMERGENCY, RADIOACTIVE IODINE COULD BE RELEASED INTO THE AIR. POTASSIUM IODIDE (A FORM OF IODINE) CAN HELP PROTECT YOU. IF YOU ARE TOLD TO TAKE THIS MEDICINE, TAKE IT ONE TIME EVERY 24 HOURS. DO NOT TAKE IT MORE OFTEN. MORE WILL NOT HELP YOU AND MAY INCREASE THE RISK OF SIDE EFFECTS. *DO NOT TAKE THIS DRUG IF YOU KNOW YOU ARE ALLERGIC TO IODIDE.* (SEE SIDE EFFECTS BELOW.)

INDICATIONS

THYROID BLOCKING IN A RADIATION EMERGENCY ONLY.

DIRECTIONS FOR USE

Use only as directed by State or local public health authorities in the event of a radiation emergency.

DOSE

Tablets: ADULTS AND CHILDREN 1 YEAR OF AGE OR OLDER: One (1) tablet once a day. Crush for small children.
BABIES UNDER 1 YEAR OF AGE: One-half (1/2) tablet once a day. Crush first.

Take for 10 days unless directed otherwise by State or local public health authorities.

Store at controlled room temperatures between 15° and 30°C (59° to 86°F). Keep container tightly closed and protect from light.

WARNING

Potassium iodide should not be used by people allergic to iodide. Keep out of the reach of children. In case of overdose or allergic reaction, contact a physician or the public health authority.

DESCRIPTION

Each white, round, scored, monogrammed THYRO-BLOCK® Tablet contains 130 mg of potassium iodide. Other ingredients: magnesium stearate, microcrystalline cellulose, silica gel, and sodium thiosulfate.

HOW POTASSIUM IODIDE WORKS

Certain forms of iodine help your thyroid gland work right. Most people get the iodine they need from foods, like iodized salt or fish. The thyroid can "store" or hold only a certain amount of iodine.

In a radiation emergency, radioactive iodine may be released in the air. This material may be breathed or swallowed. It may enter the thyroid gland and damage it. The damage would probably not show itself for years. Children are most likely to have thyroid damage.

If you take potassium iodide, it will fill up your thyroid gland. This reduces the chance that harmful radioactive iodine will enter the thyroid gland.

WHO SHOULD NOT TAKE POTASSIUM IODIDE

The only people who should not take potassium iodide are people who know they are allergic to iodide. You may take potassium iodide even if you are taking medicines for a thyroid problem (for example, a thyroid hormone or antithyroid drug). Pregnant and nursing women and babies and children may also take this drug.

HOW AND WHEN TO TAKE POTASSIUM IODIDE

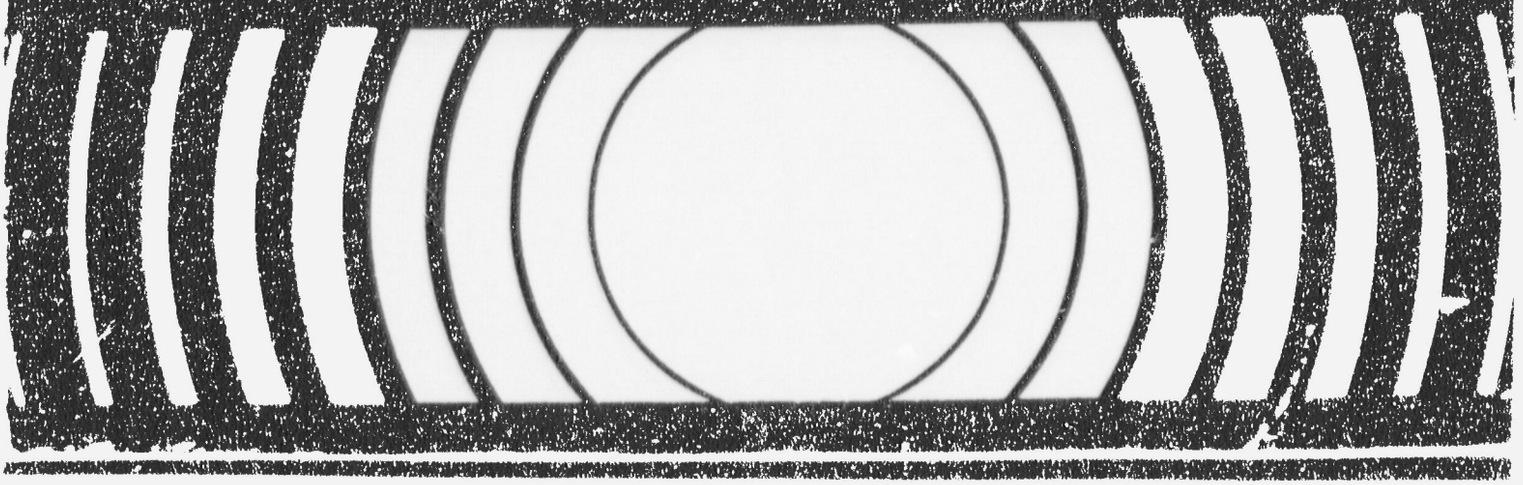
Potassium iodide should be taken as soon as possible after public health officials tell you. You should take one dose every 24 hours. More will not help you because the thyroid can "hold" only limited amounts of iodine. Larger doses will increase the risk of side effects. You will probably be told not to take the drug for more than 10 days.

SIDE EFFECTS

Usually, side effects of potassium iodide happen when people take higher doses for a long time. You should be careful not to take more than the recommended dose or take it for longer than you are told. Side effects are unlikely because of the low dose and the short time you will be taking the drug.

EPA

Manual Of Protective Action Guides And Protective Actions For Nuclear Incidents



former PAG for whole body exposure provides public health protection comparable to that provided by the new PAG expressed in terms of effective dose equivalent. This is demonstrated in Table C-9 (Appendix C), which shows comparative doses for nuclear power plant fuel-melt accident sequences having a wide range of magnitudes. The PAG for the thyroid is unchanged. On the other hand, application of these PAGs to alpha emitting radionuclides leads to quite different derived response levels from those based on earlier health physics considerations, because of new dose conversion factors and the weighting factors assigned to the exposed organs (EP-88).

5.5 Protective Actions

This section provides guidance for implementing the principal protective actions (evacuation and sheltering) for protection against the various exposure pathways resulting from an airborne plume. Sheltering means the use of the closest available structure which will provide protection from exposure to an airborne plume, and evacuation means the movement of individuals away from the path of the plume.

Evacuation and sheltering provide different levels of dose reduction for the principal exposure pathways (inhalation of radioactive material, and direct gamma exposure from the plume or from material deposited on surfaces). The effectiveness of evacuation will depend on many factors, such as how rapidly it can be implemented and the nature of the accident. For accidents where the principal source of dose is inhalation, evacuation could increase exposure if it is implemented during the passage of a short-term plume, since moving vehicles provide little protection against exposure (DO-90). However, studies (NR-89a) continue to show that, for virtually all severe reactor accident scenarios, evacuation during plume passage does not increase the risk of acute health effects above the risk while sheltering. Sheltering, which in most cases can be almost immediately implemented, varies in usefulness depending upon the type of release, the shelter available, the duration of the plume passage, and climatic conditions.

Studies have been conducted to evaluate shelter (EP-78a) and evacuation (HA-75) as protective actions for incidents at nuclear power facilities. Reference EP-78b suggests one method for evaluating and comparing the benefits of these two actions. This requires collecting planning information before and data following an incident, and using calculations and graphical means to evaluate whether evacuation, sheltering, or a combination of sheltering followed by evacuation should be recommended at different locations. Because of the many interacting variables, the user is forced to choose between making decisions during the planning phase, based on assumed data that may be grossly inaccurate, or using a time-consuming more comprehensive process after the

incident when data may be available. In the former situation, the decision may not have a sound basis, whereas in the latter, the decision may come too late to be useful.

The recommended approach is to use planning information for making early decisions. The planned response should then be modified following the incident only if timely detailed information is available to support such modifications.

The planner should first compile the necessary information about the emergency planning zone (EPZ) around the facility. For the case of power reactors, some of this information is described in NUREG-0654 (NR-80). It should include identifying the population distribution, the sheltering effectiveness of residences and other structures, institutions containing population groups that require special consideration, evacuation routes, logical boundaries for evacuation zones, transportation systems, communications systems, and special problem areas. In addition, the planner should identify the information that may be available following an incident, such as environmental monitoring data, meteorological conditions, and plant conditions. The planner should identify key data or information that would justify specific protective actions. The evaluation and planning should also include the selection of institutions where persons should be provided with stable iodine for thyroid protection in situations where radioiodine inhalation is projected.

The following sections discuss key factors which affect the choice between evacuation and sheltering.

5.5.1 Evacuation

The primary objective of evacuation is to avoid exposure to airborne or deposited radioactive material by moving individuals away from the path of the plume. Evacuation, if completed before plume arrival, can be 100 percent effective in avoiding future exposure. Even if evacuation coincides with or follows plume passage, a large reduction of exposure may be possible. In any case, the maximum dose avoided by evacuation will be the dose not avoidable by sheltering.

Some general conclusions regarding evacuation (HA-75) which may be useful for planning purposes are summarized below:

1. Advanced planning is essential to identify potential problems that may occur in an evacuation.

2. Most evacuees use their own personal transportation.

3. Most evacuees assume the responsibility of acquiring food and shelter for themselves.

4. Evacuation costs are highly location-dependent and usually will not

be a deterrent to carrying out an evacuation.

5. Neither panic nor hysteria has been observed when evacuation of large areas is managed by public officials.

6. Large or small population groups can be evacuated effectively with minimal risk of injury or death.

7. The risk of injury or death to individual evacuees from transportation does not change as a function of the number of persons evacuated, and can be conservatively estimated using National Highway Safety Council statistics for motor vehicle accidents (subjective information suggests that the risks will be lower).

Evacuation of the elderly, the handicapped, and inhabitants of medical and other institutions may present special problems. When sheltering can provide adequate protection, this will often be the protective action of choice. However, if the general public is evacuated and those in institutions are sheltered, there is a risk that attendants at these institutions may leave and make later evacuation of institutionalized persons difficult because of a lack of attendants. Conversely, if evacuation of institutions is attempted during evacuation of the public, traffic conditions may cause unacceptable delays. If evacuation of institutions is attempted before evacuating the public, increased risk to the public from a delayed evacuation could occur, unless the incident is very slow in developing to the point of an atmospheric release. Because of the above difficulties, medical and other institutions located within the EPZ should be evaluated to determine whether there are any logical categories of persons that should be evacuated after the public (or, when time permits, before).

5.5.2 Sheltering

Sheltering refers here to the use of readily available nearby structures for protection against exposure to an airborne plume.

Sheltering may be an appropriate protective action because:

1. It positions the public to receive additional instructions when the possibility of high enough doses to justify evacuation exists, but is small.

2. It may provide protection equal to or greater than evacuation.

3. It is less expensive and disruptive than evacuation.

4. Since it may be implemented rapidly, sheltering may be the protective action of choice if rapid evacuation is impeded by, a) severe environmental conditions--e.g. severe weather or floods; b) health constraints--e.g. patients and workers in hospitals and nursing homes; or c) long mobilization times--certain industrial and farm workers, or prisoners and guards; d) physical

constraints to evacuation--e.g. inadequate roads.

5. Sheltering may be more effective against inhalation of radioactive particulates than against external gamma exposure, especially for short-term plumes.

The use of large structures, such as shopping centers, schools, churches, and commercial buildings, as collection points during evacuation mobilization will generally provide greater protection against gamma radiation than use of small structures.

As with evacuation, delay in taking shelter during plume passage will reduce the protection from exposure to radiation. The degree of protection provided by structures is governed by attenuation of gamma radiation by structural components (the mass of walls, ceilings, etc.) and by outside/inside air-exchange rates.

If external dose from the plume or from deposited materials is the controlling criterion, shelter construction and shelter size are the most important considerations; ventilation control and filtering are less important. Although sheltering will reduce the gamma exposure rate from deposited materials, it is not a suitable protective action for this pathway for long duration exposure. The main factors which reduce whole body exposure are:

1. Wall materials and thickness and size of structure,

2. Number of stories overhead, and

3. Use of a central location within the structure.

If a major release of radioiodine or respirable particulate materials occurs, inhalation dose will be the controlling pathway. For releases consisting primarily of noble gases, external gamma exposure will be most important. However, when inhalation is the primary exposure pathway, consideration should be given to the following:

1. Ventilation control is essential for effective sheltering.

2. Dose reduction factors for sheltering can be improved in several ways for the inhalation pathway, including reducing air exchange rates by sealing cracks and openings with cloth or weather stripping, tape, etc. Although the risk to health from the action could be a constraint (particularly for infants and the infirm), using wet towels or handkerchiefs as a mask to filter the inhaled air will reduce dose from inhalation.

3. Following plume passage, people should open shelters to reduce airborne activity trapped inside, and they should leave high exposure areas as soon as possible after cloud passage to avoid exposure to deposited radioactive material.

4. Consideration should be given to the prophylactic administration of potassium iodide (KI) as a

thyroid-blocking agent to workers performing emergency services and other groups in accordance with the PAGs in Table 2-1 and the provisions in reference FD-82.[3]

5.5.3 General Guidance for Evacuation and Sheltering

The process of evaluating, recommending, and implementing evacuation or shelter for the public is far from an exact science, particularly in view of time constraints that prevent thorough analysis at the time of an incident. Their effectiveness, however, can be improved considerably by planning and testing. Early decisions should be based on information collected from the emergency planning zone during the planning phase and on information regarding conditions at the nuclear facility at the time of the incident. Best estimates of dose projections should be used for decisions between evacuation and sheltering.

The following is a summary of planning guidance for evacuation and sheltering, based on the information in Sections 5.5.1 and 5.5.2.

1. For severe incidents, where PAGs may be significantly exceeded, evacuation may be the only effective protective action close to the facility.

2. Evacuation will provide total protection from any airborne release if it is completed before arrival of the plume.

3. Evacuation may increase exposure if carried out during the plume passage, for accidents involving inhalation dose as a major contributor.

4. Evacuation is also appropriate for protection from groundshine in areas with high exposure rates from deposited materials.

5. Sheltering may be appropriate (when available) for areas not designated for immediate evacuation because:

   a. It positions the public to receive additional instructions; and

   b. It may provide protection equal to or greater than evacuation.

6. Sheltering is usually not appropriate where high doses are projected or for exposure lasting longer than two complete air exchanges of the shelter.

7. Because sheltering may be implemented in less time than evacuation, it may be the temporary protective action of choice if rapid evacuation is impeded by a) certain environmental conditions--e.g. severe weather or floods; b) health constraints--e.g. patients and workers

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[3]Each State has the responsibility for formulating guidance to define when (and if) the public should be given potassium iodide. Planning for its use is discussed in "Potassium Iodide as a Thyroid-blocking Agent in a Radiation Emergency: Final Recommendations on Use" (FD-82).

in hospitals and nursing homes; or c) long mobilization times--e.g. certain industrial and farm workers, or prisoners and guards; d) physical constraints to evacuation--e.g. inadequate roads.

8. If a major release of radioiodine or particulate materials occurs, inhalation dose may be the controlling criterion for protective actions. In this case:

a. Breathing air filtered through common household items (e.g., folded wet handkerchiefs or towels) may be of significant help, if appropriate precautions are taken to avoid possible suffocation.

b. After confirmation that the plume has passed, shelters should be opened to avoid airborne activity trapped inside, and persons should leave high exposure areas as soon as possible after cloud passage to avoid exposure to deposited radioactive material.

c. Consideration should be given to the prophylactic administration of potassium iodide (KI) as a thyroid-blocking agent to emergency workers, workers in critical industries, or others in accordance with the PAGs in Table 2-1 and reference FD-82.

9. If dose from external gamma radiation is the controlling criterion, shelter construction and size are the most important considerations; ventilation control and filtering are less important. The main factors which reduce whole body external dose are; a) wall thickness and size of structure, b) number of stories overhead, c) central location within the structure, and d) the height of the cloud with respect to the building.

5.6 Procedures for Calculating Dose Conversion Factors

This section provides information used in the development of the DCFs in Tables 5-1 and 5-2. Three exposure pathways are included: whole body exposure to gamma radiation from the plume, inhalation from the plume, and whole body exposure to gamma radiation from deposited materials. Although exposure of the skin from beta radiation could be significant, evaluations show that other exposure pathways will be controlling for evacuation and sheltering decisions. Therefore, DCFs for skin are not provided. Individual DCFs for the three exposure pathways are provided in the following sections. They are each expressed in terms of the time-integrated air concentration so that they may be combined to yield a composite DCF for each radionuclide that reflects all three pathways. These data may be used to facilitate revising the DCFs in Tables 5-1 and 5-2 when more specific or technically improved assumptions are available, as well as to evaluate the relative importance of the individual pathways for specific radionuclide mixes.

Peter G. Crane / 4809 Drummond Avenue / Chevy Chase, MD 20815 / 301-656-3998 / pgcrane@erols.com

August 24, 1998

Lawrence G. Weinstock
Acting Director, Office of Radiation and Indoor Air
6601J
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Mr. Weinstock:

As the New York Times reported on August 21, the Commissioners of the Nuclear Regulatory Commission voted in late June to initiate a rule change by which states will be required to consider the radiation antidote potassium iodide (KI) as part of nuclear emergency planning. This is to be coupled with an offer by the Federal Government to make KI available, at Federal cost, to any state wishing to establish a stockpile of the drug.

This commendable action by the Commissioners comes 20 years after the Food and Drug Administration declared KI to be "safe and effective" and approved it for over-the-counter sale, and 19 years after the President's Commission on the Accident at Three Mile Island recommended creation of regional stockpiles of the drug. As the Federal Emergency Management Agency pointed out to the NRC in an April 9, 1998, letter from Assistant Administrator Kay C. Goss, the validity of the 1978 FDA finding was reinforced empirically by the Polish experience in administering millions of doses of KI during and after the Chernobyl accident, with minimal side effects.

The NRC Commissioners took this action — the grant of a rulemaking petition which I filed in 1995 — despite a recommendation from the NRC technical staff that the petition be denied. In support of its recommendation, the NRC staff prepared a "technical assessment," which has been published in draft form as NUREG-1633 with a request for comment. Curiously, the July 20 Federal Register notice announcing the availability of the document made no mention of the Commissioners' recent action in support of KI stockpiling.

The NRC staff's "technical assessment" has many grave flaws, but none so glaring or so revealing of the authors' mindset as the omission of any reference to what sister agencies -- primarily FDA, but also EPA -- have had to say on the potassium iodide issue. Ordinarily, it might be assumed that the FDA's "safe and effective" finding of 1978 would be the starting point for any evaluation of KI by another federal agency. But NUREG-1633 is no ordinary evaluation, and it does not even mention the FDA position. Instead, the authors seem to have set themselves up as a sort of rump FDA, making their own judgments on drug safety, based on selective and misleading citations to a long outdated edition of the Physician's Desk Reference. It would all be comical if it the underlying issue — the protection of American children from

cancer — were not so serious.[1]

EPA, in 1992, published a "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents," EPA-400-R-92-001. This includes an extensive, thoughtful analysis of the pros and cons of different protective actions (evacuation, sheltering, iodine prophylaxis) and the circumstances under which each might be appropriate. For several years, in comments I have filed with the NRC, I have tried to persuade the NRC staff to come to grips with the EPA analysis. The NRC staff has never acknowledged its existence, and if you look in the list of references in NUREG-1633, you will find no mention of it.

I do not believe that the NRC staff should run roughshod over the other agencies that have addressed the KI issue. By the same token, I do not believe that these other agencies should sit passively by as the NRC staff ignores what they have had to say on important health and safety issues within their sphere of responsibility. I therefore urge EPA to review NUREG-1633 and present its comments to the NRC in the most straightforward terms. (I am making the same suggestion to FDA.)

The failure to mention the FDA finding and the EPA study seems explicable enough, however. NUREG-1633 appears calculated to raise such apprehensions about KI's safety, and about the risk of lawsuits over side effects, that states will reject the offer of free KI. The EPA study makes clear that the issue is not one of evacuation vs. KI, as the NRC staff would like to portray it, but of whether KI can provide additional protection in those situations in which evacuation is impracticable or inadvisable, or where there is a risk of exposure to radioiodines during evacuation.

I have called on the NRC Commissioners to withdraw and disavow NUREG-1633. I hope they will do so; I do not think it serves the NRC's interest to have its name associated with so defective a study.

I am enclosing a copy of a talk I recently gave at an international symposium on the subject of radiation and thyroid cancer, held at Cambridge University in England under the joint sponsorship of the European Commission, the Department of Energy, and the National Cancer Institute. The talk is a case study of the handling of the KI issue by the U.S. Government over the past 20 years. It contains background information that may perhaps be helpful. In addition, I am enclosing a copy of comments I recently filed with the NRC on the subject of NUREG-1633. I hope that you will review them, and also review NUREG-1633. If you do so, I believe that you will agree with me that such a document should be withdrawn from public circulation — not

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[1]The unfitness of the authors to venture into the evaluation of drug safety is further illustrated by their discussion of tincture of iodine. They report that it was used by 6% of parents in Poland to administer iodine prophylaxis to their children, and they say that a 4-ounce bottle "contains enough iodine to block 22 thyroids," from which statements they reader could well infer that tincture of iodine is an acceptable substitute for KI. Tincture of iodine is, of course, a poison, but the reader of NUREG-1633 would have no way of knowing that.

because of its policy viewpoint, but because of the way in which it represents, or fails to represent, relevant facts.

From September 9-11, 1998, EPA will be holding an "International Radiological Post-Emergency Response Issues Conference" in Washington. My understanding is that one of your keynote speakers is the NRC staff official who as technical director of NUREG-1633 oversaw its preparation. (However, you are fortunate to have on your program Dr. Janusz Nauman of Warsaw, the distinguished Polish thyroid specialist who oversaw Poland's successful use of KI during the Chernobyl emergency.)

I believe it might be useful for your audience to be informed briefly and accurately about the current status of the KI issue in the U.S. and about the grave flaws in NUREG-1633, which might otherwise appear to the unwary as the U.S. Government's definitive statement on the KI issue. If you can find just 10 or 15 minutes someplace to fit me in to the schedule, I'll adapt my Cambridge remarks and my comments on NUREG-1633 and give a talk that is to the point and doesn't run over the time limit. (I had just ten minutes in Cambridge.) Needless to say, I would prepare and give this talk on my own time, in my capacity as a private citizen.

Please let me know what you think. With best regards,

Sincerely,

Peter Crane

Peter G. Crane

Attachments:

1. Talk at Cambridge (July 22, 1998), with cover note to Commissioners (August 5, 1998)
2. Comments on NUREG-1633 (August 20, 1998)

cc: (w/o enclosures)

Chairman Shirley Ann Jackson
Commissioner Nils J. Diaz
Commissioner Edward McGaffigan
L. Joseph Callan, Executive Director for Operations
Hugh L. Thompson, Deputy Executive Director for Operations

Peter G. Crane / 4809 Drummond Avenue / Chevy Chase, MD 20815 / 301-656-3998 / pgcrane@erols.com

August 24, 1998

Michael A. Friedman, M.D.
Lead Deputy Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Friedman:

As the New York Times reported on August 21, the Commissioners of the Nuclear Regulatory Commission voted in late June to initiate a rule change by which states will be required to consider the radiation antidote potassium iodide (KI) as part of nuclear emergency planning. This is to be coupled with an offer by the Federal Government to make KI available, at Federal cost, to any state wishing to establish a stockpile of the drug. This commendable action by the Commissioners comes 20 years after the Food and Drug Administration declared KI to be "safe and effective" and approved it for over-the-counter sale. As the Federal Emergency Management Agency pointed out to the NRC in an April 9, 1998, letter from Assistant Administrator Kay C. Goss, the validity of the 1978 FDA finding was reinforced empirically by the Polish experience in administering millions of doses of KI during and after the Chernobyl accident, with minimal side effects.

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The unfitness of the authors to venture into the evaluation of drug safety is further illustrated by their discussion of tincture of iodine. They report that it was used by 6% of parents in Poland to administer iodine prophylaxis to their children, and they say that a 4-ounce bottle "contains enough iodine to block 22 thyroids," from which statements they reader could well infer that tincture of iodine is an acceptable substitute for KI. Tincture of iodine is, of course, a poison, but the reader of NUREG-1633 would have no way of knowing that.

I have called on the NRC Commissioners to withdraw and disavow NUREG-1633. I

hope they will do so; I do not think it serves the NRC's interest to have its name associated with so defective a study, or one that treats a sister agency with such disrespect.

I strongly urge the Food and Drug Administration to examine the document and make its views known to the NRC. I believe it is incumbent on the FDA to do so, for two reasons: first, because the health of American children is involved, and second, because of FDA's own institutional interest in not allowing its role as the arbiter of drug safety questions for the Federal Government to be bypassed or ignored.

I am enclosing a copy of a talk I recently gave at an international symposium on the subject of radiation and thyroid cancer, held at Cambridge University in England under the joint sponsorship of the European Commission, the Department of Energy, and the National Cancer Institute. The talk is a case study of the handling of the KI issue by the U.S. Government over the past 20 years. It contains background information that may perhaps be helpful. In addition, I am enclosing a copy of comments I recently filed with the NRC on the subject of NUREG-1633. I hope that you will review them, and also review NUREG-1633. If you do so, I believe that you will agree with me that such document should be withdrawn from public circulation — not because of its policy viewpoint, but because of the way in which it represents, or fails to represent, relevant facts.

Sincerely,

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