Protective Action Guides: Theory and Application
Lessons from the Three Mile Island Accident

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During the Three Mile Island Nuclear accident, the Food and Drug Administration (FDA), Department of Health, Education and Welfare (HEW), fulfilled its traditional role in insuring a safe food supply, and together with other elements of HEW, provided advice and assistance in the response to health concerns. This paper will present two aspects of FDA's role: 1) actions relative to the use and availability of potassium iodide (KI) as a thyroid-blocking agent; and 2) protective action guidance (PAG's) relative to human food and animal feed.

KI AS A THYROID BLOCKING-AGENT

By a notice in the Federal Register of December 15, 1978[1], entitled "Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency," the FDA did the following:

1) In the interest of public safety it requested submission of New Drug Applications (NDA's) for potasium iodide in oral form for use as a thyroid-blocking agent in a radiation emergency.
2) It announced the availability of labeling guidelines for potasium iodide for such use.

Many organic and inorganic drugs were considered for emergency use as thyroid-blocking agents. Potassium iodide was chosen over the other drugs because of: 1) the high degree of blocking achieved; 2) the rapidity of onset of action; 3) a long high duration of its blocking effect; and 4) its relative safety Although potassium iodide acts on the thyroid in several ways, its usefulness for this purpose is primarily predicated on its ability to saturate the iodide transport system, effectively abolishing entry of radioiodine. Complete blocking is achieved, that is, over 90 percent of radioiodine is blocked by the recommended oral administation of 130 milligrams of KI. This is equivalent to 100 milligrams of iodide. The recommended dose for infants under one year of age is 65 milligrams. Onset of block ing occurs within 30 minutes. Therefore, administration before or immediately after initial exposure yields the best results. However, substantial benefit can still be achieved if potassium iodide is given within three or four hours after exposure. The duration of time that a blocking agent is required is not likely to exceed 10 days.

As with any drug, certain cautions have to be recognized. The number of reports of adverse reactions for the use of potassium iodide when it is given in greater doses than for blocking and over a longer period of time has been very low. The risk is judged to be low for the short-term use of potassium iodide in a radiation emergency.

The Federal Register notice offers no guidance as to when to use potassium iodide as a blocking agent. Other sources of guidance are available. The National Commission on Radiation Protection and Measurements Report No. 55[2] suggests that potassium iodide should be considered for blocking at a projected or anticipated thyroid dose from radioiodine of 10 - 30 rads to the thyroid.

The Three Mile Island episode graphically demonstrated the need for effective planning for the use of potassium iodide as a component of public health emergency reponse capability. The drug was not available for mass distribution in the proper dosage forms at the time of the Three Mile Island accident. FDA had not as yet received nor approved an NDA for potassium iodide as a thyroid-blocking agent. To meet the emergency, FDA arranged for the manufacture of a supply of potassium iodide before any decision to employ the drug had been made. Pennsylvania Officials had a plan for distribution of the supplies of KI and patient information. The Three Mile Island emergency was unique in that FDA supplied the drug. The Agency does not stockpile nor will it be a source of the drug in the event of other accident situations.

Among significant factors which influence the decision as to whether or not KI should be employed as a thyroid-blocking agent in a radiation accident are:

1. The efficacy of potassium iodide as a thyroid-blocking agent depends on the pathway of radiation exposure.
2. There is an absence of Federal guidelines for the use of potassium iodide as a thyroid-blocking agent.
3. The area and population potentially affected by the release of radioactivity are important to the decision as to when and how to use potassium iodide.
4. There are logistical problems of storage and distribution because of the need for prompt administration in the event of an accident.
5. Alternative protection actions must be considered instead of, or in concert with, the use of potassium iodide.

Discussion of these problem areas requires more space and time than are available here, and is the subject of a paper in preparation[3].

PAG's FOR HUMAN FOOD AND ANIMAL FEED

"Proposed" Protective Action Guidance for the food pathway also appears in the Federal Register of December 15, 1978[1]. These recommendations are for use by appropriate State and local agencies in response planning for radiation emergencies in the event of an accident resulting in the contamination of food or

animal feed by radioactive substances. Events which may result in radiation emergencies include, but are not limited to, accidents at nuclear facilities, transportation accidents, and fallout from nuclear devices. Although such incidents could lead to a general contamination of the environment, the FDA's recommendations are limited to the food pathway.

The proposed protective actions are intended for implementation within hours or days from the time an emergency is recognized, and the duration should not exceed a month or two. Other Federal agencies are responsible for guidance in the event of exposure to the population from pathways other than for food, and for action of a longer duration.

The FDA protection action guidance does not imply an acceptable radiation dose from food containing radioactivity during normal peacetime conditions. Rather, their purpose is to reduce or avoid further radiation dose to the population via the food chain in the event of a radiation accident. These recommendations are not a license to needlesssly permit environmental levels of radiation to rise.

Protective action guides or PAG's define the projected dose commitment to individuals in the general population that warrants protective actions following the release of radioactive material. Projected dose commitment, is defined as the dose commitment that would be received in the future by individuals in a population group from a contaminating event if no protective action were taken. In other words, the protective action guidance is based on anticipated or projected doses. The purpose of the PAG's is to provide guidance in order to prevent additional radioactive contamination from entering the human food chain and to reduce or avoid future radiation doses to the population after an accidental contaminating event.

Two protective action guidance levels have been proposed. They are:

1. The Preventive PAG is applicable to situations where protective actions causing minimal impact are justified. These protective actions prevent or reduce concentrations of radioactivity in food. The preventive PAG is 1.5 rem projected dose commitment to the thyroid, or 0.5 rem projected dose commitment to the whole body, bone marrow, or any other organ.
2. The Emergency PAG is applicable to incidents where protective actions of high impact are justified because of the greater projected health hazards. Levels at which food should be isolated from commerce are appropriate at the emergency PAG level. The emergency PAG is 15 rem projected dose commitment to the thyroid, or 5 rem projected dose commitment to the whole body, bone marrow, or any other organ.

A practical means of employing the PAG's is through the use of

derived response levels. Derived response levels refer to the activity of a specific radioactive substance per unit weight or volume of food, or animal feed, which corresponds to a particular numerical PAG limit previously mentioned. Response levels have been calculated based on recent metabolic and agricultural models. Specific derived response levels are given in the FDA recommendations for radioactive substances which are thought to be relatively abundant under emergency conditions, easily enter the food chain, and are taken up and retained by the human body. These radionuclides are iodine-131, cesium-137, strontium-90, and strontium-89. Derived response levels are given specifically for initial deposition on pasture, concentration in forage and in milk, and total intake. Variations in the basic model permit calculation of derived response levels for different food products and mixtures of radionuclides.

A large number of milk samples were collected following the Three Mile Island accident from farms and dairies in the vicinity of the accident site. Based on the peak concentration of iodine-131 detected in these samples, the dose to the thyroid of an infant drinking one liter of milk daily for the entire time during which positive milk samples were found, would be 0.005 rem over the lifetime of the individual[4]. The maximum iodine-131 levels detected at Three Mile Island were thus 300 times smaller than the preventive action level.

Two problems which arose during the Three Mile Island accident relative to the PAG's were their application over an extended period of time and their effect on the "marketability" of food. The PAG's are intended for use up to one or two months. They include a derived response limit for total radionuclide intake which may be used as a basis on which to evaluate chronic intake during this period.

Producer's general experience with food contaminated with other materials indicates the general public's reluctance to accept "contaminated" products. This problem involves public perception of radiation risks and governmental credibility. The issuance of PAG recommendations should influence public perceptions of radiation risks in a manner to encourage rational action relative to maketing and acceptance of foods.

REFERENCES

1. Accidental Radioactive Contamination of Human Food and Animal Feeds and Potassium Iodide as a Thyroid-Blocking Agent, Federal Register, December 15, 1978.
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3. Halperin, J.A., Shleien, B. and Kahana, S.E., Thyroid-Blocking with Potassium Iodide: Useful Radiation Protection Guidance, in preparation.
4. Ad Hoc Population Dose Assessment Group, Population Dose and Health Impact of the Accident at the Three Mile Island Nuclear Station, May 10, 1979.