UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

OFFICE OF THE
CHAIRMAN

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CORR

October 29, 1979

The Honorable Ella T. Grasso
Governor of Connecticut
Hartford, Connecticut 06115

Dear Governor Grasso:

Thank you for your letter of July 19, 1979, expressing your concerns on radiological emergency response planning activities. We at the Commission are also concerned about this and we are now reviewing all aspects of the program. This review will no doubt result in recommendations for improvements.

Let me specifically address the numbered questions and points in your letter:

1. You asked about actions to make a thyroid blocking drug available for institutionalized citizens, emergency workers and the general public.

   The recent letter concerning thyroid blocking sent to Mr. Alan Hekking of your Office of Civil Preparedness staff by Mr. Jerome Halperin of the U.S. Food and Drug Administration (enclosed) partially answers this question. In addition, we also believe that all involved agencies (State, Federal, local) must resolve the issue of stockpiling a thyroid blocking agent and associated funding shortly. At a recent meeting between FDA and NRC staff, this was one of the topics of discussion. Whatever policy does result will probably be developed under the auspices of the several Federal agencies involved in radiological emergency response planning with State and local governments. Mr. Frank Mancuso, the Director of your Office of Civil Preparedness will be kept abreast of developments through an Interorganizational Advisory Committee of State and local government emergency preparedness officials of which he is a member.

2. You proposed that I recommend to the Secretary of Transportation that his Department work with Commissioner Powers of the Connecticut Department of Transportation to provide highway signs showing evacuation routes and contaminated areas.

   I have written a letter to Secretary Goldschmidt of the Department of Transportation asking that he honor your request. A copy of the letter is enclosed.

3. You asked when refresher training will be available for State emergency response personnel.

   I am pleased that Connecticut has taken advantage of the training provided by the NRC. The training programs are still available and we will entertain additional requests for training of those personnel who have not received the training. As a matter of fact, as a result of a recent request from some of the other New England States, we are contemplating scheduling two of the courses in New England within the next several months. These would be the Radiological Emergency Response Planning Course and the Radiological Emergency Response Coordinators Course. If you have personnel who would benefit by attendance, please inform Robert G. Ryan, Director of the Office of State Programs. He can be reached at (301) 492-8170.

   We do not as yet have any formal programs for refresher training since the job of initial training has absorbed available training resources. We do expect to be in a position to work on refresher training during the next calendar year. Messrs. Frank Mancuso and Arthur T. Heubner, your Radiation Control Director, will be advised when refresher training is available.

4. You expressed concern about nuclear reactors in other States close to the borders of Connecticut and the need for sharing resources to respond to an accident at one of these reactors.

   We share your concerns about contiguous State planning. As a matter of fact, section II.C of our Emergency Planning Guide and Checklist NUREG-75/111 (which was published in 1974) contains the elements of this planning which we believe should be addressed in State and local Radiological Emergency Response Plans. Contiguous State/local planning is necessary before we will concur in a State plan.

   Specifically with regard to New England, we have recently been in contact with representatives of Vermont, New Hampshire, Massachusetts and Maine to discuss the development of their plans for concurrence. Contiguous State planning and accident classifications and notifications have been covered in these discussions. At the most recent meeting, in which representatives of three of those States participated, Vermont agreed to write an emergency plan annex which could be used by all four States to describe mutual support and assistance during an accident. We have informed Vermont of your concerns in this area and you will receive a copy of the draft annex when it is ready.

We are aware of the New England Radiological Health Compact to which all New England States belong and which allows each State to call upon its neighbors in time of need in responding to radiological emergencies. We believe this is essential, especially in New England, because of the relatively small geographical area covered by each State. We are also pleased by the passage on May 15, 1979 of Resolution Number 206 by the New England Regional Commission which expresses the Governors' desire to work together as a region in planning for nuclear emergencies. We look forward to the reports which each State will be preparing this fall to determine if there is any help we can provide.

5. You asked how we propose to handle the media during an accident at a nuclear power plant, particularly in light of the lessons learned at Three Mile Island.

In regard to communicating with the news media during an accident, the NRC Office of Public Affairs will be working with the NRC Office of Nuclear Reactor Regulation to provide facilities for the news media as part of an Emergency Operations Center to be established in the vicinity of all nuclear power plants. Establishment of such a center is one element of an action plan developed by the NRC Office of Nuclear Reactor Regulation to improve emergency preparedness at all of these facilities and is intended to accommodate Federal, State and local personnel as well as news media representatives. Coordination with State and local officials is a key part of this overall plan. Moreover, there are a number of ongoing investigations into the Three Mile Island accident which may provide some additional recommendations for working with the media to provide accurate reporting in cases of future nuclear accidents. The Commission will be giving all recommendations in this area careful attention.

6. You expressed concern about Connecticut's ability to handle a nuclear crisis.

You have a good radiological emergency response plan. This paper plan is of limited value, however, unless it is annually tested and supported by appropriate preparedness resources. This is the main reason we have a requirement for an annual exercise as a condition to maintaining NRC concurrence in the State plan. This, we believe, is the best way to identify deficiencies and correct them.

In this connection, we are in the process of developing accident scenarios for exercising State plans. Our initial effort is to provide this scenario for those States, such as Connecticut, which already have a concurred plan. For the long term, we have a contract for the development of a series of 10-12 scenarios which we hope will provide a spectrum of postulated accidents which can be used to exercise either part of a plan or the entire plan.

Monitoring will play a big part in response and we realize that help is needed in this area. You can be sure that the Federal government will respond with assistance as was the case during the Three Mile Island accident.

Related to monitoring of airborne radiological releases is an identified need to be able to measure a dominant radioisotope, i.e., radioiodine. Under contract to us, Brookhaven National Laboratory has developed a relatively inexpensive radioiodine monitoring instrument which is currently undergoing independent evaluation by the Idaho National Engineering Laboratory (INEL).

We also have another research program with INEL to develop a series of guidance documents for the use of Federal, State and local agencies in responding to radiological emergencies. This guidance will provide information on measuring certain critical isotopes such as radioiodine, radiostrontium and radiocesium which might be components of any serious radiological release. These documents are scheduled for completion by about the end of 1980.

Finally, you should be aware that the Congress is also concerned about responses to radiological emergencies and the coordination of responses by all parties. In S.562, the Senate version of the NRC 1980 Authorization Bill, there is a requirement that the NRC develop an agency plan for response to nuclear emergencies and another requirement that the Federal government develop a Federal response plan over and above the existing Interagency Radiological Assistance Plan which is being reevaluated.

Please be assured that we do share your concerns and that we will continue to work with you to be better prepared to respond to nuclear emergencies.

Sincerely,

Joseph M. Hendrie
Chairman

Enclosures:
As stated

August 21, 1979

Mr. Alan M. Hekking
Operations Officer
State of Connecticut
Department of Public Safety
Office of Civil Preparedness
360 Broad Street
Hartford, Connecticut 06115

Dear Mr. Hekking:

Your letter of July 24, 1979 requests that the Bureau of Drugs issue general guidance on use of potassium iodide for thyroid blocking and encourage production of the drug for use by state groups in conjunction with the state Radiological Emergency Response Plan. It also suggests that the Food and Drug Administration make funds available for regional stockpiles of the drug.

In the opening paragraph of your letter you cite a letter which I wrote to Mr. Robert G. Ryan, Director of the Office of State Programs of the Nuclear Regulatory Commission, on May 21, 1978. You appear to be aware of the fact that the Food and Drug Administration published a notice in the Federal Register on December 15, 1978 inviting applicants to submit new drug applications for manufacture of potassium iodide in tablet or liquid forms for thyroid blocking in nuclear emergencies. The notice also announced the availability of guideline labeling for such products. I am enclosing copies of these documents for your use. In addition, the Federal Register of Friday, August 17, 1979, contains a notice of availability of an amended guideline labeling (also enclosed). I am enclosing a copy of this new labeling for your use.

You will note that the announcement inviting applications was in the public domain more than three months before the accident at Three Mile Island. During this time no pharmaceutical manufacturers expressed an interest in making the drug. Since the Three Mile Island accident, new drug applications for potassium iodide tablets and saturated solution were submitted by the Mallinckrodt Company of St. Louis, Illinois (in a recent acquistion, that part of the Mallinckrodt organization has been purchased by Carter-Wallace Inc., Cranbury, New Jersey). We expect that these applications will be approved shortly and that the products will be available for marketing. If the State of Connecticut is interested in purchasing a supply of potassium iodide to stockpile around nuclear

sites in Connecticut, you may wish to contact the Carter-Wallace firm and inquire about price and availability. In that regard, you may wish to contact Joseph S. Harun, M.D., Corporate Vice President, Medical and Scientific Services, Carter-Wallace, Inc., Half Acre Road, Cranbury, New Jersey, 08512, phone, 609-655-6000.

The Food and Drug Administration has long advocated the desirability of stockpiling potassium iodide products for thyroid blocking in response to radiological emergencies. We worked closely with the Ad Hoc Committee on Thyroid Blocking of the National Council on Radiation Protection and Measurements (NCRP) in the development of its Report No. 55. That report was an important element in the process through which we established the safety and effectiveness of potassium iodide for this purpose and thereby were able to waive the requirement for clinical trials and pre-clinical (animals) tests to determine the drug's safety and effectiveness as a condition of granting a new drug application. I am pleased that the applications will be approved shortly and that the drug will finally be available for stockpiling.

Speaking of stockpiling, the Food and Drug Administration is not a drug supplier. With the exception of the Three Mile Island accident, where we had a supply of potassium iodide solution manufactured and transported to Harrisburg, Pennsylvania, we have not been a supplier of drugs before and we do not intend to do so in the future. In fact, the supply that was stockpiled in Harrisburg has since been retrieved by FDA and is now being stored in an FDA facility in Arkansas. Our job is to evaluate the safety and effectiveness of drugs for marketing but not to act as a supplier. Therefore, your request for funding is not possible to grant. We believe that supplies of the drug can be made available either by State emergency response agencies purchasing and stockpiling it or by Federal (NRC) or state agencies requiring that utilities operating nuclear power plants as a condition of their operating licenses or permits, be required to purchase adequate supplies of the drugs for use by states in conjunction with emergency radiological response plans.

In terms of guidance for use of the drug, the only guidance currently available is that contained in the NCRP Report No. 55. My colleagues and I are preparing a paper which we hope to submit to the literature shortly which may be helpful in terms of amplifying some of that guidance. From the experience at Three Mile Island, it was found that in addition to the requirement for a stockpile of the drug, it was also necessary to have a detailed plan for its distribution. The State of Pennsylvania prepared such a plan and you may wish to contact Dr. Gordon MacLeod, Secretary of the Commonwealth Department of Public Health in Harrisburg, to request a copy of the Pennsylvania plan as an example of what one state has done. In addition to the distribution plan, it is also important that

the state develop a decision rule and document what conditions would have to prevail for the drug to be used and to determine who would be the official responsible for directing its use and how that decision would be communicated to the general public and environs of the plant. These are elements of state emergency response plan which can be done well in advance of actually securing a stockpile of the drug.

I hope that I have been able to clear up any misconceptions you had about the status of potassium idodide for thyroid blocking and FDA's role in terms of making it available for use. If I can be of further assistance, please feel free to contact me.

Sincerely yours,

Jerome A. Halperin
Deputy Director
Bureau of Drugs

Enclosures:
December 15, 1978 Federal Register
Guideline Labeling
August 17, 1979 Federal Register
Amended Guideline Labeling

cc:
HFA-224
JAHalperin/mkg/8/20/79