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

FEB 14 1994

Mr. Glenn S. Podonsky
Deputy Assistant for Security Evaluation
U.S. Department of Energy
19901 Germantown Road - C304
Germantown, Maryland 20874

Dear Mr. Podonsky:

The purpose of this letter is to follow-up on the telephone conversation between you and Bill Brach of my staff on January 31, 1994, concerning Nuclear Regulatory Commission coordination with the Department of Energy (DOE) on review of Atomic Energy Commission (AEC) files on studies, research and experiments involving human subjects.

During the past several weeks, NRC headquarters and regional staffs have been reviewing readily available files to identify information about former AEC licensees that may have conducted research studies using AEC-licensed radioactive materials, or the radiation therefrom, on human subjects prior to 1975. The 29 Agreement States were also requested by NRC to review their available licensee files for similar information. This information was sought to enable the NRC to respond to potential requests for information from DOE, the Presidential Task Force investigating human radiation research or any other Federal agency involved in this effort. The enclosed memorandum for the Commission summarizes the results of our efforts.

In accordance with DOE's requests, NRC has already provided DOE with copies of the Naval Radiological Defense Laboratory license documents for Camp Parks, California, and Camp Stoneman, California, and available documents on the Walter E. Fernald School and its successor, the Eunice Kennedy Shriver Center, which has a license for non-human uses. The NRC is also searching for early AEC documents describing procedures used to approve licensing requests for research on human subjects.

As discussed in the January 31, 1994, telephone conversation, the NRC would like to establish a formal liaison with your organization to coordinate any future requests for support. The NRC has received a few requests for information from the press and members of the public concerning early licensed human uses of radioactive material. The NRC would like to coordinate with

DOE the release of this information. I believe that it is important that we coordinate our actions and that NRC be responsive and aware of informational needs DOE may have. I have been designated to be the NRC point of contact for future coordination with DOE on this matter. I am also the initial point of contact for the Agreement States Programs. I understand that you are directing the development of the DOE plan for record retrieval and review process. I look forward to receiving an informational copy of this DOE plan.

If you have any questions, I can be contacted at (301) 504-2659.

Sincerely,

Carl J. Paperiello, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Commission Memo dtd 2/4/94

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NRC ANNOUNCES PROGRESS TO DATE ON REVIEW OF LICENSE FILES FOR RADIATION EXPERIMENTS ON HUMANS

The Nuclear Regulatory Commission is reporting on its review to date of available files for certain licensees that may have conducted radiation research on humans.

The agency has reviewed 80 files that contain information on licenses issued by the Atomic Energy Commission before it was dissolved and the NRC was established in 1975. The review was limited to pre-1975 data, which conforms with the President's January 15 Executive Order establishing an Advisory Committee on Human Radiation Experiments and instructing it to review human experiments conducted from 1944 to May 30, 1974.

Forty-six of the 80 files included some evidence of studies using humans in research other than radiopharmaceutical development. The majority of these involved the use of small quantities of radioactive material as tracers in metabolic studies of bodily functions.

Most of the files reviewed by the NRC did not contain the names of human subjects participating in the studies. There were indications that some researchers used institutionalized individuals (prisoners and mental patients) as well as military personnel and Department of Veterans Affairs patients in their studies. Issues concerning informed consent or ethical appropriateness of patient selection were generally not addressed in the files.

Since the review dealt with only readily available files physically located in NRC headquarters and regional offices, complete information was not available. In some cases the files contained no pre-1975 information. Old licenses and backup information, as well as records of terminated licenses, are stored in archives in the Washington, D.C., area, Oak Ridge, Tenn., and near the regional offices. Because of these limitations, NRC cannot readily confirm whether certain AEC licensees were actually conducting human research prior to 1975.

Before the NRC was established in 1975, the AEC reviewed and authorized requests for research on new drugs containing

radioactive material. Requests reviewed by AEC were subject to an exemption from the Food and Drug Administration's requirements for investigational new drugs. Shortly after the NRC was created, FDA revoked the exemption. NRC license conditions restrict the use of radioactive materials for research and development unless FDA procedures are followed. NRC depends on FDA or FDA-approved committees to review research proposals and protocols for research on new drugs containing radioactive material and other medical research on humans, including studies on metabolism.

Currently NRC's medical licensees use radioactive materials in radiopharmaceutical development studies, development of medical devices and other forms of research designed to advance medical treatment of patients. An estimated 100 to 200 of the largest medical institutions licensed by the NRC conduct human research. Institutions licensed by Agreement States also may be involved in this type of research.

To conduct the research, licensees must have an FDA-approved Institutional Review Board or other appropriate review committee approve the studies based on ethical considerations, scientific merit and radiation safety considerations. The NRC has not developed independent guidelines for these review committees, but requires confirmation that they have been approved by FDA.

Among the files that NRC reviewed were studies performed by the former Naval Radiological Defense Laboratory (NRDL) at Camp Parks and Camp Stoneman, Calif. One study involved deliberate skin contamination of the arms of individuals to test decontamination effectiveness. Unlike most files reviewed by the NRC, the NRDL files contained a document listing the names of radiation workers and volunteers who received radiation doses while participating in decontamination exercises.

In response to a Department of Energy (DOE) request, NRC retrieved an AEC license issued in 1966 (expired in 1968) to the Walter E. Fernald School for the Retarded in Waltham, Mass., for a different research project. These records also identified license guidelines for review of the experiments and include reference to obtaining parental-guardian consent. The Fernald School is now part of the Eunice Shriver Center, which has an active NRC license for non-human uses. On January 5 NRC provided documents to DOE on both of these institutions.

The NRC is also coordinating its efforts with the 29 Agreement States, which regulate most uses of nuclear material in their states, other than for nuclear power plants. NRC asked these states on January 10 to review their available licensee files for similar information related to any authorization for human use research.

To date, six Agreement States have determined, through a review of their files and interviews with present and former employees, that some evidence exists to indicate potential authorization of human research. The remaining 23 Agreement States indicate that they found no evidence of any authorization for human research use other than for radiopharmaceutical development. The NRC intends to assist in obtaining any further information from the Agreement States, if requested by the Human Radiation Interagency Working Group.

The NRC and Agreement States did not review files for examples of participation by patients or healthy individuals in research trials for the development of drugs containing radioactive materials. Because of time and resource constraints, this type of research was excluded in order to capture the types of nutritional, scientific, military and other human-use research studies believed to be of greater public interest.

The NRC notes that a better picture of the AEC human research studies involving radioactive material could be obtained from a systematic search of the archived files. However, due to the resource-intensive effort needed to review over 30,000 files in multiple locations, the NRC does not plan to retrieve and review all archived files. Also, the search might only duplicate the ongoing efforts of DOE (and other federal agencies) to locate information on human experiments, since DOE and NRC are both successors of the former AEC.

However, in support of the Interagency Working Group, NRC will continue discussions with representatives of the Group's various government agencies (such as DOE, Department of Veterans Affairs, Department of Navy, and Department of Air Force) and respond to their requests as needed. As a part of this effort, the NRC will give DOE new information on the Fernald School or other research studies as it is requested or becomes available.

In addition, the NRC plans to retrieve information for four licensees--MIT, Harvard University, Massachusetts General Hospital and the University of Cincinnati--for an in-depth review. These licensees are known to have had active human research programs before 1975.

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