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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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