UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 4, 1994

MEMORANDUM FOR: The Chairman
Commissioner Rogers
Commissioner Remick
Commissioner de Planque

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: SURVEY OF NRC RECORD FILES FOR RECORDS RELATED TO RESEARCH INVOLVING HUMAN SUBJECTS

This memorandum summarizes the following: (1) the results of the staff's survey to determine what readily available Commission and Agreement State files may have information about licensees that may have conducted research studies using AEC licensed radioactive materials, or the radiation therefrom, on human subjects; (2) a description of the types of human research currently authorized by Nuclear Regulatory Commission materials licenses and the review criteria for those authorizations; and (3) a summary of future actions.

Survey Results

The staff's survey of available and accessible information is limited to pre-1975. This conforms with later guidance provided in President Clinton's January 15, 1994, Executive Order: "Advisory Committee on Human Radiation Experiments" (Enclosure 1) which, among other things, established the advisory committee, instructed the committee to review human experiments conducted from 1944 to May 30, 1974, and defined "human radiation experiments."

A. Information sources. The staff identified the information sources described in Enclosure 2 that may be helpful in locating specific files for retired or archived license documents and identifying facilities that may have had human research programs in the late 1940's and early 1950's.

B. Survey of Currently Active and Available Files. To determine the extent of human use research information available in the active NRC license files, the regions targeted certain kinds of licenses and reviewed them for evidence of pre-1975 studies using humans in research (see Enclosure 3). The regions were not asked to review files for examples of participation by patients or healthy individuals in trials for the

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development of drugs containing radioactive materials. The staff believed, with the proposed survey's time and resource constraints, this type of research had to be excluded in order to capture the types of nutritional, scientific, military, and other human-use research studies of interest to the public and the media. The Office of State Programs also asked the Agreement States to review their active files for the same type of information.

The regions identified a sample of 80 licensees that met the selection guidance (e.g., large research and medical licensees) identified in the memorandum in Enclosure 3, and reviewed the available records for each. Based on licensing and inspection documents, 46 licensees were identified that may have conducted non-radiopharmaceutical development human research. The majority of the studies involved limited quantities of tracers used in metabolic studies on research subjects. Human research subjects may be healthy individuals, patients included in research studies unrelated to their conditions, or patients included in research studies of their conditions. None of the active files contained the names of the 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. Because most of the information came from copies of licenses and not the licensees' requests and clarifications, questions concerning informed consent or ethical appropriateness of patient selection were generally not addressed. A summary of the regional reviews (which includes a small number of available retired files from Region V) is provided in Enclosure 4, and a summary of Agreement State findings, to date, is provided in Enclosure 5.

Since this review was limited to available information in the active license files, it was difficult to confirm whether licensees were conducting human research before 1975. In a number of cases, the active license files contain no pre-1975 information. Both the retirement of terminated licenses and archiving of the old materials license and backup information are important factors in not being able to determine if licensees were actually conducting human research before 1975. A better picture of the human research studies might be achieved by a systematic search of the archived files. However, this would be a very resource intensive review because the files are in multiple locations and manual searches are needed and may only duplicate the Department of Energy's (DOE's) ongoing review efforts. The archived files are stored in boxes that contain commingled medical, human use, and industrial research and development license files. Before 1965, there were 10,674 docket files/general license files and folders. From 1965 to 1985, there were over 20,000 active byproduct materials license and inspection files.

In response to a specific request by a Philadelphia television reporter, Region I redacted the privacy information from the active files of 15 large medical use licensees. Two of these files were reviewed during the survey for human research information and the remaining 13 will be reviewed before release. A knowledgeable regional reviewer will be available to assist the reporter and put the information in the files into context.

C. **Limited Review of Retired and Archived Documents.** Region V reviewed specific available retired license files for human research information on studies performed by the Naval Radiological Defense Laboratory (NRDL) at Camp Parks, California, and Camp Stoneman, California. One study involved deliberate skin contamination with a short half-life radionuclide, on the arms of individuals, to test decontamination effectiveness. A document in the NRDL file lists the names of radiation workers and volunteers who received radiation doses while participating in the "Camp Stoneman II" decontamination exercises.

NMSS reviewed specific retired license files for human research studies performed at the Walter E. Fernald School for the Retarded, in Waltham, Massachusetts. The Fernald school license backup information indicated that consent would be provided for the research subjects. Other retired files for the Massachusetts Institute of Technology (MIT), Massachusetts General Hospital, and Harvard University have been retrieved because these facilities may have participated in earlier studies at the Fernald School. However, these files have not been reviewed at this time.

D. **The U.S. Department of Energy (DOE) Requested Information.** DOE requested assistance in locating AEC licensing information on Camp Parks decontamination studies and the radioactive nutritional research on students at the Walter E. Fernald School for the Retarded, in Waltham, Massachusetts. Region V provided DOE with copies of the Naval Radiological Defense Laboratory license documents for Camp Parks and "Camp Stoneman II" studies. NMSS staff identified a human-use AEC license issued in 1966 (expired in 1968) to the Fernald School for a different radioactive research project. The Fernald School is now part of the Eunice Kennedy Shriver Center which has an active license for non-human uses. NMSS provided documents from the Fernald School and Eunice Kennedy Shriver Center license files to DOE on January 5, 1994. These records also identified license guidelines for review of the experiments and include reference to obtaining parental-guardian consent. The staff has established contacts within DOE for coordination and will attempt to provide information, as requested.

DOE also requested early AEC documents describing procedures used to approve licensing requests for research on human subjects. NMSS staff reviewed available historical reports of the AEC (i.e., available Semiannual Reports of the AEC from 1947 to 1960), and available meeting minutes of the Advisory Committee on Isotope Distribution (established January 1948) and the Advisory Committee on Medical Uses of Isotopes (established in 1958).

Two referenced documents were identified as possible sources for guidance on the use of normal subjects for experimental purposes. These documents are: "The Medical Use of Isotopes: Recommendations and Requirements," published in 1955 by the AEC Isotopes Division; and the AEC Licensing Guide - Medical Programs, "A Guide for the Preparation of Applications for the Medical Use of Radioisotopes," published February 1957 and designated RC-12. To date, neither document can be located. We located a copy of the 1965 AEC license guide that superseded the 1957 document and will provide a copy to DOE. Staff is continuing to search for the two licensing guides referenced above, and, if successful, will provide copies to DOE.

E. **Post-1975 License File Information.** Although the survey was limited to before 1975, one of the regions did observe and record that 12 licensees were authorized to conduct human research after 1975 (under the controls discussed below). No additional information was gathered by NRC about the post-1975 human research authorizations.

Current NRC Practices for Authorizing Human Use Research

A. **Regulations.** NRC regulations in Title 10, Code of Federal Regulations, Part 30, explicitly specify that the general authorization for research and development does not include administration of byproduct material, or the radiation therefrom, to human beings. NRC's regulations and licenses do permit research into the development of new drugs using byproduct material and for obtaining scientific information at institutions meeting specific criteria. The Food and Drug Administration (FDA) has specific regulations for the control of this type of research and reviews investigational proposals for new drugs containing radioactive materials. NRC published proposed regulations for, among other things, research involving human subjects on June 17, 1993. The proposed rule would require, at a minimum, that licensees obtain informed consent from human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board."

It is important to note that before 1975, the AEC authorized use of investigational new drugs containing byproduct material. In 1963, FDA adopted regulations requiring FDA submittals for all proposals for use of investigational drugs. FDA granted an exemption from this regulation for radioactive drugs approved for use by the AEC. In 1975, FDA began to exercise its regulatory authority in this area. NRC's regulations were changed to provide that any licensee may use any investigational new drug for which FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug."

B. **Licensing Guidance.** NRC's medical use licensees currently participate in radiopharmaceutical development studies, development of medical devices, and other forms of medical research designed to advance medical treatment of patients. NRC staff also grants the authorization to

perform other types of human research to some medical licensees. The staff estimates 100 to 200 of the NRC's largest medical institutions are participating in human research. Since there are more Agreement State than NRC licensees, the staff expects more Agreement State licensees may be participating in this type of research. This research may be performed to obtain information about metabolism, biodistribution of compounds, monitor patient treatments, or develop screening studies. The licensing criteria for issuing this authorization includes a commitment that the licensee has and uses an Institutional Review Board, or other appropriate review committees to approve the studies based on ethical considerations, scientific merit, and radiation safety considerations. The staff has not developed independent guidelines for these review committees, but requires confirmation that the committees, as constituted, have been approved by FDA. The staff intends to revise future inspection instructions to require inspectors to review licensees' implementation and use of review committees and the committees' approval procedures for human-use research.

C. **Follow-up of Human Research Subjects.** The staff is unaware of any formal government medical follow-up of human research subjects before the current government-wide review. However, NRC's procedures for following up of significant occupational exposures or medical misadministrations is to refer the involved subject to DOE's Office of Epidemiology and Health Surveillance, which sponsors a voluntary lifetime morbidity study of personnel involved in radiation incidents. This study includes the gathering of clinical and epidemiological data at an early stage following a significant exposure to radiation, and continues throughout the lifetime of the individual involved. The purpose of this study is to compile the best human radiobiological data available for improving immediate medical care, to develop the best prophylactic and anticipatory care for possible late effects, and to upgrade the bases for radiation risk estimates.

Participation in the follow-up program is totally voluntary, and individuals may stop their participation at any time. The medical information obtained during participation is covered by legal constraints, to protect the identity and privacy of living participants. Any expenses involved in providing medical records to the follow-up program are borne by the program and not the individual.

Future Activities

A. **File Review.** Based on the current review, the staff believes only a few of the active files will have backup information on pre-1975 human research studies. The reviewed active files contained only limited consent information and did not include specific names of research subjects. The staff believes the retired and archived files may contain the licensees' specific requests and clarifications. The archived information should be more informative and may name some specific research subjects. A more extensive review including archived files would be very resource-intensive and would require use of contractor

assistance. Any major information collection effort by the staff will require significant diversion of NRC's program resources.

The staff does not intend to make a broad effort to retrieve all the archived files. The staff will retrieve the retired licenses and archived files for 4 licensees and have a contractor review their contents. MIT, Harvard University, Massachusetts General Hospital, and the University of Cincinnati were selected for this indepth review. They were selected because they had active human research programs before 1975, the media identified them as participating in research of interest to the "Advisory Committee on Human Radiation Experiments," and the information in their files is probably similar to that in other archived files.

The staff, or a contractor, will retrieve and review other AEC-NRC files in cooperation with the ongoing efforts described in paragraph B or in response to specific requests by other government agencies or members of the public.

B. **Response to Government Requests.** The staff will continue discussions with representatives of various government agencies (e.g., DOE, the Department of Veterans Affairs, the Department of the Navy, and the Department of the Air Force) needing information NRC or the Agreement States possess, to support the President's Task Force. The staff contacted Glenn S. Podonsky, the DOE point of contact, and prepared the enclosed letter to offer NRC assistance in DOE's review of old AEC records currently maintained by NRC or the Agreement States and to identify the NRC point of contact for NRC-DOE coordination (Enclosure 6).

We will provide DOE with new information on the Walter E. Fernald School for the Retarded or other research studies, as it is requested or becomes available. Future responses will be made, as needed, for those specific requests from other government agencies for information contained in active or retired AEC-NRC files. We will also continue to work with the Agreement States to meet specific needs for information from Agreement State program files.

C. **Release of Information to the Public.** The Office of Public Affairs has prepared a press release (Enclosure 7) to apprise the public of NRC activities.

The staff plans to place in the Public Document Room (PDR): (1) this staff memorandum to the Commission; (2) the regional memoranda responding to the Hugh L. Thompson, Jr., memorandum to the Regional Administrators dated January 7, 1994; and (3) the Agreement State letters responding to the Office of State Programs letter (in Enclosure 4, dated January 10, 1994, from Richard L. Bangart) requesting review of the available state licensing files for human-use research.

Interested members of the public can request review of license files, identified by the regional memorandums, in the normal manner, i.e., at the PDR or regional offices.

James M. Taylor
Executive Director
for Operations

Enclosures:
1. Executive Order dtd 1/18/94
2. Info Sources for AEC Licensees Involved in Human Research
3. Memo dtd 1/7/94, from H. L. Thompson, Jr. to Rgns
4. Summary of NRC Active Files Survey
5. Status of Agreement State Info RE Authorization for Human Use
6. Staff Ltr to DOE
7. Draft Press Release

cc: SECY
OCA
OGC
OPA

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

January 18, 1994

EXECUTIVE ORDER

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ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Establishment. (a) There shall be established an Advisory Committee on Human Radiation Experiments (the "Advisory Committee" or "Committee"). The Advisory Committee shall be composed of not more than 15 members to be appointed or designated by the President. The Advisory Committee shall comply with the Federal Advisory Committee Act, as amended, 5 U.S.C. App. 2.

(b) The President shall designate a Chairperson from among the members of the Advisory Committee.

Sec. 2. Functions. (a) There has been established a Human Radiation Interagency Working Group, the members of which include the Secretary of Energy, the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of Veterans Affairs, the Attorney General, the Administrator of the National Aeronautics and Space Administration, the Director of Central Intelligence, and the Director of the Office of Management and Budget. As set forth in paragraph (b) of this section, the Advisory Committee shall provide to the Human Radiation Interagency Working Group advice and recommendations on the ethical and scientific standards applicable to human radiation experiments carried out or sponsored by the United States Government. As used herein, "human radiation experiments" means:

(1) experiments on individuals involving intentional exposure to ionizing radiation. This category does not include common and routine clinical practices, such as established diagnosis and treatment methods, involving incidental exposures to ionizing radiation;

(2) experiments involving intentional environmental releases of radiation that (A) were designed to test human health effects of ionizing radiation; or (B) were designed to test the extent of human exposure to ionizing radiation.

Consistent with the provisions set forth in paragraph (b) of this section, the Advisory Committee shall also provide advice, information, and recommendations on the following experiments:

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ENCLOSURE 1

(1) the experiment into the atmospheric diffusion of radioactive gases and test of detectability, commonly referred to as "the Green Run test," by the former Atomic Energy Commission (AEC) and the Air Force in December 1949 at the Hanford Reservation in Richland, Washington;

(2) two radiation warfare field experiments conducted at the AEC's Oak Ridge office in 1948 involving gamma radiation released from non-bomb point sources at or near ground level;

(3) six tests conducted during 1949-1952 of radiation warfare ballistic dispersal devices containing radioactive agents at the U.S. Army's Dugway, Utah, site;

(4) four atmospheric radiation-tracking tests in 1950 at Los Alamos, New Mexico; and

(5) any other similar experiment that may later be identified by the Human Radiation Interagency Working Group.

The Advisory Committee shall review experiments conducted from 1944 to May 30, 1974. Human radiation experiments undertaken after May 30, 1974, the date of issuance of the Department of Health, Education, and Welfare ("DHEW") Regulations for the Protection of Human Subjects (45 C.F.R. 46), may be sampled to determine whether further inquiry into experiments is warranted. Further inquiry into experiments conducted after May 30, 1974, may be pursued if the Advisory Committee determines, with the concurrence of the Human Radiation Interagency Working Group, that such inquiry is warranted.

(b)(1) The Advisory Committee shall determine the ethical and scientific standards and criteria by which it shall evaluate human radiation experiments, as set forth in paragraph (a) of this section. The Advisory Committee shall consider whether (A) there was a clear medical or scientific purpose for the experiments; (B) appropriate medical follow-up was conducted; and (C) the experiments' design and administration adequately met the ethical and scientific standards, including standards of informed consent, that prevailed at the time of the experiments and that exist today.

(2) The Advisory Committee shall evaluate the extent to which human radiation experiments were consistent with applicable ethical and scientific standards as determined by the Committee pursuant to paragraph (b)(1) of this section. If deemed necessary for such an assessment, the Committee may carry out a detailed review of experiments and associated records to the extent permitted by law.

(3) If required to protect the health of individuals who were subjects of a human radiation experiment, or their descendants, the Advisory Committee may recommend to the Human Radiation Interagency Working Group that an agency notify particular subjects of an experiment, or their descendants, of any potential health risk or the need for medical follow-up.

(4) The Advisory Committee may recommend further policies, as needed, to ensure compliance with recommended ethical and scientific standards for human radiation experiments.

(5) The Advisory Committee may carry out such additional functions as the Human Radiation Interagency Working Group may from time to time request.

Sec. 3. Administration. (a) The heads of executive departments and agencies shall, to the extent permitted by law, provide the Advisory Committee with such information as it may require for purposes of carrying out its functions.

(b) Members of the Advisory Committee shall be compensated in accordance with Federal law. Committee members may be allowed travel expenses, including per diem in lieu of subsistence, to the extent permitted by law for persons serving intermittently in the government service (5 U.S.C. 5701-5707).

(c) To the extent permitted by law, and subject to the availability of appropriations, the Department of Energy shall provide the Advisory Committee with such funds as may be necessary for the performance of its functions.

Sec. 4. General Provisions. (a) Notwithstanding the provisions of any other Executive order, the functions of the President under the Federal Advisory Committee Act that are applicable to the Advisory Committee, except that of reporting annually to the Congress, shall be performed by the Human Radiation Interagency Working Group, in accordance with the guidelines and procedures established by the Administrator of General Services.

(b) The Advisory Committee shall terminate 30 days after submitting its final report to the Human Radiation Interagency Working Group.

(c) This order is intended only to improve the internal management of the executive branch and it is not intended to create any right, benefit, trust, or responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers, or any person.

WILLIAM J. CLINTON

THE WHITE HOUSE,
January 15, 1994.

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INFORMATION SOURCES FOR THE U.S. ATOMIC ENERGY COMMISSION LICENSEES INVOLVED IN HUMAN RESEARCH

1. BACKGROUND

In the early days of the U.S. Atomic Energy Commission (AEC), facilities were not licensed. Therefore, the list of the institutions associated with the national laboratories provides the earliest identification of institutions with research reactors or using AEC regulated materials. The list of "current" unclassified AEC contracts for medical, chemical and physical science research provides the first public information of the types of research being funded by the AEC. Up until 1955-56, supplies of reactor-produced radionuclides were limited, and the AEC "allocated" specific radionuclides to individual researchers in research facilities. Many early research facilities had working relationships with research-oriented medical institutions. When the supplies were considered adequate, AEC stopped issuing allocation documents and began to issue licenses. The earliest Agreement State program originated in 1960. Before this time, all the available records are AEC records. The active licensing files, which may have contained early AEC "allocation" and licensing documents, were transferred to the States as they became Agreement States. The AEC and appropriate Agreement States would have the license files authorizing human use from 1960 to 1975. As licenses were retired and backup information was superseded, these records were archived by the AEC, the U.S. Nuclear Regulatory Commission, and the Agreement States.

2. HISTORICAL DOCUMENTS

Reports. Two lists found in the "Semiannual Reports of the AEC" identify early AEC licensees with possible involvement in human research studies. The first lists AEC research centers and institutions associated with the national laboratories from 1947 on. The second provides the names and a brief description of the "current" AEC unclassified research contracts for biological, medical, and physical studies for the years 1949, 1951, 1952, 1956, and 1959. These lists include facilities located in the Agreement States.

License Card File. The "License Card File" in the Document Control Center of One White Flint North contains AEC license issuing data from 1955-56 when the first AEC materials licenses were issued. Before that time, the AEC "allocated" byproduct material, because of its scarcity, to specific individuals and institutions. This card file identifies AEC-NRC licensees by institution identification codes and lists all licenses issued to each code. The individual institution code cards contain a sequential listing of all licenses issued to that institution by license number, and includes the date of each initial new license request, the name of the authorized users, and the isotopes listed on the license.

The card file provides a means of identifying expired and superseded licenses. This information is not found in the regions, because the expired licenses and early licensing information have been archived. Some of the former AEC licensees are now located in Agreement States. Neither the information from the license cards nor the location of the archived files for most of the pre-1965 backup files is available in any automated computer system and must be searched manually.

Archived NRC License Files. The Office of Nuclear Materials Safety and Safeguards (NMSS) has archived license files that are stored in the Washington, DC area and Oak Ridge, Tennessee. The regions have additional archived records in storage. NMSS archived records include licenses and older backup documents that were retired when the "active" license files were sent to: the States, when they became Agreement States; the regions, when the licensing activities were regionalized; and the Navy and Air Force, when they became "Master Material Licensees."

When radionuclides were "allocated" by the AEC, the "allocation documents" contained information on the radionuclide, the amount allocated to each researcher, and a brief description of the specific research project. These "allocation documents" were superseded by AEC licenses in 1956-57 when radionuclide supplies became adequate. Mr. Richard E. Cunningham believes that some of these allocation documents are in the institution files that became the early AEC license files. It was not unusual for large research programs, with AEC licenses in 1956-57, to receive 19 to 20 separate new licenses a year, until the 1960's and 70's, when these licensing activities were consolidated into a broad research and development license. These files should also include voting sheets used by the Advisory Committee on Medical Uses of Isotopes in deciding whether to recommend that AEC authorize the licensees' human research or uncommon practice requests. Most of these early licenses, which seem to have been issued for each distinct research project, were retired prior to the assumption of licensing activities by Agreement States, NRC regions, and Master Material Licensees.

Agreement States Archived Files. The Agreement States may have retired or archived documents from retired and active licensing files that cover the pre-1975 timeframe. States that became Agreement States after the mid 70's probably do not have licensing or "allocation" documents before the mid 60's.

3. CURRENT DOCUMENTS

U.S. Department of Energy (DOE) list of DOE Contract Recipients. Per NRC request, DOE provided a list of DOE human research contract recipients, as an identification source for NRC licensees. DOE provided 21 pages entitled, "Current Human Subjects Research Projects - Work for Others by Respective Laboratory", 24 pages entitled "Current Human Subjects Research Projects by Respective Laboratory", and one page entitled "Current Human Subjects Research Projects Addendum." Agreement State facilities are also listed in these documents. The DOE contract lists were compared to the historical lists of AEC contracts, but no new information was found.

Active NRC Regional License files. The regions used broad guidance, provided in the January 7, 1994, memorandum to the Regions from Mr. Hugh L. Thompson, Jr., to identify active licensees that may have participated in human research with radioactive material or radiation before 1975. This guidance specifically excluded human use research involving the development of radiopharmaceuticals (i.e.,to exclude examples of participation by patients or healthy individuals in trials for the development of drugs containing radioactive materials). Staff wanted to ensure the identification of other types of research (e.g., nutritional, scientific, military) studies of interest to the public and the media. The regions identified a sample of 60 licensees that met the identification criteria and reviewed the license files. Although the active license files included copies of a number of AEC license amendments and renewals, for the most part, they did not include the pre-1975 licensee requests, AEC request for clarification, licensee responses, and the licensee's retired licenses. These documents were archived.

Active Agreement State License Files. The Agreement States were also asked to identify and review license documents for licensees meeting the guidance criteria in the January 7, 1994, memorandum from Mr Thompson. The Agreement States were asked to provide responses by January 25, 1994.

4. PERSONAL RECOLLECTION

Additional licensees were identified by present and past NRC employees, based on memories of inspection and licensing as well as memories of work experience outside NRC. Information on specific human research studies was recalled, but the regions lacked licensing documents to confirm all the information. Some of the licensees identified by this manner are located in the Agreement States.

Region III staff identified four licensees that may have conducted some human medical research activities. The first three were Proctor and Gamble, UpJohn Corporation, and Borgess Medical Center Hospital. The staff had no specifics pertaining to these licensees; they were not authorized to perform medical research; and there were no documents, in the file, that would indicate that medical research was conducted. The fourth was the University of Cincinnati (Dr. Eugene Saenger's research activities). The staff believes Dr. Saenger was involved with human research studies in the 1950's. Although the University of Cincinnati file was reviewed, there was no indication of Dr. Saenger's association with the one research study found or any other research. References to Dr. Saenger's research are probably in the archived files.

In Region V, three former NRC radiation specialists recalled specific examples of studies involving human research. One recalled first-hand examples of human research other than New Drug Applications. His recollections of three instances occurring at the Naval Radiological Defense Laboratory, while he was employed by the AEC licensee, are included in the region's review. The second recalled that he had participated in an AEC inspection assignment in Philadelphia, during which testing on prisoners was discussed. He was not sure if the testing was ever actually conducted. The region passed that information on to Region I, for follow-up. The third believed that the Universities of

California at Los Angeles and San Francisco; the University of Oregon at Portland; and the U.S. Naval Hospital, at San Diego, were authorized to conduct human research before the U.S. Food and Drug Administration oversight committees were in place. The region did not have those files.

Two Headquarters employees recalled separate types of human-use studies. The first identified thermal neutron-boron capture treatments at the Massachusetts Institute of Technology (MIT) and Brookhaven National Laboratory. Staff is reviewing the MIT records. The second remembered a proposal to perform studies using prisoners at a prison in Walla Walla, Washington.