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

January 7, 1994

MEMORANDUM FOR: Those on Attached List

FROM: Hugh L. Thompson, Jr.
Deputy Executive Director for Nuclear
Materials Safety, Safeguards and
Operations Support, EDO

SUBJECT: REVIEW OF LICENSE FILES FOR RECORDS RELATED TO RESEARCH INVOLVING HUMAN SUBJECTS

This memorandum is to request each Region to conduct a review of available license files for certain licensees likely to have conducted medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975. The purpose of this review is to identify those files containing information on experiments in which humans were deliberately exposed to radiation for purposes other than radiopharmaceutical development. For example, experiments such as studies where volunteers were used to clean up deliberately contaminated sites or studies performed to determine the potential harmful and beneficial effects of radiation exposure to humans should be reviewed.

The regional staff should select the specific licensees meeting the following criteria and review the license files in their entirety, starting with the earliest available records:

1. Military (Department of Defense(DOD)) research facilities and affiliates

2. Military hospitals and medical centers

3. Broad scope facilities for licenses issued before 1975 to include:

   a) Land grant universities and colleges
   b) Department of Veterans Administration hospitals
   c) Large state and private medical research and teaching facilities.

Initially, the review should be targeted at research facilities that are associated with a long history of involvement in these types of experiments. It may also be beneficial to talk to long-time NRC staff members who may recall specific licensees who conducted human radiation biology experiments or other experiments on humans. For this initial review, you should try to review all of the most likely candidates but no fewer than five licenses.

The following information should be submitted to the Office of Nuclear Material Safety and Safeguards (NMSS) for each file reviewed: license number, docket number, institutional name, and whether there was evidence of radiation

ENCLOSURE 3

studies involving humans. If no evidence of human research is identified, that fact should be reported. If evidence of human research is identified, provide a brief description of the research that includes: 1) dates of the studies; 2) types and purpose of research studies; 3) whether identification of individual research subjects is available; 4) range of activities or doses reported; and 5) sponsor of research (e.g., DOD, AEC, etc.). NMSS will share the information with the current Presidential Task Force via the Department of Energy (DOE) to assure a uniform federal response to inquiries. Similarly, if you otherwise obtain information regarding individual subjects of radiation experiments, that knowledge will be shared with DOE. The information will be reviewed to ensure that it can be made available pursuant to applicable Federal laws regarding disclosure of such information.

Although, at this time, the review is limited to available files, if there is evidence that information may be available in archived files, the region should make note of that for possible future use. Due to the heightened public awareness of many radiation studies, the requested information should be forwarded to this Office by noon January 14, 1994.

In addition, a summary, entitled "Background Information on Human Research involving Radioactive Materials," is enclosed. This summary should be read by your staff and referred to when responding to inquiries from the regulated community and members of the public.

The contact for this project is John E. Glenn of this staff. Any questions concerning this review should be directed to him at (301) 504-3418.

Hugh L. Thompson, Jr.
Deputy Executive Director for Nuclear
Materials Safety, Safeguards and
Operations Support, EDO

Enclosure: As stated

Background Information on Human Research Involving Radioactive Materials

The NRC does not conduct or directly fund research on human beings. NRC issues licenses to authorize medical research by its licensees based on an applicant's representations that it performs research in accordance with regulations of the Food and Drug Administration. Other types of human research administrations of radiation or radioactive material may be authorized on an NRC license if the applicant demonstrates that the appropriate FDA approved committees have been established, such as a Radioactive Drug Research Committee or Institutional Review Board or Committee. The NRC currently does not have separate regulations or review procedures but depends upon FDA or FDA approved committees to review research protocols in accordance with FDA regulations on such matters as conflict-of-interest or informed consent. The NRC does not inspect its licensees for compliance with FDA regulations. If NRC becomes aware of information or allegations about violations of FDA requirements, it will share those findings with FDA as part of a Memorandum of Understanding. A Proposed Rule was published on June 17, 1993, which would require that human research be conducted only in accordance with the Uniform Federal Policy on Research in Humans, and any proposed research not in compliance with the Federal Policy must receive prior approval by NRC.

The Atomic Energy Commission (AEC) was established by the Atomic Energy Act of 1946 to develop programs for the production and distribution of fissionable materials, development of nuclear reactors primarily aimed at the production of power, and safe industrial use of nuclear materials. AEC operated several research laboratories to advance the field of nuclear science by providing large scale qualified staff and expensive equipment which private industry could not financially afford. At the direction of AEC, some laboratories conducted research studies to determine the potential harmful and beneficial effects of radiation exposure to humans. Most of this AEC work was done by AEC contractors or subcontractors on an unlicensed basis. In an effort to promote the safe use of radiopharmaceuticals for patient diagnosis and therapy at hospitals and other medical facilities, AEC established investigational radioactive drug approval procedures for new drugs or uses, including drug safety and efficacy. With the dissolution of AEC in 1975, licensed AEC activities were transferred to the newly established NRC while AEC-sponsored research activities were transferred to an organization later incorporated into the U.S. Department of Energy. Also in 1975, FDA revoked a 1963 exemption for radioactive drugs from FDA's investigational drug regulations. As a result, NRC took over the licensing of, possession and use of radioactive materials formerly performed by the AEC but not the safety and efficacy review of new radioactive drugs nor the AEC contractor oversight. Thus NRC became the regulator and custodian of AEC issued licenses.

Some of these license files may contain information regarding individuals who were the subjects of research investigations or experiments using licensed radioactive materials or radiation from these materials. NRC's regional offices have been asked to review those files which they believe are most likely to contain information about individual human subjects (large teaching hospitals or research labs). If NRC identifies, or otherwise learns of information regarding individual subjects of radiation experiments, it will share that information with the current Presidential Task Force via the Department of Energy to assure a uniform federal response to inquiries. Information will be made available in accordance with applicable Federal laws regarding disclosure of such information.

ENCLOSURE

MEMORANDUM FOR: Those on Attached List Dated:

SUBJECT: REVIEW OF LICENSE FILES FOR RECORDS RELATED TO RESEARCH INVOLVING HUMAN SUBJECTS

Thomas T. Martin,
Regional Administrator, Region I

Stewart D. Ebneter
Regional Administrator, Region II

John B. Martin
Regional Administrator, Region III

L. J. Callan
Regional Administrator, Region IV

Kenneth E. Perkins
Acting Regional Administrator, Region V

SUMMARY OF NRC ACTIVE FILES SURVEY

TYPE OF LICENSE REVIEWED	TOTAL REVIEWED	HUMAN RESEARCH INFORMATION IN FILES YES	NO*	METABOLIC STUDIES[1]	DRUG RELATED STUDIES[2]	THERAPY STUDIES[3]	OTHER	INSTITUTIONALIZED SUBJECTS
UNIVERSITY	13	5	8	4**	1	3	S, U	H, ?H, P
VA HOSPITAL	27	17	10	>65	>10	1	17I, 6U	
MILITARY HOSPITAL	5	3	2	35	3		2I	
UNIV HOSPITAL	13	6	7	10	1	1	2I, 3U	H, P
RESEARCH HOSPITAL[4]	7	7		18	4	1	U	H, 3P, O
HOSPITAL	8	2	6				2I, 2S, U	
GOVERNMENT	7	6	1	23	1		2I, 2S, 2M	
TOTALS	80	46	34	>155	>20	6	25I, 5S, 12U, 2M	3H, ?H, 5P, O

KEY

1 - TRACER QUANTITIES OF BYPRODUCT MATERIAL IN NORMAL BODY CONSTITUENTS (E.G., SALTS, AMINO ACIDS, SUGARS, FATS) TO MONITOR NORMAL OR STRESSED HUMAN METABOLISM

2 - CAN BE EITHER OF TWO TYPES: (A) SMALL QUANTITIES OF BYPRODUCT MATERIAL LABELED TO CONVENTIONAL DRUGS TO MONITER THE DRUG'S METABOLISM; (B) RADIOPHARMACEUTICALS TO MONITOR CONVENTIONAL DRUG ACTION AND MEDICAL PROCEDURES

3 - SEALED OR UNSEALED SOURCES OF BYPRODUCT MATERIAL IN EXPERIMENTAL TREATMENT OF MEDICAL CONDITIONS

4 - INCLUDES THE NATIONAL INSTITUTES OF HEALTH

* - SOME ACTIVE FILES HAD NO PRE-1975 INFORMATION
** - INDICATES NUMBER STUDIES IDENTIFIED IN RECORDS

I - INJECTED/INGESTED IMAGING RESEARCH
[2I - 2 IMAGING STUDIES COULD BE IDENTIFIED]
S - SEALED SOURCE IMAGING RESEARCH
U - UNKNOWN RESEARCH
M - MILITARY RESEARCH INVOLVING CONTAMINATION
P - PRISONERS
H - MENTAL PATIENTS
?H - MENTAL PATIENTS MAY NOT BE INSTITUTIONALIZED
O - RESIDENTS OF AN OLD SOLDIERS' HOME

STATUS OF AGREEMENT STATE INFORMATION
REGARDING AUTHORIZATION FOR HUMAN USE

On January 10, 1994, the 29 Agreement States (A/S) were requested by NRC's Office of State Programs to review their available licensee files for information relative to any authorization for human use research (SP-94-011). As of February 1, 1994, six A/S determined, through a review of their files and interviews with present and former employees, that some evidence exists to indicate potential authorization of human use research. The remaining 23 A/S indicated they found no evidence of any authorization for human use research other than for radiopharmaceutical development. The NRC intends to assist in obtaining further information from the A/S, if requested by the Presidential Task Force. Below is a brief synopsis of each State's response to SP-94-11.

Arkansas Department of Health: Letter from Greta Dicus, Director, Division of Radiation Control and Emergency Management, dated January 18, 1994: University of Arkansas at Fayetteville's license file indicates that none of the research projects involved human exposures for experimental purposes. The University of Arkansas for Medical Sciences' license file indicates that research projects did involve human exposures but all of these projects appear to be associated with radiopharmaceutical research and were not bioeffects studies.

California Department of Health Services: Letter from Edgar Bailey, Chief, Radiologic Health Branch, dated January 18, 1994: California has identified 9 radioactive materials licensees that might have conducted experiments in which humans were deliberately exposed to radiation for purposes other than radiopharmaceutical development prior to 1975. Since all licensees identified are broad scope licensees and have authority to issue their own use permits for research projects, documentation was not required to be submitted to the California regulatory program for review. The documentation was, however, required to be maintained by the licensee and made available for inspection.

Mr. Bailey has requested that NRC provide him with any similar information that the NRC has with regard to the State of California.

Colorado Department of Health: Letter from Robert Quillin, Director, Radiation Control Division, dated January 13, 1994: Colorado has conducted some interviews with Dr. Conrad Riley who was Chair of the very first "Human Research Committee," beginning in the late 1960's at what was then the University of Colorado Medical Center and Dr. Marvin Daves, who is still with the Colorado's Department of Radiology, and was the Chairman of the Department of Radiology beginning in 1961, with continuing major involvement in the "Institutional Radiation Committee." Documents from the 1960's indicate authorizations to use byproduct materials at several off-campus locations, including the State Home and Training School in Wheatridge, the Colorado State Penitentiary, and Regis College. Based on the nature of these locations of use, one might logically surmise that human study populations at those institutions would have been involved.

The Committee files go back to 1969, with a complete summary log of authorized protocols beginning in 1970 (date, investigator's name, radionuclide, amount

authorized, designation of human vs. non-human use), although Colorado is not sure that they can locate the rest of the related applications. Any detailed information on the early studies would probably require arduous efforts at locating and interviewing faculty members from those times, in order to determine the names of the responsible investigators and considerable research work in followup, if any records can be located at all. A more expeditious way to locate relevant records might be to locate the letters from the University of Colorado Medical Center to the AEC to request license amendments to License No. 5-902-5, if they are in the AEC files, wherever those files are located. Colorado does not possess copies of those letters.

A January 14, 1994 letter to Bob Quillin from Janet A. Johnson, Colorado State University (CSU) indicates that interest in radiation bioeffects and use of tracers in biological research at CSU dates back to 1959. Two incidents have been identified. One involved administration of 1.0 microcurie of K-42 to each of approximately six faculty members and, possibly, a graduate student, sometime between 1965 and 1967 for the purpose of calibrating the "Whole Body Counter." This device is used to measure radioactivity in humans and animals. The CSU "Whole Body Counter" was originally used for fallout and body composition studies. The second involved exposure of several individuals to Rn-222 to determine distribution of radon daughters in the body in conjunction with research on radon daughter exposure to uranium miners. Records have been requested in both cases and should be available within the next few weeks. Each of these cases involved knowledgeable individuals performing functions with which they were familiar on the basis of their occupation and professional training and the doses were within the occupational radiation dose limits in effect at that time.

Two other incidents have been reported on an anecdotal basis, but no evidence has been found to verify them. At one time, one or more animals were injected with radioactively labeled steroids. The beef from the animals apparently was ingested by volunteers and the radioactivity in the volunteers measured in the "Whole Body Counter." One other individual recalled getting permission of the Colorado Department of Health to consume meat from an animal used previously in research simply so the meat would not go to waste. An incident involving voluntary ingestion of milk containing I-131 for the purpose of calibrating the "Whole Body Counter" has also been identified, although the individual who has been responsible for the "Whole Body Counter" since the time of its construction does not recall either incident. At this time, no written record has been located regarding these anecdotal incidents.

Note that U.S. Senator Ben Nighthorse Campbell's letter dated January 14, 1994 to Bob Quillin expresses support for President Clinton's and NRC's efforts to commence a full and comprehensive review of the nation's nuclear medicine activities and records. He also asks Mr. Quillin to provide his office with the results of records searches in Colorado as soon as possible.

Florida Department of Health and Rehabilitative Services: Letter from William Passetti, Radioactive Materials Section, dated January 18, 1994 states that three broad scope medical and five broad scope academic license files were reviewed as requested. There was no evidence to indicate experiments in which

humans were deliberately exposed to radiation for purposes other than radiopharmaceutical development.

Illinois Department of Nuclear Safety: Letter from Steven Collins, Chief, Division of Radioactive Materials, dated January 21, 1994: As a preliminary response, the Department is currently limiting its search to facilities in the Chicago area, and has determined that 31 facilities originally licensed by the AEC as broad scope medical, academic or research facilities should be reviewed. The Department is actively reviewing the license files for these facilities to determine if there was any human research conducted.

Nebraska Department of Health: Harold Borchart, Director, Division of Radiological Health indicated via a January 27, 1994 telephone conversation with the Office of State Programs that the State had no information in their files but had received an inquiry from an individual regarding a possible incident at the University of Nebraska Medical Center involving a child. Mr. Borchart asked NRC to share any information we may have available regarding this incident and any other pertinent information relating to human research studies in the State of Nebraska prior to their becoming an Agreement State.

New York State Department of Environmental Conservation: Letter from Norman Nosenchuck, Director, Division of Hazardous Substances Regulation, dated January 18, 1994 indicates there are no such files in their Bureau of Radiation.

New York State Department of Health: Letter from Christopher Parker, Associate Radiological Health Specialist, dated January 26, 1994 encloses a list of research projects conducted by some New York State Department of Health radioactive materials licensees involving the use of radioactive materials in humans for purposes other than radiopharmaceutical development. Seven licenses were reviewed for documentation of research activities.

Mr. Parker notes that the list is not a comprehensive summary of human-use research. Most broad medical licensees are conducting human-use research that is not necessarily reflected in the files. Also, the available files only go back to the mid-1980's. Older files in storage have not been reviewed. None of the research projects described involve efforts to determine radiotoxicity or other effects of radiation, but rather utilize radioactive materials in the study of a certain process unrelated to radiation. All of the research activities involved patient or volunteer consent.

New York State Labor Department: Clayton Bradt, Radiological Health Unit, reported February 1, 1994 that the New York State Labor Department has no such records.

New York City Health Department: Robert Kulikowski, Director, Bureau of Radiological Health reported January 31, 1994 that he has not yet conducted a physical search of the office files; however, he does not recall any such records within the New York City Health Department files. He will notify NRC of the results of his search upon completion.

Nevada Department of Human Resources: Letter from Stanley Marshall, Supervisor, Radiological Health Section, dated January 24, 1994 states that a review of the files and interviews with program staff employed by the Nevada Health Division during the 1970's indicate that no Nevada licensees were authorized nor was any suspected medical or scientific radiation effects research on humans in Nevada documented during Division inspections.

Tennessee Department of Environment and Conservation: Letter from Johnny Graves, Licensing, Registration Policy Manger, dated January 14, 1994 transmits the following information: The University of Tennessee, Memphis - A letter dated September 26, 1963 from Cecil Buchanan of the AEC to John Q. Adams concerning Iodine-131 research on humans; Vanderbilt University, Nashville - a letter dated January 31, 1958 from George Meneely to Cecil Buchanan discussing human use dose and committee interactions and a letter dated July 25, 1962 to John E. Bowyer of the AEC from John C. Burch discussing the undertaking of "an experimental investigation of the elimination of radon gas from the lungs."

Washington Department of Health: Letter from Terry Frazee, Supervisor, Radioactive Materials Section, dated January 25, 1994 provides information on three licensees involved in Pm-143 distribution in volunteers, thymidine in testes of convicts and neutron irradiation of gonads of convicts.

The following Agreement States telephoned to say they found no evidence upon a review of their files and interviews with present and former employees of any authorization for human use other than radiopharmaceutical development:

Alabama State Department of Public Health: Kirk Whatley, Director, January 26, 1994.

Arizona Radiation Regulatory Agency: William Wright, Program Manager, January 26, 1994.

Georgia Department of Natural Resources: Tom Hill, Manager, Radioactive Materials Program, January 18, 1994.

Iowa Department of Public Health: Dan McGhee, Radioactive Materials, January 26, 1994.

Kansas Department of Health and Environment: Gerald Allen, Chief, X-ray and RAM Control Section, January 31, 1994.

Kentucky Cabinet for Human Resources: Vicki Jeffs, Supervisor, Radioactive Materials Section, January 27, 1994.

Louisiana Office of Air Quality and Radiation Protection: Hall Bohlinger, Administrator, Radiation Protection Division, January 26, 1994.

Maine Radiologic Health Program: Jay Hyland, Radioactive Materials Licensing, January 27, 1994.

Maryland Department of the Environment: Charles Flynn, Radioactive Material Licensing, January 24, 1994.

Mississippi State Department of Health: Bob Goff, Radioactive Materials Branch, January 26, 1994.

New Hampshire Radiological Health Bureau: Dennis O'Dowd, Supervisor, Radioactive Materials Section, January 24, 1994.

New Mexico Department of the Environment: Benito Garcia, Chief, Bureau of Hazardous and Radioactive Materials, January 31, 1994.

North Carolina Department of Environment, Health and Natural Resources: Mel Fry, Deputy Director, Division of Radiation Protection, January 26, 1994.

North Dakota Department of Health: Kenneth Wrangler, Manager, Radiation Control Program, January 26, 1994.

Oregon Department of Human Resources: Ray Paris, Manager, Radiation Control Section, January 26, 1994.

Rhode Island Department of Health: Marie Stoeckel, Chief, Division of Occupational and Radiological Health, January 26, 1994.

South Carolina Bureau of Radiological Health: Jim Peterson, Radioactive Health and Environmental Control, January 13, 1994.

Texas Department of Health: Richard Ratliff, Chief, Bureau of Radiation Control, January 26, 1994.

Texas Natural Resource Conservation Commission (TNRCC): Letter from Alice Hamilton Rogers, Manager, UIC, Uranium and Hazardous Waste Section, dated January 13, 1994 states that the TNRCC's jurisdiction is limited to the disposal of radioactive substances and uranium recovery processing, both of which allow little scope for such experimentation.

Utah Department of Environmental Quality: Craig Jones, Section Manager, Division of Radiation Control, January 14, 1994 and William Sinclair, Director, Division of Radiation Control, January 26, 1994.

TIME SENSITIVE INFORMATION

JAN 10 1994

ALL AGREEMENT STATES

TRANSMITTAL OF STATE AGREEMENTS PROGRAM INFORMATION (SP-94-011)

Your attention is invited to the attached correspondence which contains:

INCIDENT AND EVENT INFORMATION.....

PROGRAM MANAGEMENT INFORMATION.....

TRAINING COURSE INFORMATION.....

TECHNICAL INFORMATION.....

OTHER INFORMATION.....XX Authorization for Human Use

Supplementary information: The NRC has recently requested its Regional Offices, by memorandum dated January 7, 1994 (enclosed), to conduct a review of available license files, including terminated license files, to obtain information on certain licensees who were likely to have conducted medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975. The purpose of this review is to identify those files containing information on experiments in which humans were deliberately exposed to radiation for purposes other than radiopharmaceutical development. The enclosed memorandum further details the specific criteria to be considered in this review.

We are also requesting at this time that the Agreement States review their files as well to identify and report to the Office of State Programs those files containing information on experiments in which humans were deliberately exposed to radiation for purposes other than radiopharmaceutical development. Initial information would be most useful if provided by January 18, 1994, with follow-up of final information by January 25, 1994.

If you have further questions regarding this correspondence, please contact the individual named below.

POINT OF CONTACT: Rosetta Virgilio
TELEPHONE: (301) 504-2307
FAX (301) 504-3502

Original Signed By
RICHARD L. BANGART
Richard L. Bangart, Director
Office of State Programs

Enclosure:
As stated

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

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 NRC 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 the Nuclear Regulatory Commission 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 the Department of Energy, the Presidential Task Force investigating human radiation research or any other Federal agency involved in this effort.

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. These efforts were undertaken at DOE's request.

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 State Programs. I understand that you are directing the development of the DOE record retrieval and review process and look forward to receiving, for our information, the 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

DRAFT

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, DC, area, Oak Ridge, Tenn., and near the regional offices. Because of these limitations, NRC cannot 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. This review was carried out under an exemption from the Food and Drug Administration, which normally regulates research on new drugs. Shortly after the NRC was created, FDA revoked the exemption. NRC regulations governing the use of radioactive materials for research and development prohibit use on humans unless FDA procedures are followed. As such, 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. Institutes licensed by Agreement States also may be involved in this type of research.

To conduct the research, licensees must have an FDA 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, California. 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, Massachusetts, 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 institutes.

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 use. The remaining 23 Agreement States indicate that they found no evidence of any authorization for human use other than for radiopharmaceutical development. The NRC intends to assist in obtaining any further information from the Agreement States, as 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, search might only duplicate the DOE's ongoing efforts to locate information on human experiments, since DOE and NRC were both part 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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