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AMERICAN NUCLEAR GUINEA PIGS: THREE DECADES OF RADIATION EXPERIMENTS ON U.S. CITIZENS

REPORT

PREPARED BY THE

SUBCOMMITTEE ON ENERGY CONSERVATION AND POWER

OF THE

COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

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LETTER OF TRANSMITTAL

U.S. HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON ENERGY CONSERVATION AND POWER,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC, October 24, 1986.

Hon. JOHN D. DINGELL,
Chairman, Committee on Energy and Commerce, Rayburn House Office Building, Washington, DC.

DEAR MR. CHAIRMAN: I am forwarding to you, for the Committee's use, a report prepared by the staff of the Energy Conservation and Power Subcommittee titled, "American Nuclear Guinea Pigs: Three Decades of Radiation Experiments on U.S. Citizens." This report describes material contained in Department of Energy documents on radiation experiments using human subjects.

A review of these documents reveals the frequent and systematic use of human subjects as guinea pigs for radiation experiments. Some of these experiments were conducted in the 1940's and 1950's, and others were performed during the supposedly more enlightened 1960's and 1970's. The report describes in detail 31 experiments during which about 695 persons were exposed to radiation which provided little or no medical benefit to the subjects. The report notes that it seems appropriate to urge the Department of Energy to make every practicable effort to identify the persons who served as experimental subjects, to examine the long-term histories of subjects for an increased incidence of radiation-associated diseases, and to compensate these unfortunate victims for damages.

This report is the result of an ongoing Subcommittee examination of the health and safety policies of the Department of Energy. The previous Subcommittee Chairman, Mr. Ottinger, requested from the Department documentation on experiments involving human test subjects and radiation, which were funded by DOE or its predecessor agencies. During the 99th Congress, the Subcommittee initiated an intensive review of the documents, and requested further information on specified experiments. This report is the result of that intensive review.

It should be noted that this report was prepared by the Subcommittee staff for discussion purposes and may not represent the views of all Committee members. I believe the Committee and others will find this report to be extremely useful in examining issues of radiation health and safety and victims' compensation.

Sincerely,

EDWARD J. MARKEY, *Chairman.*

AMERICAN NUCLEAR GUINEA PIGS: THREE DECADES OF RADIATION EXPERIMENTS ON U.S. CITIZENS

Summary and Conclusions

Documents provided by the Department of Energy reveal the frequent and systematic use of human subjects as guinea pigs for radiation experiments. Some experiments were conducted in the 1940s at the dawn of the nuclear age, and might be attributed to an ignorance of the long term effects of radiation exposure, or to the atomic *hubris* that accompanied the making of the first nuclear bombs. But other experiments were conducted during the supposedly more enlightened 1960s and 1970s. In either event, such experiments cannot be excused.

These experiments were conducted under the sponsorship of the Manhattan Project, the Atomic Energy Commission, or the Energy Research and Development Administration, all predecessor agencies of the Department of Energy. These experiments spanned roughly thirty years. This report presents the findings of the Subcommittee staff on this project.[1]

Literally hundreds of individuals were exposed to radiation in experiments which provided little or no medical benefit to the subjects. The chief objectives of these experiments were to directly measure the biological effects of radioactive material; to measure doses from injected, ingested, or inhaled radioactive substances; or to measure the time it took radioactive substances to pass through the human body. American citizens thus became nuclear calibration devices.

In many cases, subjects willingly participated in experiments, but they became willing guinea pigs nonetheless. In some cases, the human subjects were captive audiences or populations that experimenters might frighteningly have considered "expendable": the elderly, prisoners, hospital patients suffering from terminal diseases or who might not have retained their full faculties for informed consent. For some human subjects, informed consent was not obtained or there is no evidence that informed consent was granted. For a number of these same subjects, the government covered up the nature of the experiments and deceived the families of deceased victims as to what had transpired. In many experiments, subjects received doses that approached or even exceeded presently recognized limits for *occupational* radiation exposure. Doses were as great as 98 times the body burden recognized at the time the experiments were conducted.

[1] This report does not necessarily reflect the views of the Members of the Committee.

A later section of this report, Description of Human Radiation Experiments, provides details on 31 experiments, during which about 695 persons were exposed. Experiments are listed by Category and Number as designated by the Department of Energy. Some of the more repugnant or bizarre of these experiments are summarized below.

During 1945 to 1947, as part of the Manhattan Project, 18 patients who were diagnosed as having diseases which gave them expected survivals of less than 10 years were injected with plutonium, to measure the quantity retained by the human body. These experiments were carried out at the Manhattan District Hospital at Oak Ridge, Tennessee; Strong Memorial Hospital in Rochester, New York; the University of Chicago; and the University of California, San Francisco. Despite the original diagnoses, seven of these patients lived longer than 10 years, and five lived longer than 20 years. Internal investigations by the Atomic Energy Commission found that informed consent was not granted in the initial experiments, since even the word "plutonium" was classified during World War II; and living patients were not informed that they had been injected with plutonium until 1974. (Category 1.001, Number 1).

From 1961 to 1965 at the Massachusetts Institute of Technology, 20 subjects, aged 63 to 83, were injected or fed radium or thorium to estimate internal doses and to measure passage of these substances through their bodies. Many of these subjects came from the nearby Age Center of New England, a research facility established to investigate the process of aging and the needs of the elderly. These experiments thus represent a perversion of the Center's original purpose, since feeding the subjects radium and thorium did not benefit them as individuals or the elderly population as a whole. (Category 1.002, Number 118).

During the 1960s, at the Los Alamos Scientific Laboratory, 57 normal adults were fed microscopic spheres containing radioactive uranium and manganese. These experiments were designed to determine how fast such spheres would pass through the human body after ingestion. It was believed that particles of this size could be produced by the atmospheric reentry and burnup of rockets propelled by nuclear reactors, or of radioactive power supplies. (Category 1.003, Number 106).

During 1946 and 1947, at the University of Rochester, six patients with good kidney function were injected with uranium salts to determine the concentration which would produce renal injury. One patient was diagnosed as being in a "hallucinatory state," another was considered suffering from "emotional maladjustment," and a third, admitted to the hospital for a fifth time, was described as follows: "As he had no home, he agreed willingly to enter the metabolic unit for special studies." (Category 1.003, Number 119).

From 1963 to 1971, 67 inmates at Oregon State Prison and 64 inmates at the Washington State Prison received x-rays to their testes to examine the effects of ionizing radiation on human fertility and testicular function. These experiments were conducted by the Pacific Northwest Research Foundation and the University of Washington. Subjects had to agree to receive vasectomies after completion of the experiments. The Energy Research and Development Administration planned to begin medical follow up of the irradiated prisoners, but these plans were dropped in 1976 at the request of the U.S. Attorney in Portland after several irradiated inmates filed suits against state and federal governments. (Category 2.001, Number 2 and Category 2.002, Number 189).

From 1953 to 1957, at Massachusetts General Hospital, Boston, approximately 12 terminal brain tumor patients were injected with uranium to determine the dose at which kidney damage began to occur. Most of the patients were described as comatose or in a "semi-coma." (Category 9.001, Number 166).

From 1963 to 1965, at the Atomic Energy Commission National Reactor Testing Station in Idaho, radioactive iodine was purposely released on seven separate occasions. In one of these experiments, seven human subjects drank milk from cows which had grazed on iodine-contaminated land. This experiment was designed to measure the passage of iodine through the food chain into the thyroids of the human subjects. In a second experiment, three human subjects were placed on the pasture during iodine release, and seven subjects were placed on the pasture in a third experiment. In addition, "several" individuals were contaminated during yet another experiment when vials of radioactive iodine accidentally broke. Cows grazed on contaminated land and their milk was counted in four of the experiments; in the remaining three, radiation measurements were made only on the pasture. (Category 10.001, Number 173).

During May 1945, at the Clinton Laboratory, Oak Ridge, Tennessee, two groups of 10 subjects were exposed to beta rays, to determine the dose that would begin to cause reddening of the skin. (Category 11.001, Number 51).

During 1951 and 1952, at least 14 human subjects were exposed to tritium in air, by immersion of body parts in water, or by drinking. These experiments were designed to measure the retention or excretion of tritium by the human body. The experiments were carried out by the Los Alamos Scientific Laboratory, or the General Electric Company in Richland, Washington. (Category 11.001, Numbers 112, 123, 125, 126, 127).

During 1956, the U.S. Air Force sent manned planes through radiation clouds from atomic bomb tests at Eniwetok and Bikini Atolls in the Pacific to measure radiation doses in the clouds and to the crew. (Category 11.001, Number 133).

During the early 1950s. Foster D. Snell, a consulting firm, carried out experiments for the U.S. Army by placing "synthetic" radioactive soil on the hands of about 118 human subjects, and measuring the ability of different cleaning agents to remove the contamination. (Category 11.001, Number 134).

From 1961 to 1963, at the University of Chicago and Argonne National Laboratory, 102 human subjects were fed real fallout from the Nevada Test Site; simulated fallout particles that contained strontium, barium, or cesium; or solutions of strontium and cesium. This experiment was designed to measure human absorption and retention of these radioactive substances. (Category 11.001, Number 186, Part A).

During the early 1960s, at the Oak Ridge Institute for Nuclear Studies, 54 hospital patients with normal intestinal tracts were fed

lanthanum-140. This experiment was designed to measure the rate at which this radioactive substance passed through the body. (Category 11.001, Number 186, Part B).

During the late 1950s, at Columbia University and Montefiore Hospital, the Bronx, 12 terminal cancer patients were injected with radioactive calcium and strontium. This experiment was designed to compare the distribution of these two substances among body tissues after autopsy. (Category 12.001, Number 15).

In 1967 at the Hanford Environmental Health Foundation and the Battelle Memorial Institute, both at Richland, Washington, radioactive promethium was administered to 14 subjects by injection or drinking. These experiments were designed to measure the passage of this substance through the body and the ability of a drug (chelating agent) to increase the removal of promethium. (Category 12.001, Number 110).

During 1963, at the Battelle Memorial Institute, Richland, Washington, five subjects were injected with radioactive phosphorus. In addition, five subjects were fed fish from the Columbia River which contained radioactive phosphorus, produced and discharged into the river by reactors at the Atomic Energy Commission's Hanford Site. These experiments were designed to estimate the doses to humans eating contaminated fish. (Category 12.001, Number 111).

In many of the reported experiments, radiation was used as treatment for diseases which were resistant to more conventional methods. Most frequently, radiation was used in attempts to treat cancer, leukemia, or other malignant disorders of the blood. The Subcommittee staff does not question these applications, since patients were irradiated in an attempt to treat their diseases, and in some cases the treatment was successful. In these cases, the radiation exposure was meant to carry some medical benefit for patients, and observation of the effects of exposure, which enhanced understanding of radiation effects, was incidental to the treatment. In some cases, however, long term medical follow up of the surviving patients, which might have provided information for useful comparison with other treatments that might seem promising, was not conducted.

The studies provided by the Department of Energy amply demonstrate the need for long term medical follow up. Category 10.001, Number 69, describes a retrospective study on the health of humans exposed to radioactive iodine, and includes as a study population the group of Marshallese Islanders exposed to fallout from early atomic bomb tests. This report notes that thyroid nodules, produced by exposure to radioactive iodine, did not first appear among inhabitants of the atoll with the highest fallout until 9 years after the testing. Nodules began appearing some years later among inhabitants of atolls where the doses were lower; and after 22 years, nodules were still being observed.

If there is one thing the government can do for these experimental victims and their families, even at this late date, it is to conduct long term medical follow up of populations exposed to radioactive material. That practice has been adopted by the Defense Department through its Nuclear Test Personnel Review, a registry for military personnel exposed to fallout from atmospheric nuclear tests. The primary objectives of the Review are to identify the approximately 200,000 Defense Department personnel involved in such tests, to determine their exposures, to identify incidences of death or illness, and to assist veterans in claims for compensation. If this effort can be carried out for military personnel acting in the line of duty, surely a similar effort should be possible for the far smaller number of peaceful atomic soldiers used as human subjects in radiation experiments.

Recommendations

1. It seems appropriate to urge the Department of Energy to make every practicable effort to identify the persons who served as subjects for the experiments described below, to examine the long term histories of subjects for an increased incidence of radiation-associated diseases, and to compensate these human guinea pigs for damages they have suffered.

These victims face severe obstacles to compensation under current law, embodied by the Federal Tort Claims Act. The Department of Energy should therefore be encouraged to work with the Subcommittee to develop legislation that provides adequate compensation.

2. Human experiments of this nature must never be repeated. Many of these experiments would not be allowed under current federal guidelines, and it is gratifying that experiments of this nature apparently did not continue after the early 1970s.

Two overriding principles for human experimentation must be followed: The first is that the risks of the experimental treatment must be reasonable in relation to anticipated benefits. The second is that subjects must be fully informed, and capable of understanding the benefits and risks of the treatment. Current federal regulations embody these principles, with exceptions that are clearly spelled out in cases where knowledge from the treatment might benefit society as a whole. The Appendix to this report describes these federal regulations.

The Subcommittee is gratified that the Department of Energy follows current regulations in its own experiments. However, the sad history of human radiation experimentation makes it clear that standards that were acceptable forty years ago appear repugnant today. It therefore seems appropriate to urge that all applicable federal agencies, including the Department of Energy, frequently review their regulations to ensure that human experimentation is conducted under the highest ethical standards.

Background

The investigation into human radiation experiments began as part of an ongoing Subcommittee examination of the health and safety policies of the Department of Energy. In June 1984, Representative Richard Ottinger, then Subcommittee Chairman, requested from the Department a list of experiments involving human test subjects and radiation, which were funded by the Atomic Energy Commission, the Energy Research and Development Administration, or the Department of Energy. The former two agencies were predecessors of the Department of Energy. DOE responded to this initial request in September 1984, enclosing summaries of many

different experiments. In October 1984, Chairman Ottinger requested further clarification and information on the human experiments provided. DOE responded to this request in January 1985, providing supporting material and fuller descriptions of many of the experiments, and in some cases reporting more experiments.

In January 1985, Representative Edward J. Markey became Subcommittee Chairman, and initiated an intensive review of all the documents released by the DOE. Chairman Markey also requested further information on individual experiments in August, November, and December 1985, and in March 1986.

Review of Released Documents

The initial information released by the Department of Energy consisted of summary factsheets on each of several human radiation experiments. Each factsheet contained an experiment title, designation of federal agency or agencies funding the experiment, a list of institutions conducting the experiments, description of the experiment objective, a short description of the experiment, and where known, the status of long term medical follow up of experimental subjects.

In response to the Subcommittee's October 1984 request for further information, DOE released additional material including dates when experiments started and ended, names of responsible government officials, and in some cases supporting documents, such as scientific references or project reports. DOE also released some material on experiments not previously reported in the summary factsheets.

DOE placed the experiments reported in 12 different categories:

1. Metabolism and Biological Effects of Plutonium, Polonium, Thorium, Uranium, Radium, and Lead-212.
2. Testicular Irradiation.
3. Whole-body Irradiation for Treatment of Leukemia and Lymphoma.
4. Teletherapy with Particle Beams.
5. Other Teletherapy Studies.
6. Treatment of Polycythemia.
7. Hematological Effects.
8. Neutron Capture Therapy.
9. Other Radiation Therapy.
10. Biological Effects of I-131.
11. Other Biological Effects Studies.
12. Metabolic and Physiological Studies.

In many of the reported cases, radiation was used as treatment for diseases which were resistant to more conventional methods. Most frequently, radiation was used in attempts to treat cancer, leukemia, or other maligant disorders of the blood. The Subcommittee staff does not question these applications, since patients were irradiated in an attempt to treat their diseases, and in some cases the treatment was successful. In these cases, the radiation exposure was meant to carry some medical benefit for patients, and observation of the effects of exposure, which enhanced understanding of radiation effects, was incidental to the treatment. The Subcommittee staff readily acknowledges the scientific advancement

produced by such observations and commends those scientists and physicians who engaged in such research.

In many of the cases where radiation was used for medical treatment, there was little long term medical follow up of the irradiated patients. In part, this may have been due to the fact that the benefits of medical radiation were clear: irradiated patients in some cases showed higher survival rates than patients treated with other methods. But since radiation can also cause cancer, long term follow up on surviving patients may have provided information for a useful comparison with other present treatments or with treatments that might seem promising in the future.

The follow up provisions of one particular experiment, designated Category 4.004, Number 179, should be noted with approval. The objective of this project is to determine the effectiveness of neutron beam irradiation as compared to standard irradiation for the management of certain malignant tumors. This project is funded by the National Cancer Institute and is carried out at the Fermi National Acclerator Laboratory, a facility owned by the Department of Energy.

This project began in 1975 and is continuing today. Approximately 1400 patients have been referred to the program. Prior to treatment, patients must agree to comply with long-term follow up requirements, which include regular physical examinations and laboratory tests. Every effort is made to contact patients who miss scheduled appointments, and fewer than 1 percent of patients treated at this facility are currently considered lost to follow up. The follow up efforts at this Fermilab project should be applauded, and they represent a model that should be duplicated in other DOE investigations of medical therapy.

In many of the other human experiments which DOE reported to the Subcommittee, however, subjects received little or no medical benefit from their exposure. These experiments fall into two general categories: In one group, human subjects were injected with or fed radioactive material, and its passage through the body was monitored. The major objective of these experiments was to compare results with mathematical models predicting radiation doses for occupational or accidental exposure. Although these experiments did provide information on the retention and absorption of radioactive material by the human body, the experiments are nonetheless repugnant because human subjects were essentially used as guinea pigs and calibration devices. In a second group of experiments, the administration of radioactive material was actually intended to *cause* damage to the human body, and the experimenters sought to correlate the amount of damage done with the dose received.

In some of the experiments described, the human subjects were captive populations: the elderly, prisoners, and hospital patients who might not have retained their full faculties for informed consent. In other experiments, the subjects were volunteers, but they were willing guinea pigs nonetheless.

The human radiation experiments are described in detail in the following section.

Description of Human Radiation Experiments

Category and Number labels below are as designated by the Department of Energy in its responses to the Subcommittee. In many cases, occupational exposure limits are provided for comparison with the doses or amounts of radioactive material received by subjects. Present dose limits are taken from Title 10, Code of Federal Regulations, Part 20. The maximum permissible body burden is an occupational limit for the allowable amount of a given substance that may be internally deposited in an individual. It is generally recognized among the scientific community that doses to the general population should be no more than one tenth the allowable doses to radiation workers. Values presented below for maximum permissible body burdens are taken from NCRP-22, a handbook of the National Committee on Radiation Protection, which is a non-governmental organization that recommends standards for radiation exposure.

In addition to the experiments described in the Summary and Conclusions of this report, many experiments are of special concern because of the circumstances of the persons used as subjects, or because of the doses which some subjects received, relative to present occupational limits. In experiments where the radioactive material administered was greater than the present maximum permissible body burden, doses are classified as potentially greater than present occupational limits, since not all of the material administered might have remained in the body. These experiments of special concern are listed below, and are followed by descriptions of all experiments.

Category 1.001, Number 1. Subjects were diagnosed as terminal within 10 years; one subject was a child; no evidence of informed consent; potential doses much greater than occupational limits.

1.002, Number 118. Subjects were elderly; potential doses greater than occupational limits.

1.003, Number 12. Subjects were terminal patients; potential doses greater than occupational limits.

1.003, Number 119. Subjects were hospital patients; some doses produced kidney damage.

2.001, Number 2. Subjects were prisoners; doses were greater than occupational limits.

2.002, Number 189. Subjects were prisoners; doses were greater than occupational limits.

3.001, Number 49. Doses were greater than occupational limits.

9.001, Number 166. Subjects were terminal brain tumor patients, and most were comatose; some doses produced kidney damage.

10.001, Number 178. Radioactive iodine was intentionally released to the environment.

11.001, Number 51. Doses were greater than occupational limits.

11.001, Number 53. Doses were greater than occupational limits.

11.001, Number 121. Subjects were hospital patients; doses were greater than occupational limits.

11.001, Number 123. Potential doses were greater than occupational limits.

11.001, Number 127. Potential doses were greater than occupational limits.

11.001, Number 133. Doses were greater than occupational limits.

11.001, Number 186, Part B. Subjects were hospital patients; potential doses were greater than occupational limits.

Category 12.001, Number 15. Subjects were terminal cancer patients; potential doses were greater than occupational limits.

12.001, Number 109. Potential doses were greater than occupational limits.

12.001, Number 128. Potential doses were greater than occupational limits.

Category 1. Metabolism and Biological Effects of Plutonium, Polonium, Thorium, Uranium, Radium, and Lead-212

CATEGORY 1.001, NUMBER 1

Plutonium injections into humans

During 1945 to 1947, 18 patients were injected with plutonium. These experiments were carried out by the Manhattan Project. The following hospitals were involved in the experiments, with the number of patients involved for each indicated:

Manhattan District Hospital, Oak Ridge, Tennessee (1).

Strong Memorial Hospital, Rochester, New York (11).

Billings Hospital, University of Chicago (3).

University Hospital, University of California, San Francisco (3).

According to an Energy Research and Development Administration (ERDA) fact sheet of February 1976, the rationale for this experiment was that several thousand Manhattan Project workers had been involved in handling plutonium, accurate information was needed on the retention and excretion of internally deposited plutonium for setting safety criteria, and animal experiments had produced conflicting data which could not be extrapolated to humans.

In choosing subjects, the original criteria specified that subjects should be older, with relatively short life expectancies. All subjects chosen were diagnosed as having existing diseases that gave them an expected survival of less than 10 years. Most were over 45, but one subject was five years old, and another was 18. The oldest patients were 68. The quantities of plutonium injected ranged from 1.6 to 98 times the body burden value recognized at the time of the experiments, where a body burden is the permissible occupational limit for an internally deposited radioisotope. 13 of the patients received between 7 and 10 body burdens. Patients were monitored for their excretion of plutonium. They received no medical benefits from the injections.

In 1967, a Berkeley radiobiologist learned that one of the injected patients had lived for 20 years. She investigated the whereabouts of other patients, and in 1972 published a scientific paper noting that four patients were then alive. In a subsequent follow up investigation, the Department of Energy determined that 9 patients died within 3 years, one in 8 years, one each in 11 and 14 years, and four after 20 years. One was lost to follow up, and one was still living as of October 1983. In one case, the original diagnosis of disease later proved to be inaccurate.

In 1974, following the report that four patients were still alive, the Atomic Energy Commission conducted internal investigations to determine if the experimental patients had granted informed consent for their exposures. A report transmitted in August 1974 found that experimenters had failed to obtain informed consent in several instances. Formalized standards for patient consent to experimental procedures did not exist prior to 1946. In addition, even the word "plutonium" was classified until the end of World War II. The AEC, which succeeded the Manhattan Project, established a policy of formalized patient consent in 1947. One patient, injected in 1947, was the only subject injected after the AEC had been formed. This patient's hospital record contained a statement by attending physicians that the individual had been properly informed of the experimental nature of the injection. The AEC could find no records of consent for any other patient, and determined from oral testimony that at least one patient had not been informed.

On this issue, a June 1983 Department of Energy memo concluded that:

The issue of informed consent, if raised, will be difficult to deal with in the light of present DOE and Federal policies and procedures regarding human subjects. These are vastly more codified and explicit than any guidance available at the time the injections were given, and the procedures used at that time would not meet standards adopted and currently applied by DOE and other federal organizations. (Memo from Nathaniel F. Barr to Alvin W. Trivelpiece, Director, Office of Energy Research, Department of Energy, June 30, 1983.)

In 1973, the Center for Human Radiobiology (CHR), Argonne National Laboratory, initiated a follow up study of surviving patients and a program to exhume deceased patients for whom permission could be obtained. These studies were designed to examine how much plutonium remained in the bodies of subjects. The 1974 AEC investigations found that even by 1973 standards, informed consent had not been obtained for these studies. A memorandum dated December 21, 1972 from [name deleted], Argonne National Laboratory, to [name deleted], Center for Human Radiobiology, contained the following instructions in regard to studies on the surviving patients:

Please note that outside of CHR we will *never* use the word *plutonium* in regard to these cases. 'These individuals are of interest to us because they may have received a radioactive material at some time' is the kind of statement to be made, if we need to say anything at all [emphasis in original]. (Quoted in Division of Inspection Report 44-2-326, U.S. Atomic Energy Commission, August 16, 1974, p. 19.)

Consequently, patients alive in 1973 were not informed that they had been injected with plutonium in the 1940s. Relatives of deceased patients were told that exhumation was necessary to determine the composition of an "unknown" mixture of injected radioactive isotopes. Injection was also represented as having been an experimental treatment for the patients' diseases, a statement that is not true. As a second AEC investigation concluded:

Relative to the study undertaken in 1973, informed consent was not obtained from surviving patients who were the subject of the study.

Consent, following improper disclosure, was obtained from the next of kin of an exhumed patient. Improper disclosure was made to the next of kin of additional deceased patients who have not been exhumed. (Division of Inspection Report 44-2-330, U.S. Atomic Energy Commission, August 12, 1974, pp. 11, 12.)

As a result of the 1974 investigation, the AEC contacted the doctors of the four living patients, and asked the doctors to inform the patients of the nature of the Manhattan Project injections. One doctor did not tell his patient because he felt the information would be detrimental to her health; this patient has since died. The other three patients were informed.

A scientific paper published in 1976 calculated doses to the injected patients, and concluded from these calculations that in spite of the apparent lack of induced tumors among the patients:

The liver doses do not appear to be high enough to be carcinogenic, but comparison of the bone-surface doses with radium doses that have induced bone tumors indicates that six of these cases have received doses high enough to be considered carcinogenic. (R.E. Rowland and P.W. Durbin, Survival, causes of death, and estimated tissue doses in a group of human beings injected with plutonium, in The Health Effects of Plutonium and Radium, J.W. Press, Salt Lake City, 1976.)

CATEGORY 1.002, NUMBER 118

Administration of radium and thorium to humans

During the period 1961-1965, doses of the nuclides Radium-224, and Thorium-234 were given to 20 volunteers, 13 men and 7 women, aged 63 to 83. Six subjects were injected with radium, six were injected with thorium, one ingested radium, one ingested thorium, and six ingested both radium and thorium. These experiments were funded by the AEC and carried out at the Massachusetts Institute of Technology.

The experiments were designed to examine the metabolism from radioactive substances that might be smiliar to those ingested by radium dial painters in the earlier part of the 20th century, many of whom subsequently developed cancer of the jaw or mouth. The specific matter of concern was whether Thorium-228, which may have been present in dial paints, would have contributed a significant dose to painters. After the subjects were fed or injected with the radioactive substances, the substances were monitored by measuring their presence in blood, in the breath, in excreted matter, and by whole-body counting of the subjects. Patients were monitored for up to 120 days.

Doses given to patients were 0.2 to 2.4 microcuries of radium, or 1.2 to 120 microcuries of thorium. For comparison, maximum permissible body burdens are 0.07 microcuries for Radium-224, and 20 microcuries for Thorium-234.

Most of the subjects were obtained from the Age Center of New England, Boston. A few were retired MIT employees. The subjects received no medical benefits from the experiment.

According to material received from the Department of Energy, the Age Center of New England was a non-profit research facility established in 1954 to investigate the process of aging and the needs of the elderly. The Center's pool of subjects consisted of several hundred "apparently healthy men and women" over the age of 50 who had declared their willingness to be studied in a variety of research projects on aging. These subjects lived elsewhere and had to be active enough to come to the Center to participate in research.

In 1957, the first published annual report of the Age Center described the following ongoing reseach projects: "Correlates of Anxi-

ety in Older Persons;" "The Nutrition of Apparently Normal Aging Persons;" "Prejudice and Older People," and "A Thematic Analysis of Later Life," which obtained the attitudes of elderly persons through questionnaires and oral interviews. The AEC experiments with Age Center subjects thus represent a perversion of the Center's original purpose: Feeding the subjects radium and thorium was of no direct benefit to the subjects or to the elderly population as a whole, and was not related to phenomena connected to the aging process.

The study was conducted in two phases. In the first phase, subjects were injected with either radium or thorium, and the passage of the material through the body was measured. The principal reason for these experiments was to calibrate counting equipment that would be used in the second phase, which was the oral ingestion of mixtures of radium and thorium. Excretion and whole body counting was also monitored for the phase two patients. These experiments were reported to the AEC in annual progress reports in 1964 through 1966.

In a January 2, 1985 letter to the Subcommittee Chairman, the Department of Energy reported that no follow up had been conducted on the health of the experimental subjects. The Age Center no longer exists and one professor who conducted the study had "no idea how any records of survival history could be obtained." He stated that finding the patients, if still alive, may be "like doing a missing persons search." The youngest volunteer would be approaching 85 years old today.

CATEGORY 1.003, NUMBER 12

Polonium administered to humans

From 1943 to 1947, radioactive polonium was injected into 4 hospital patients, and given orally to a fifth. Rates of excretion were measured. These studies were funded by the Manhattan Project and the AEC, and were conducted at the University of Rochester.

The objective of the experiment was to obtain data on human excretion of polonium to obtain a correlation with more extensive data from rats. Hospital patients were used as subjects because the experimenters wanted persons who had not been exposed to polonium through work or accidents.

The experiments were described in a scientific publication: Studies of polonium metabolism in human subjects, Chapter 3 of Biological Studies with Polonium, Radium, and Plutonium, National Nuclear Energy Series, Volume VI-3, McGraw-Hill, New York, 1950. All subjects had incurable diseases. Patient 1 was suffering from lymph cancer, and was injected with 22 microcuries of polonium. Patient 2 had acute leukemia, was injected with 11 microcuries, and died six days later. Patients 3 and 4 suffered from chronic leukemia, and were injected with 12 and 9 microcuries, respectively. Patient 5 suffered from chronic leukemia, and ingested 18 microcuries of polonium. Excretion of polonium was followed, and an autopsy was conducted on the deceased patient to determine which organs absorbed the polonium. The age of the patients ranged from early thirties to early forties.

The isotope administered is not specified, but the most readily available isotope at the time was Polonium-210. For comparison with the doses, the maximum permissible body burden for Polonium-210 is 0.4 microcuries.

In Janaury 1985, the Department of Energy transmitted to the Subcommittee summary factsheets on this, and many other experiments. The factsheet for this experiment reported no follow up on these experimental subjects.

CATEGORY 1.003, NUMBER 21

Absorption of lead-212 by the human gastrointestinal tract

Lead-212 was fed to three human subjects and gastrointestinal absorption and excretion over 24 hours were examined. Similar measurements were made on two human subjects injected with Lead-212, and the results for ingestion and injection were compared. These experiments were conducted to compare experimental results with existing models used by the International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection (NCRP), organizations which recommend radiation exposure standards. These experiments were carried out at the University of Rochester, were funded by the AEC, and were reported in UCRL-18140, Lawrence Radiation Laboratory, University of California, Berkeley, April 1968, pp. 217-232. The material from the Department of Energy on this experiment reported no information on doses, and no follow-up on the experimental subjects.

CATEGORY 1.003, NUMBER 106

Some biological aspects of radioactive microspheres in humans

During the 1960s, 57 normal adults were fed very small spheres containing radioactive Uranium-235 and Manganese-54, to determine how long it would take these spheres to pass through the gastro-intesinal tract. The human subjects received no medical benefit from this experiment.

The experiment was designed to assess the potential hazards from atmospheric reentry and burnup of rockets propelled by nuclear reactors, or of radioactive power supplies. Such burnup could produce particles small enough to be inhaled or ingested. In order to estimate internal radiation doses that humans might receive from such accidents, information was needed on the time that radioactive particles might remain in the body. The human subjects were all workers at Los Alamos Scientific Laboratory, except for one individual who was the wife of the principal investigator.

During the experiment, subjects were given a gelatin capsule containing U-235 and Mn-54, in spheres 100-200 microns in diameter (a micron is one-millionth of a meter). Both U-235 and Mn-54 emit radiation which would penetrate the gelatin. The Mn-54 spheres were coated with ceramic, the U-235 spheres were uncoated. Subjects each swallowed a capsule, and feces were collected and counted to determine how long the capsules remained in the body. One subject repeated ingestion of the sample 10 different times to provide an estimate of variation within the same individual. "Sev-

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eral others" repeated ingestion at different times of the day to provide an estimate of how results might change with time of day.

The experiment was conducted at Los Alamos Laboratory, was funded by the Atomic Energy Commission, and was reported in document LA-3365, Los Alamos Scientific Laboratory, August 1965.

The factsheet which the Department of Energy supplied the Subcommittee reported no follow up on these experimental subjects.

CATEGORY 1.003, NUMBER 119

Injection of uranium salts

During 1946 and 1947, six patients with good kidney function were injected in increasing doses with uranium nitrate, enriched in U-234 and U-235. The objectives of the experiment were to: determine the dose of uranium salt which produced renal injury; measure the rate of excretion of uranium salts; and observe the effects of modifying rates of excretion. These experiments were carried out at the University of Rochester, Atomic Energy Project.

The experiments are described in UR-37, dated June 1948, which apparently was a project report to the Atomic Energy Commission. The human subjects received no medical benefits from these experiments, and in fact the treatment seemed designed to induce kidney injury in at least one patient. It was recognized that uranium salts could damage the kidney, and the experiment planned to identify the concentration that would produce "just detectable renal injury." (UR-37, p. 7)

The experimental subjects were chosen from a large group of hospital patients; those selected had reasonably normal kidney function. In addition, "The probability that the patient would benefit from continued hospitalization and medical care was also a factor in the choice. When higher levels of dosage were contemplated, individuals from the older age groups were preferred in view of the remote possibility that late radiation effects might occur . . ." (UR-37, pp. 8, 9).

Patient 1 was in the hospital because of rheumatoid arthrithis and urethral strictures. Patient 2 was hospitalized because of acute alcololism, "hallucinatory state," cirrhosis of the liver, and possible neural damage. Patient 3 was a young woman "in fairly good physical condition except for mild chronic undernutrition which was thought to be secondary to an emotional maladjustment." (UR-37, p. 18) Patient 4 entered the hospital because of chronic alcoholism and bleeding from the gastrointestinal tract; 12 days after uranium injection, patient 4 was injected with citrate to examine its effect in further removal of uranium. "Unfortunately, this solution was so hypotonic" that blood appeared in the patient's urine and his temperature rose to 39.5 degrees C [103 degrees F]." (UR-37, p. 29).

Patient 5 suffered from chronic cough, had a history of rather high alcohol consumption, and was diagnosed as having pneumonia when he entered the hospital. Uranium doses had been successively increased with each new patient. Patient 5 showed trace amounts of protein in his urine, a sign of kidney disfunction, on the last day before leaving the hospital. He was not followed up. Patient 6 remained in the hospital from October 1946 to April 1947. This was his fifth admission to the hospital. Previous diagnoses had included heart disease, chronic alcoholism, and pneumonia; the present admission was for an ulcer. "As he had no home, he [Patient 6] agreed willingly to enter the metabolic unit for special studies." (UR-37, p. 41) Patient 6 received the largest dose, 70 microgram of uranium per kilogram weight, and clinical analysis suggested that "tolerance had been reached" for kidney injury. (UR-37, p. 55)

The summary factsheet which the Department of Energy submitted to the subcommittee reports no follow up on the experimental subjects. Funding for the experiment is not specified, but it presumably would be from the Manhattan Project, since the AEC was not established until 1947.

Category 2. Testicular Irradiation

CATEGORY 2.001, NUMBER 2

Testicular irradiation of inmates at Oregon State Prison

From August 1963 to May 1971, 67 volunteers at the Oregon State Prison were subjected to testicular irradiation by x-rays. Radiation doses ranged from 8 to 600 roentgen in single acute exposures, except that six prisoners were irradiated a second time, one a third time, and one was given weekly irradiations of 5 roentgen per week for eleven weeks. For comparison, the present occupational limit for exposure to reproductive organs is 5 roentgen per year. These experiments were carried out by the Pacific Northwest Research Foundation, Seattle; the Atomic Energy Commission provided a total of $1.08 million for these studies.

The objective of this experiment was to obtain data on the effects of ionizing radiation on human fertility and the function of testicular cells. It was considered that data from animals could not be readily extrapolated to humans. Studies included examination of testicular tissue, sperm counts, and evaluation of urinary or blood steroids and hormones.

Prisoners ranged in age from 25 to 52. Each inmate agreed to have a vasectomy at the end of his irradiation; consent of wives was required for this procedure. All prisoners in the Oregon group did eventually have vasectomies. All volunteers were required to sign statements of informed consent. Consent procedures involved an explanation of short term and long term effects, including the possibility of testicular cancer. No Catholics were allowed as subjects. Small sums of money were paid to prisoners: $5 to $10 for each treatment, and $100 at the time of vasectomy. However, according to the Energy Research and Development Administration "records suggest that the prime incentive to participate may have been the feeling that they were making important contributions to the state of medical knowledge." (ERDA background information on AEC human testicular irradiation projects in Oregon and Washington state prisons, March 1976, p. 2)

The prisoner irradiation program was terminated in 1973 after the principal investigator suffered an incapacitating stroke, and because of "subsequent state re-evaluation of correctional institutional involvement in experimental programs." (C.G. Heller et al., "Protection of the rights of welfare of prison volunteers: Policies

followed throughout a 17-year medical research program," unpublished manuscript, p. 7) The same document noted that the vasectomies on subjects after the experiment were necessary "to avoid any possibility of contaminating the general population with irradiation-induced mutants." (Ibid., p. 5)

In a summary factsheet provided the Subcommittee in January 1985, the Department of Energy described the follow up of experimental subjects:

> Complete recovery as shown by a return to pre-irradiated sperm concentrations and germinal cell numbers was found to be within 9-18 months for doses of 100 rad and below, 30 months for doses of 200 and 300 rad and 5 or more years for doses of 400 and 600 rad.

The need for follow up over a longer term was recognized as early as 1971, in a letter from an AEC official to Carl Heller, the principal investigator for the experiments. The letter concluded,

> Thus, I am suggesting that you prepare a protocol for the long-term follow-up of the irradiated volunteers after their release from the research program. (Frank T. Brooks, Division of Biology and Medicine, AEC, to Carl G. Heller, Pacific Northwest Research Foundation, November 30, 1971.)

In its 1976 background information material, the Energy Research and Development Administration noted:

> ERDA bolieves that there is a need for continued medical surveillance of prisoners involved in both sets of experiments [Oregon and Washington], and will explore with prison officials the best methods to achieve this. Among health effects which should be monitored is the possibility of testicular tumors, occurring after a long latency period (25-30 years). (ERDA background information, March 1976, pp. 2-3.)

However, at the request of the U.S. Attorney in Portland, Oregon, this follow up program was cancelled after several irradiated inmates filed suits against state and federal governments. In September 1976, the District Court for the District of Oregon dismissed the suit against federal defendants.

The experiments resulted in the publication of several scientific papers. The most recent one cited was M.J. Rowley et al, Radiation Research 59, 665-678, 1974.

CATEGORY 2.002, NUMBER 189

Testicular irradiation of inmates at Washington State Prison

During the period June 1963 to May 1970, 64 inmates at the Washington State Prison received testicular irradiation from x-rays. Each subject was irradiated once, and doses ranged from 7 to 400 roentgen. Following irradiation, tissue samples and sperm were examined for indications of damage; urine samples were examined for hormone levels. The Atomic Energy Commission granted $505,000 to support these studies, which were conducted by University of Washington researchers.

The objective of these studies was to determine the effects of radiation on gonadal function. The studies were reportedly proposed after a radiation accident at the AEC Hanford facility. Three men were overexposed, and no clear scientific data was available to advise them on possible sterility effects. The experiments were designed to determine the minimum effective dose that would render an individual temporarily sterile.

The criteria for selection were similar to the experiments with Oregon inmates: Participants had to agree to vasectomies after completion of the experiment. However, several of the Washington inmates subsequently did not receive vasectomies: 2 declined and were released from prison; 1 declined and remained in prison; 1 was released before the scheduled vasectomy; 1 did not undergo surgery for psychiatric reasons after mutual agreement with the prison physician; 1 who had heart problems and a life sentence was not vasectomized after mutual agreement (AEC Contract AT(45-1)-2225, Task Agreement 6, Terminal Report, January 1973, p. 3) Because of the lack of follow up information, it is not known if any experimental subjects subsequently fathered any children.

The experiments were terminated after a Human Subjects review board at the University of Washington refused in July 1969 to authorize further irradiation of prisoners. (George W. Farwell, University of Washington, to John R. Totter, Director, Division of Biology and Medicine, Atomic Energy Commission, July 16, 1969)

In the factsheet submitted to the Subcommittee in January 1985, the Department of Energy had this description for follow up: "Recovery of cell morphology and function were found after a maximum of 501 days. It was concluded that man is very sensitive in regard to temporary sterility, but is very resistant to complete sterility." As with the Oregon prisoners, there was no long-term follow up of subjects

Several scientific publications resulted from these experiments. The most recent cited was T.W. Thorslund and C.A. Paulsen, in Proceedings of the National Symposium on Natural and Man-Made Radiation in Space, NASA Document NAS No. 2440, pp. 229-232, January 1972.

Category 3. Whole Body Irradiation

In most of the cases in this category reported to the Subcommittee, whole body irradiation was used as treatment for diseases which were resistant to more conventional methods. Most frequently, whole body irradiation was used in attempts to treat leukemia, cancer, or polycythemia vera (a disorder characterized by excessive levels of red blood cells in the blood). The Subcommittee staff does not question the propriety of these particular applications, since patients were irradiated in an attempt to treat their diseases, and in some cases the treatment was successful. However, one case covered below appeared questionable.

CATEGORY 3.001, NUMBER 49

Blood changes in human beings following total-body irradiation

During 1943 and 1944, three groups of persons were given whole body irradiation doses from x-rays. The first group was eight persons with cancer. The second group consisted of one cancer patient and two persons with arthritic conditions. The third group was three normal volunteers. The objective of the study was to observe the changes in blood or blood cells following treatment. Although whole body irradiation was a recognized treatment for malignancies, it provided no benefit to the normal subjects, who received

doses which were greater than maximum allowable occupational exposures at the time. In addition, the treatment seemed of little use for arthritis, and the Department of Energy reported in April 1986 that x-ray irradiation for arthritis "is not considered to be standard practice." The experiments were conducted at the University of Chicago and were funded by the Manhattan Project.

The experiment is described in a scientific publication, J.J. Nickerson, Blood changes in humans following total body irradiation, in Industrial Medicine on the Plutonium Project, National Nuclear Energy Series, Vol. IV-20, pp. 308-337, McGraw-Hill, 1951. Page 309 contains the following comment on clinical treatment:

> The people used in groups 1 and 2 were individuals to whom the medical profession could offer no treatment that was at all specific or known to be helpful. The x-ray exposures that were given were as likely to benefit the patient as any other known type of treatment, or perhaps even more likely than any other. Since this manuscript is concerned only with the effects on the blood, the clinical condition of the patients is not discussed at any length.

Group 1 consisted of 8 patients with cancer of the throat, mouth, breast, or larynx. These patients received total body doses of 27, 60, or 120 roentgen in single doses from x-rays. Group 2 consisted of one patient with cancer of the hand, one patient with chronic arthritis who had received no previous known radiation therapy, and one patient with joint stiffness and pain who had received local radiation therapy to the knee. These patients received 500, 300, and 100 roentgen, respectively of total-body doses in multiple doses from x-rays. The radiation produced no significant change in the arthritis of those two patients. Group 3 consisted of three young male subjects who were normal in every known respect. These subjects received 7 roentgen (r) on three successive days, for a total of 21 roentgen from x-rays to each of them. Patients in groups 1 and 2 showed a decrease in the number of lymphocytes in the blood following radiation treatment. Group 3 showed no change in blood elements. For Group 3, the experimenters commented that:

> These cases were of particular interest to us inasmuch as they indicated that acute exposure to far more than the maximum permissible level of 0.1 r per working day could not be expected to produce diagnostic changes in the elements of the peripheral blood which were studied. (Ibid., p. 336)

The summary factsheet which the Department of Energy submitted to the Subcommittee in January 1985 reported no follow up on these subjects.

Category 4. Teletherapy with Particle Beams

These experiments consist of applications of cyclotron beams in attempts to treat patients suffering from cancer or other malignancies. The treatment was applied because conventional methods of therapy had often been unsuccessful in arresting the spread of disease. In some cases, the beam therapy proved more effective than conventional methods. In other tests, this therapy offered no advantages over existing methods and was discontinued. One item reported to the Subcommittee did seem disturbing, because experimental subjects received no apparent medical benefits. This item, in Category 4.006, is discussed below.

CATEGORY 4.004, NUMBER 179

Neutron therapy facility

The follow up provisions of this experiment should be noted with approval. The objective of this activity is to determine the effectiveness of neutron beam irradiation as compared to standard irradiation for the management of certain malignant tumors. This project is carried out at the Fermi National Accelerator Laboratory, a facility owned by the Department of Energy, and is funded by the National Cancer Institute.

The project began in 1975 and is continuing. Approximately 1400 patients have been referred to the program. Prior to treatment, patients must agree to comply with long-term follow up requirements, which include regular physical examinations and laboratory tests. Every effort is made to contact patients who miss scheduled appointments, and fewer than 1 percent of patients treated at this facility are currently considered lost to follow up. The benefits of radiation therapy, when expressed as enhanced survival rates, may be obvious. However, information on longer-term effects of radiation treatment will be useful in comparing results with other techniques in use presently or which may be developed in the future. The follow up efforts at the Fermilab project should be applauded, and should serve as a model that can be duplicated in other DOE investigations of medical therapy.

CATEGORY 4.006, NUMBER 93

Biological effects of heavy ions on human nervous system and vision

During the early 1970s, human subjects were placed within neutron and ion beams at accelerators in Berkeley and Seattle. These experiments arose because astronauts had observed visual light-streak effects while exposed to cosmic rays in space flight. One objective of the experiments was to explore "visual sensations" in humans from exposure to ions. Two subjects observed light flashes in neutron beams of peak energy of 640 million electron volts (MeV); six subjects observed light flashes and dim but definite streaks of 25 MeV peak energy; and two subjects observed light flashes and streaks due to helium ions impinging upon human retina.

These experiments were conducted by the Lawrence Berkeley Laboratory and were funded by the Atomic Energy Commission. They were reported in Nuclear Science Abstracts in 1972 and 1973. The summary factsheet provided by the Department of Energy reports no long term follow up on the human subjects.

Category 5. Other Teletherapy

Projects in this category involved cases where patients whose cancer was not responding to conventional treatment were treated with various types of radiation from accelerators. As before, the Subcommittee staff does not question the propriety of these experiments because they contained a real possibility of benefit for patients.

Category 6. Treatment of Polycythemia

This project was a ten-year attempt, beginning in 1939, to treat polycythemia vera with radiation. The radiation therapy seemed more successful than conventional means of treatment.

Category 7. Hematological Effects

Most of the experiments in this category involved examinations of blood changes of patients who were being irradiated for purposes of diagnosis or treatment. The Subcommittee staff does not question these experiments, since the patients benefited or potentially benefited from the treatment, and the examination of blood changes could provide useful information in designing future treatment.

Category 8. Neutron Capture Therapy

Projects in this category involved the use of beams of neutrons to treat patients with brain tumors. The Subcommittee staff does not question these experiments, since the radiation treatments were meant to benefit patients.

Category 9. Other Radiation Therapy

Most of these projects involved the examination of radioactive isotopes for their ability to treat malignant diseases or to assist diagnosis by concentrating in tumor cells. One experiment, however, raised issues of concern and is discussed below.

CATEGORY 9.001, NUMBER 166

Uranium injected into brain tumor patients

From 1953 to 1957, approximately 12 terminal brain tumor patients were injected with uranium to determine the dose at which kidney damage began to occur. These experiments were conducted at Massachusetts General Hospital, Boston, with assistance from the Oak Ridge National Laboratory, and were funded by the Atomic Energy Commission.

The experiments were conducted to gain data in deriving tolerance doses for workers in uranium processing and fabrication plants. Inhaled or ingested uranium salts are known to produce kidney damage; these experiments were designed to identify the doses at which kidney damage began to occur. Data were also obtained during these experiments on the excretion and retention of uranium in the body. All subjects were terminal brain tumor patients who died within 18 months of the experiments.

An additional stated reason for conducting the experiment was as an initial evaluation of uranium toxicity in developing therapy to treat brain tumor patients with U-235. However, this does not in fact seem to be an important reason for the experiment, since no effort was made to actually treat the brain tumor patients with this isotope. Moreover, neutron capture therapy with U-235 has never been proven as an effective treatment for brain tumor patients.

Several scientific papers resulted from this experiment. One paper, Bernard et al., Proc. Health Physics Soc., 33–48, June 1956, reported the injection of 11 patients, 10 of whom were in coma or semi-coma. One of these patients died in 2.5 days, and one died 18 days after injection. Doses ranged from 4 to 50 milligrams (mg) of uranium. A second paper, A.J. Lussenhop et al., Am. J. Roentgenol. 79, 83–100, 1958, reported on the injection of five patients, four of whom "were in coma or semicoma and remained so until their demise." Patients were injected with 4 to 15 mg uranium. The three patients with the highest doses, 0.12 to 0.28 mg uranium per kg body weight, showed evidence of kidney toxicity. Based on comparisons with animal data, the experimenters determined that a lethal dose for humans would have been 1 mg uranium per kg.

Another paper, S.R. Bernard, Health Physics 1, 288–305, 1958, reports on the injection of eight terminal brain tumor patients, six of whom were comatose. Doses ranged from 4 to 50 mg uranium. There may be some overlap among the patients covered by the three scientific papers. This last paper referred to earlier studies (which were the experiments reported in Category 1.003, Number 119), and notes that these studies lacked some information: "autopsy data were not obtained since none of the subjects were terminal patients." (S.R. Bernard, Ibid., 288) Using terminal subjects thus provided the "advantage" that the distribution of uranium in the body could be determined after autopsy.

Category 10. Biological Effects of I-131

CATEGORY 10.001, NUMBER 69

Study of changes in thyroids irradiated with radioactive iodine

This project, begun in 1951, is a retrospective study of the health of humans exposed to I-131, chiefly for medical reasons. The study has been carried out at Case Western Reserve University, and has been funded sequentially by the Atomic Energy Commission, the Energy Research and Development Administration, and the Department of Energy. This is not considered an experiment, but the project shows clearly the necessity and usefulness of long term medical follow up of irradiated populations.

The significant non-patient population in this study is the group of Marshallese Islanders who were exposed to radioactive iodine from atomic bomb test fallout. The findings on this population were described in TID-27160, a June 1976 Progress Report to the Energy Research and Development Administration. The report noted the long latency period for the onset of clinical effects, and commented on the likely relation between exposure and thyroid nodules:

> The lengthy interval in man is clearly shown in the Marshallese where in spite of thorough annual physical examinations the first palpable nodule was not found for 9 years and neoplasms are still appearing at 22 years. (p. 4)
>
> To date 6 carcinomas have been removed from 10 individuals from several atolls, 3 from an atoll with extremely low exposure. Since this is a population which seldom if ever develops thyroid nodules, the relationship to the radiation which was primarily radioiodine is most impressive. (p. 4)
>
> At the time of the last annual report we described a 21 year old Marshallese who we had just operated for multiple benign adenomas. He was 6 months in utero when his mother was exposed to fallout. The special studies of that thyroid tissue showed

the bizarre nuclear forms recognized as evidence of radiation effect. At the time of preparation of this report, we have just operated and removed several benign but atypical adenomas from the thyroid of his mother who had developed masses in the last year. (p. 5)

The factor of long delay in the development of neoplasms is emphasized in both animals and men . . . . The first Marshallese lesion did not develop for 9 years. Many of the early lesions came from the atoll with the highest fallout (Rongelap). It was quite some years later that lesions began appearing in people who were on the next nearest atoll (Alingnae) where the dose had been somewhat less. While lesions were appearing on the nearer atolls, the low dose received on an atoll much further away (Uterik) seemed to have produced no lesions, but in the most recent years, 8 individuals have been operated and 3 carcinomas found. These observations seem to emphasize the risk of the low dose range. (p. 5).

Nine years after the 1954 thermonuclear bomb accident, the first thyroid neoplasm appeared. (p. 6).

CATEGORY 10.001, NUMBER 165

Milk containing I-131 fed to humans

In 1962, five human subjects drank milk containing radioactive Iodine-131, for periods of time ranging from 1 to 63 days. In the first experiments all subjects drank daily doses of I-131 milk for periods from 4 to 63 days. Doses each day were 150 or 1840 picocuries. The largest dose was 1840 picocuries per day for 63 days, for a total of 115,920 picocuries. In a second experiment, two of the same subjects drank single doses of 92,000 picocuries each. These experiments were funded by the Atomic Energy Commission and carried out by Oak Ridge National Laboratory.

The objective of the experiment was to validate calculations which standard setting organizations were using to establish occupational radiation exposure limits. Subjects drank the milk, radioactive iodine uptake was measured by counting the area around the thyroid, and excretion of iodine was also measured. Cows milk containing radioactive iodine was obtained from an AEC Agricultural Research Laboratory. The Department of Energy reported that no follow up of subjects was conducted. These experiments were reported in a scientific paper, S.R. Bernard et al., Health Physics 9, 1307-1323, 1963.

CATEGORY 10.001, NUMBER 173

Planned radioiodine exposures to humans

From May 1963 to November 1965, radioactive iodine was released intentionally on seven separate occasions. On three occasions, human subjects were exposed. The experiments were funded by the Atomic Energy Commission and were conducted at the National Reactor Testing Station in Idaho.

The experiments were designed to improve knowledge of the transport of radioactive iodine, which is produced by nuclear reactors and nuclear bomb tests, through the air-vegetation-cow-milk sequence in the human food chain. This information was considered desirable in developing reactor siting criteria, in the preparation of safety analysis reports, and as an aid to planning for emergency action after a radiation accident.

Seven separate experiments were conducted. The general design was that radioactive iodine was released in gaseous form, and prevailing winds took the iodine over an area designated the "hot pasture." Monitoring devices in the pasture determined the radioactivity deposited. A herd of cows was then led to the pasture to graze for several days. The cows were milked and the milk monitored for radioiodine. Humans were exposed either by drinking the milk or by direct exposure to the released iodine gas. The experiments collectively were called the Controlled Environmental Radioiodine Tests (CERT).

During Experiment CERT-1, conducted in May 1963, one curie of radioactive iodine was released into the hot pasture. Six cows were placed on the contaminated pasture. Cows were milked twice a day, and the milk from one cow saved for human ingestion. Seven human subjects each drank 0.5 liter of radioactive milk over a period of 18 days. Radioactive iodine uptake was determined by counting the thyroid of each subject. (IDO-12035, Controlled Environmental Radioiodine Tests at the National Reactor Testing Station, U.S. Atomic Energy Commission, June 1964).

Experiment CERT-2 was conducted in September 1964. Approximately one curie of radioactive iodine was again released over the hot pasture. Milk samples were again tested, but were not consumed by humans. Instead, three human subjects were placed on the pasture during iodine relase, and their thyroids counted after exposure. This was not a food chain experiment, but was designed to measure the direct iodine dose from inhalation.

During Experiment CERT-3, conducted in December 1964, and CERT-4 and -5, both conducted in June 1965, no cows or humans were exposed, and measurements were only made on the pasture. Amounts of iodine released were lower than in previous tests. CERT-4 released 0.01 curie; CERT-5 0.1 curie; and the amount released in CERT-3 was not specified. (IDO-12047, Controlled Environmental Radioiodine Tests at the National Reactor Testing Station, 1965 Progress Report, U.S. Atomic Energy Commission, February 1966)

During Experiment CERT-6, conducted in summer 1965, radioactive iodine in the methyl iodide form was released. As the experiment progress report states:

Unfortunately, several of the vials, each containing 2 curies of methyl iodide-131, were accidentally broken in transit or were leaking when received. Those that were not broken were subsequently opened in the hot cell of the Idaho Chemical Processing Plant (ICPP) and the methyl iodide (2 to 6 curies) escaped to the atmosphere from a 75-meter stack. The stack was located 4 kilometers upwind of the test grid at the Experimental Dairy Farm (EDF). (IDO-12053, Controlled Environmental Radioiodine Tests, Progress Report Number Two, U.S. Atomic Energy Commission, August 1966, p. 2).

Six cows grazed over the 27 acre area of the EDF, and iodine concentration in their milk was determined by counting. In addition, "Several individuals were inadvertently exposed to airborne radioiodine from the leaking and broken containers, and efforts were made to obtain data on the retention of this form of iodine in humans." (Ibid., p. 2) These exposures from ruptured vials occurred over a four-day period, and a few people received multiple exposures; thyroids of these individuals were counted.

Experiment CERT-7 was conducted in November 1965; 1 curie of I-131 in the gaseous molecular form was released over the pasture at the EDF. Six cows grazed, and milk samples were counted. In

addition, seven human volunteers were placed seated on the pasture area. Uptake of radioactive material was determined by counting the subjects' thyroids.

The Department of Energy reported to the Subcommittee that no medical follow up of the experimental subjects in the CERT tests was performed.

Category 11. Other Biological Effects

CATEGORY 11.001, NUMBER 51

Reactions of human skin to beta rays

During April and May 1945, two groups of 10 human subjects were exposed to plastic disks containing Phosphorus-32, which emits beta rays. These disks were placed directly on the skin to expose subjects. In one set of experiments, 10 persons were exposed to 140 to 250 rep (roentgen equivalent physical); in a second set of experiments, 10 subjects received a series of four exposures each in doses varying from 635 to 1180 rep. In most instances the forearm was the point of exposure, except for three cases in the second series where the inner mid-thigh was exposed. These experiments were funded by the Manhattan Project and were carried out in Clinton Laboratory, Oak Ridge, Tennessee. (One roentgen equivalent physical of beta rays is approximately one rem. For comparison, present occupational exposure limits are 30 rem per year to the skin, and 75 rem per year to hands and forearms.)

The objective of this experiment was to determine the beta ray dose at which skin erythema (reddening of the skin) would first be seen. In the first set of experiments, 8 of 10 subjects showed a "visible reaction" of mild tanning at a dose of 250 rep. In the second set of experiments, 6 subjects showed erythema at 635 rep, and 8 showed erythema at 813 rep. These experiments were reported in J.E. Wirth and J.R. Raper, Chapter 12, Biological Effects of External Beta Radiation, National Nuclear Energy Series, Volume IV-22E, McGraw-Hill, 1951.

The Department of Energy reported no follow up on these subjects.

CATEGORY 11.001, NUMBER 53

Studies of radium applied to human skin

During 1955, experiments carried out on human subjects demonstrated that the biological effects of Thorium X (Radium-224), as judged by erythema and skin pigmentation, can be increased by using an electrical current to cause greater penetration of the skin by radioactive material. These experiments were carried out at New York University and were funded by the Atomic Energy Commission.

Three subjects were exposed in these experiments. During the experiment, squares of blotting paper saturated with Radium-224 were placed on the forearms of each subject. An electric current was applied for 20 minutes to the paper on the left forearm, and no current was applied to the right forearm. For each patient, the left forearm showed intense reddening after 48 hours, and some skin

pigmentation at 75 days after exposure; the right forearms showed no visible reactions at the same times. The Department of Energy estimated that doses to the right forearm were 350 rem, and 1000 rem to the left forearms. Irradiated tissues were surgically removed, and no medical follow up on subjects was conducted. For comparison with the doses, present occupational exposure limits are 75 rem per year to the hands and forearms. These experiments were reported in AECU-3061, Atomic Energy Commission, a publication presented at the Sixteenth Annual Meeting of the Society for Investigative Dermatology, 1955. This publication discusses the application of Thorium X to certain skin diseases, but there is no indication that any of the subjects received medical benefit from the experiment.

CATEGORY 11.001, NUMBER 83

Analysis of illness of children receiving fetal irradiation

In 1948, a program of routine pelvis examination by x-ray early in pregnancy for 1008 mothers who were to bear their first child was carried out at Chicago Lying-In Hospital. The objective of the exposures was to make delivery and labor more predictable and easier by measuring the sizes of pelvis and fetal head. In preceding and succeeding years, no such measurements were made and these groups serve as a control population. The estimated tissue dose to the pelvis for irradiated mothers was 1.5 to 3 rem. About half of these children were also exposed to 5 x-ray films during the first day of life. The estimated dose to new-born infants was 0.5 rem.

The Atomic Energy Commission subsequently funded the Argonne Cancer Research Hospital to conduct analyses of health of the exposed children. Between 1962 and 1965 the parents of these children were contacted and asked for information on diseases and hospitalization. The first study found an increase in benign hemangiomas, a tumor which produces skin discoloration, but no increase in congenital malformations, eye diseases, or malignant tumors. A second survey made between 1966 and 1970 confirmed the results of the first follow up. The Department of Energy commented in 1985 that, "It is hoped that further data will be obtained from these subjects and if possible from their children."

CATEGORY 11.001, NUMBER 112

Human absorption of tritium oxide through skin

During 1951, 14 human subjects were exposed over a small area (about 10 square centimeters) on the forearm (12 subjects) or abdomen (2 subjects) to a water-vapor atmosphere labeled with tritium oxide (HTO). A single subject was in addition exposed over his total skin area while breathing uncontaminated air. Absorption of tritium oxide was estimated by measurments of tritium excreted in urine. The data from these experiments indicated that humans absorbed tritium at a rate 4 times faster than measured for rats. These studies were funded by the Atomic Energy Commission and were conducted by the General Electric Company, Richland, Washington.

The objective of these experiments was to determine the rate of absorption of tritium oxide through human skin. This information would assist in evaluating the hazard to individuals who might handle tritium, which had promise of becoming a widely used tracer isotope for hydrogen. The Department of Energy reported that no medical follow up was carried out on these subjects. These experiments were reported in C.W. DeLong et al., Am. J. Roentgenol. Radium Therapy Nucl. Med. 71, 1038-1045, 1954.

CATEGORY 11.001, NUMBER 121

Effects of x-rays on human fingers

During 1947, fifteen subjects were exposed in the nail fold area of the left fourth finger to doses of 200 to 600 roentgen. (For comparison, present occupational exposure limits are 75 roentgen per year to the hands.) Fourteen of these subjects were patients being treated by x-rays or radium for other purposes, but none of them had received previous irradiation to the hands. The other subject was a staff member who occasionally prepared radium material for treatments. He was observed before and after the preparation of an item containing 130 milligrams of radium. These experiments were funded by the Atomic Energy Commission and were conducted at the University of Chicago.

The objective of the experiment was to examine the changes which may occur in the fingers of persons occupationally exposed to radiation. The left fourth finger was chosen for irradiation because the skin is fairly thin as compared to other fingers, and this finger is "less likely to have been subjected to previous trauma." Microscopic observations were made of the fingers before and immediately after treatment, and for up to two weeks after treatment. Some irradiated patients showed temporary symptoms such as enlarged or broken blood vessels, or reddening of the skin. The report on the experiment noted no permanent changes to the skin of the finger, and concluded with the statement, "It is proposed that test doses be given at higher levels." (CH-3833, Effect of Single Dose X-Ray to the Nail Fold Area of Human Subjects, Preliminary Report, July 1947, p. 4) However, no further experiments were reported. The Department of Energy reported no medical follow up of the subjects.

CATEGORY 11.001, NUMBER 123

Human absorption and excretion of tritium

During 1950, human subjects were exposed to tritium in several different experiments. Subjects were exposed to tritium in air for two hours, and the increase in tritium in body fluids was followed over time. In a second experiment, the arm of a man was immersed up to the elbow in water containing tritium, and the tritium in body fluids was again followed. In a third experiment, a man drank tritium in 0.2 liters of water and absorption into the blood stream was followed. Amounts of tritium administered were up to 3 millicuries. (For comparison, the maximum permissible body burden for occupational exposure is 2 millicuries.) These experiments were

funded by the Atomic Energy Commission and carried out at Los Alamos Scientific Laboratory.

The objective of the experiment was to obtain information on the human absorption and excretion of tritium, to aid in the setting of occupational exposure limits. The exact number of subjects exposed in not clear, but it appears that one subject immersed an arm in tritiated water, one subject drank tritiated water, and seven subjects were exposed to air containing tritium. These experiments were summarized in AECU-937, The Absorption, Distribution, and Excretion of Tritium in Men and Animals, U.S. Atomic Energy Commission, November 1950. The Department of Energy reported no medical follow up of subjects.

CATEGORY 11.001, NUMBER 125

Human absorption of tritium liquid and vapor

During 1952, the lower arms of subjects were exposed for variable lengths of time to tritiated water vapor and tritium in liquid water. Tritium activity in subjects' urine was monitored. The Department of Energy provided no further details on this experiment, and reported no follow up of subjects.

CATEGORY 11.001, NUMBER 126

Human absorption of tritium by lung

During 1952, three subjects were exposed in five experiments to tritiated water vapor. Subjects breathed tritium-saturated oxygen for 4 to 5 minutes. The tritium retained in the body during the exposure was obtained by comparing the tritium inhaled with the tritium exhaled. Retention and excretion of tritium with time were monitored through blood and urine samples. This experiment was funded by the Atomic Energy Commission and carried out at Los Alamos Scientific Laboratory.

Subjects inhaled from 0.8 to 1.0 millicuries of tritium. This can be compared with the maximum permissible body burden of 2 millicuries.

The objective of the experiment was to obtain information on absorption and retention of tritium to aid in establishing occupational exposure standards. The experiment is reported in LA-1465, Lung Absorption of HTO by Man Upon Inspiration of HTO Water Vapor, Los Alamos Scientific Laboratory, June 1952. The Department of Energy reported no medical follow up of the subjects.

CATEGORY 11.001, NUMBER 127

Human absorption of ingested tritium water

During 1952, five experiments were conducted on three subjects in which the subjects drank water containing tritium. Retention of tritium in the body was examined by taking blood and urine samples over time and counting. The experiments were funded by the Atomic Energy Commission and were carried out at Los Alamos Scientific Laboratory.

The objective of the experiments was to obtain data that would assist in evaluating the hazard of ingested tritium. Two subjects

each drank 1.6 millicuries of tritium; the third subject drank 6.2 millicuries in three separate experiments. For comparison, the occupational body burden is 2 millicuries. The experiments are reported in LA-1464, The Absorption of Ingested Tritium Water and the Water Dilution Volume of Man, Los Alamos Scientific Laboratory, June 1952. The Department of Energy reported no follow up on the subjects.

CATEGORY 11.001, NUMBER 133

Radiation exposure of aircrews in mushroom clouds

The U.S. Air Force sent manned planes through radiation clouds ("mushrooms and stems") from atomic bomb tests to measure radiation doses in the clouds and to the crews. The detonations were part of Operation Redwing, a series of 17 nuclear tests in the multimegaton range, at Eniwetok and Bikini Atolls in the Pacific, from May-July 1956. The planes, five different B-57Bs, made 27 passes through clouds from six different nuclear explosions, at times from 20 to 78 minutes after detonation. 16 passes were earlier than 45 minutes and 7 were earlier than 30 minutes after detonation.

Maximum radiation doses in the cloud were 800 roentgens per hour. Total radiation doses to crew members were as high as 15 roentgens by film badge. (For comparison, the present maximum annual dose for workers is about 5 roentgen; one chest x-ray represents 0.02 to 0.04 roentgen.)

The objective of the project was to obtain radiation dose information, in the event that an "operational situation" required flights through such clouds. The information was to assist Air Force commands in planning to insure the "most-effective utilization, consistent with crew safety, of aircraft in cloud areas."

Earlier operations had been conducted where drone aircraft were sent through clouds to obtain dose information. The report also mentions manned penetrations made during Operation Teapot. These passes were made from 17 to 41 minutes after detonation. The report on Redwing deletes information on doses measured during the Teapot flights, and gives no reference to any other published report on Teapot. The Redwing flights are described in ITR-1320, Preliminary Report, Operation Redwing: Early Cloud Penetrations, Armed Forces Special Weapons Project, May-July 1956.

On November 13, 1985, the Subcommittee chairman released this document to make it available for a hearing before the Senate Veterans Affairs Committee the following day on compensation for veterans exposed to atomic tests. The document was described in subsequent press accounts.

The Department of Energy reported no medical follow up on the exposed aircrews. However, subsequent correspondence between the Subcommittee and the Defense Department provided more information. The Defense Nuclear Agency (DNA) reported that seven of the Redwing crew members received doses greater than five rem by film badge, and were notified by the Nuclear Test Personnel Review (NTPR), a program to identify veterans exposed during atomic testing. Under this program, persons with exposures greater than five rem per year are notified and encouraged to undergo a special physical examination at the nearest Veterans Administration hospital. None of these seven have reported medical problems attributable to radiation exposure.

In addition, the Redwing aircraft were contaminated with radioactive material as a result of flying through the clouds. The planes were subsequently decontaminated by ground personnel. The DNA retains the exposure records of these personnel, as well as those of all aircrew members, and all these personnel are recorded as part of the NTPR. The DNA maintains a toll free number which veterans who believe they were exposed to atomic tests can call to report their circumstances. (Letter from Lieutenant General John L. Pickitt, Director, Defense Nuclear Agency, to the Subcommittee Chairman, December 11, 1985.)

In December 1985, Chairman Markey joined with Senator Cranston to request a General Accounting Office investigation on atomic cloud fly-through operations. GAO was asked to determine how many air crew members and how many ground presonnel were exposed during Redwing and other such operations, what doses these personnel received, and what follow up the Defense Department has conducted on all personnel.

CATEGORY 11.001, NUMBER 134

Radioactive material placed on human skin

In 1953, Foster D. Snell, a consulting firm, placed synthetic radioactive soil on the palms of over one hundred human subjects, and examined the ability of different cleaning agents to remove the radioactive material. The objective of this experiment was to determine the efficiency of various cleaning agents in removing radioactive contaminants from "human skin and hair."

These experiments were performed for the Chemical and Radiological Laboratories of the Department of the Army, and were reported in a U.S. Atomic Energy Commission technical publication, Removal of Radioactive Contaminants from Human Skin, NP-4935, June 15, 1953. It appears that at least part of the reason for conducting the experiments was to provide information that could be used on a battlefield during a nuclear exchange, since there is a reference to decontamination "from the point of view of the soldier in the field." (NP-4935, pp. 165,166)

For the experiments, a drop of a liquid mixture of radioactive material was deposited on the palms or arms of human subjects, allowed to dry, and counted with a Geiger counter. The contamination was then washed off with various cleaning agents, and the skin counted again to determine efficiency of removal. Initial experiments were conducted on metallic surfaces, then on rabbits and pigs. Preliminary work was also done on hair removed from humans, and then on 16 human subjects. Most of this work was done with a suspension of "synthetic soil," a mixture composed chiefly of soil, sand, and clay, mixed with fission products. Some experiments were performed with synthetic soil which had been irradiated in a nuclear reactor, synthetic soil mixed with Carbon-14, or a sample of soil from the Nevada test site. These other mixtures did not adhere well to skin, and were not used in later experiments. In these first human experiments, solutions registering up to 2,900 counts per minute were placed on subjects' forearms or

palms. These experiments showed that it was most difficult to wash radioactivity from palms, and most subsequent experiments placed the radioactive material on palms only.

Subsequent experiments were conducted on about 102 different human subjects, placing larger amounts of radioactivity, typically 10,000 to 20,000 counts per minute, on subjects' palms. A variety of detergents and hand creams were examined for their ability to remove the radioactive contamination. One set of experiments was conducted with "radiological warfare agents," composed of small pellets of zinc bromide which contained radioactive Tantalum. Droplets containing 13,000 to 49,000 counts per minute of these agents were placed on the palms of six human subjects.

One set of experiments was conducted with employees at the Monsanto Chemical Company's Mound Laboratory, Miamisburg, Ohio. A mixture of contaminants containing alpha emitters, and not further identified, was placed on the palms of four employees and detergents tested for removal. In addition, detergents were tested on the hands of three other employees "whose hands were contaminated in the normal course of work." (NP-4935, p. 152).

Except for the experiments at Mound Laboratory, the Department of Energy has not been able to identify where these experiments were conducted or how the 118 human subjects were obtained. Subjects were male and female, and ranged in age from 18 to 66. The Department of Energy reported no medical follow up on any of these subjects.

CATEGORY 11.001, NUMBER 183

Medical follow up studies

In its factsheet on this project, the Department of Energy described follow up studies to assess the long range health of several different populations which have been exposed to radiation. These studies have been funded by the Atomic Energy Commission, the Energy Research and Development Administration, and the Department of Energy. Some of them started in the 1950s, and they continue at present. The studies are being carried out at the Argonne Cancer Research Hospital (ACHR), Argonne National Laboratory. The studies are described below:

1. For 20 years, a joint study of more than 400 persons bearing a considerable body burden of radium has been under way. Most of these persons were painters of the radium dials on luminous watches at various plants in the Illinois River valley region during 1920-1930; others received radium chloride by injection or orally as a medical treatment between 1920 and 1933. Persons with a considerable body burden of radium were found to have characteristic defects, destructive changes, and tumors in the skeleton. These studies include accurate estimates of the body content of radium by using a total body counter; through analysis of the expired breath for the gas radon, a radium decay product; by film exposure from subjects' bodies; and through studies of the blood to reveal if destructive or malignant changes have taken place.

2. A long term follow up study is under way to examine about 1000 children who were exposed before birth to x-rays during pelvic examinations of their mothers. This study, which extended over about 25 years, is described as Category 11.001, Number 83.

3. A follow up study is under way on patients who had received radiation therapy for stomach ulcers. This study was funded by the Department of Energy, and revealed "some positive findings," which are not further specified. The study is now to be resumed under support from the National Institutes of Health.

4. During the 1950s, persons who received short treatments with low-voltage x-rays for benign conditions of the head, neck, and upper thorax during childhood were studied for possible development of carcinoma of the thyroid. All of the children with cancer of the thyroid who had been treated or seen by the investigator had been irradiated previously in such a way that the thyroid gland or portions of it had been included in the radiation field.

CATEGORY 11.001, NUMBER 186, PART A

Human ingestion of fallout

Concern about problems from the ingestion of fallout led to studies using real fallout from the Nevada Test Site; simulated fallout particles that contained Strontium-85, Barium-133, or Cesium-134; and solutions of Sr-85 and Cs-134. During 1961 to 1963, real and simulated fallout and solutions of strontium and cesium were fed to 102 human subjects. Absorption and retention of the ingested radioactivity was measured by counting the bodies of subjects. These experiments were funded by the Atomic Energy Commission and were carried out by the University of Chicago and the Argonne National Laboratory. Subjects were university students or members of the researchers' staffs.

Several different fallout or simulated fallout materials were prepared. One set of experiments used microscopic spheres of radioactive strontium, cesium, or barium. A total of 27 volunteers ingested the spheres. Transit time of the spheres through the gastrointestinal tract was measured by counting excreted matter. A second set of experiments used real fallout, obtained from the Nevada Test Site following land detonation of the nuclear test Small Boy, on July 14, 1962. Fallout samples were placed in gelatin capsules and were fed to 10 subjects. In these and subsequent experiments, retention of activity was followed by counting subjects' bodies.

Two types of simulated fallout were also prepared. They were distinguished by the size of microscopic spheres used, which simulated the size of fallout particles close to or far from the site of detonation. 21 subjects were fed simulated local fallout, and 22 simulated distant fallout. Finally, 22 subjects were fed solutions of strontium or cesium. The amounts of radioactive material fed to subjects in all experiments ranged from 0.4 to 2.5 microcuries of Strontium-85, or 0.5 to 14 microcuries of Cesium-134. These values can be compared with the maximum permissible occupational body burdens of 60 microcuries for Strontium-85, and 30 microcuries for Cesium-134.

The Department of Energy reported no long term medical follow up on these subjects. These experiments were reported in a scientific paper, G.V. LeRoy et al., Health Physics 12, 449-473, 1966.

CATEGORY 11.001, NUMBER 186, PART B

Lanthanum-140 administered to humans

The paper cited in Number 186, Part A, G.V. LeRoy et al., reported an earlier study in which 54 hospital patients were fed radioactive Lanthanum-140, and the passage of material through the gastrointestinal tract was measured by counting excreted matter. It appears that the Department of Energy did not report to the Subcommittee on this experiment, but it was published in R.L. Hayes et al., Health Physics 9, 915-920, 1963, and the Subcommittee obtained a copy of the original reference from the Library of Congress, Congressional Research Service. This experiment was carried out at the Oak Ridge Institute of Nuclear Studies, and was funded by the Atomic Energy Commission.

The objective of this experiment was to measure the movement of radioactive material through the human body, and estimate the dose to the lower large intestine from materials that the body does not absorb. The experimenters noted that movement through the body varied with individuals, and these experiments attempted to measure the extent of such variation.

Subjects were fed 10 or 20 microcuries of Lanthanum-140. (For comparison, the maximum permissible body burden for occupational exposure is 10 microcuries.) Movement of this substance through the body was examined by collecting fecal samples and counting. Subjects were patients from the clinical program at the Oak Ridge Institute, and ranged in age from 7 to 76. All subjects were selected because they had normal intestinal tracts, which were not affected by their diseases. Subjects thus received no medical benefit from the experiment. To measure variability in individuals, 8 subjects were fed lanthanum twice, and one was fed three times.

Category 12. Metabolic and Physiological Studies

CATEGORY 12.001, NUMBER 15

Strontium and calcium injected in terminal cancer patients

The material which the Department of Energy submitted to the Subcommittee on this project included ANL-6104, a 1959 report from the Argonne National Laboratory. This report summarized data on the retention by humans of calcium, strontium, and radium. One of the references cited was Schulert et al., Int. J. Applied Radiation and Isotopes 4, 144-153, 1959. The Department of Energy did not supply this reference, but the Subcommittee obtained a copy of the original through the Library of Congress, Congressional Research Service.

In these particular experiments, radioactive Calcium-45 or Strontium-85 were injected into twelve terminal cancer patients, and the distribution of each substance in tissue and bone was determined at autopsy. These experiments were carried out at Columbia University and the Montefiore Hospital, Bronx, New York.

The objective of these experiments was to measure the absorption by different parts of the body of strontium, a product of nuclear fission and a component of nuclear weapons fallout. In order to help evaluate the hazards of strontium to humans, the experimenters desired to determine the retention by different tissues of strontium compared to calcium; strontium mimics calcium chemically and concentrates in bone. As the scientific paper explained, subjects were chosen so they could be autopsied fairly soon after injection: "Since autopsy analyses were employed, the patients were, of necessity, of limited life expectancy with cancer involvement, and cannot be considered as normal healthy adults." (Schulert et al., 145)

Ten patients were injected with about 1.5 microcurie per kilogram body weight of Strontium-85, and about 0.4 microcurie per kilogram of Calcium-45. Total doses would have been 64 to 114 microcuries of strontium, and 17 to 30 microcuries of calcium. For comparison, the occupational maximum permissible body burdens are 60 microcuries for Strontium-85, and 200 microcuries for Calcium-45. These patients lived from 3 hours to 124 days. An additional terminal patient injected with strontium only survived for 251 days, and one patient injected with calcium only survived for 960 days. Patients ranged in age from 49 to 72.

CATEGORY 12.001, NUMBER 109

Technetium administered to humans

During 1965, Technetium-95 (metastable) and -96 were administered to 8 subjects. Retention and absorption of technetium were monitored by counting the bodies of subjects and by counting excretions. Doses were administered to subjects at the University of Washington, counting was carried out by the Pacific Northwest Laboratory, Richland, Washington. The Atomic Energy Commission funded the work of the Pacific Northwest Laboratory.

Technetium is a product of nuclear fission and is present in rather high concentrations in wastes from nuclear reactors. At the time of these experiments, technetium was being separated from nuclear wastes at the federal facility near Richland, Washington. In addition, technetium was also used for medical diagnoses. The objective of these experiments was to obtain information on the retention of technetium in the body, to help assign occupational exposure limits.

Four subjects were injected, and four subjects were fed technetium. Each subject received 20 microcuries of Tc-95m and 60 microcuries of Tc-96. (For comparison, the occupational maximum permissible body burdens are 70 microcuries for Tc-95m and 10 microcuries for Tc-96.) Samples of sweat, plasma, tears, urine and feces were collected, and observations were made for up to 60 days on some subjects.

These experiments were reported in a scientific paper, T.M. Beasley et al., Health Physics 12, 1425-1435, 1966. The Department of Energy reported there was no long term follow up of these subjects.

CATEGORY 12.001, NUMBER 110

Promethium administered to humans

In 1967, Promethium-143 was administered to 14 subjects. Absorption and retention were followed by counting the bodies of subjects, and by measuring the activity in blood and excretion sam-

ples. 6 subjects were injected with promethium and observed for retention. 2 subjects drank orange juice with promethium in solution. 6 subjects were injected with promethium and then injected with the chelating agent diethylenetriaminepentaacetate (DTPA), and the ability of DTPA to remove promethium from the body was examined. These experiments were funded by the Atomic Energy Commission and were carried out by the Hanford Environmental Health Foundation and the Battelle Memorial Institute, both at Richland, Washington.

The experiments were conducted to determine the uptake, retention, distribution, and excretion of promethium in humans. The information obtained would help to develop an excretion model for diagnosis of promethium in humans, to form a basis for radiation exposure, and to determine the dose from accidental exposures. These considerations were relevant to occupational exposure of persons handling promethium.

Injected subjects received 0.1 microcuries of promethium. Two subjects drank 10 microcuries of promethium. Administered preparations were mostly PN-143, but some Pm-144 was also present. Little promethium was retained by the two subjects who drank it. However, about half of the injected promethium deposited in the liver within a few minutes, and most of the remaining promethium deposited in the bone within the next 5 hours. Subjects were followed for one year, during which this distribution remained unchanged. The effectiveness of DTPA in enhancing excretion of promethium declined with time: When DTPA was injected 30 minutes after promethium, it removed 90 percent of the radioactive material; after 24 hours, it removed only 25 percent; and after 80 days, it removed only 5 percent.

These experiments were reported in a scientific paper, H.E. Palmer, I.C. Nelson, Health Physics 18, 53-61, 1970. The Department of Energy reported that no follow up was conducted beyond the one year observation after the experiment.

CATEGORY 12.001, NUMBER 111

Phosphorus-32 injected into humans

During 1963, five subjects were injected with Phosphorus-32. Three of the subjects were patients at the University of Oregon Medical School who received the P-32 as part of the therapy for blood diseases. The other two subjects were injected at the Swedish Hospital in Seattle for purposes only of calibrating equipment. These experiments were funded by the Atomic Energy Commission and carried out by the Battelle Memorial Institute, Richland, Washington.

The reasons for carrying out these experiments were described in a scientific paper:

> Fish and waterfowl that feed in the Columbia River downstream from the Hanford reactors acquire some radionuclides that enter the river with the effluent water (1). 32-P and 65-Zn are the principal nuclides found, and suckers and whitefish usually contain the greatest concentration of these nuclides. Since sportsmen obtain and eat the waterfowl and fish from the Columbia River below Hanford, a method of measuring the low level body burden of these nuclides in humans is needed. Since 65-Zn is a gamma emitter, body burdens down to 1 nc [nanocurie] can easily be measured in a whole-body counter. Foster (2) has described an experiment in which a subject ate a weekly meal of whitefish and the accumulation of the 65-Zn in the body was studied. 32-P does not emit a gamma ray and it is much more difficult to measure. This paper describes a method by which body burdens of 32-P down to 40 nc can be measured. (H.E. Palmer, Health Physics 12, 605-608, 1966. References 1 and 2 are publications designated HW-80991, 1964; and HW-SA-3060, 1963. These are probably Atomic Energy Commission documents.)

One subject was injected with 425 nc of P-32. A second subject was injected with 500 nc, then reinjected after 28 days with 425 nc more. Injection doses for the other subjects were not reported. This same scientific paper reported another experiment where humans ate radioactive fish:

> One reason for developing a sensitive, in vivo counter for 32-P was to measure people who eat Columbia River fish. The significance of this intake with relation to the maximum permissible body burden has been discussed in another publication. (1) Five subjects ate ¾ lb each of whitefish which had been caught in the Columbia River. After allowing 1 day for absorption of the 32-P, the subjects were measured for 20 min with the [radiation] counter and showed body burdens of 70, 110, 89, 72, and 93 nc . . . . The maximum permissible body burden for occupational exposure is 6000 nc.: (Ibid., 607. Reference 1 is HW-80991.)

The Department of Energy reported that no follow up was conducted on these experimental subjects.

CATEGORY 12.001, NUMBER 128

Humans inhaled tritium

During 1950, six subjects each inhaled "a few" millicuries of tritium. (For comparison, the maximum permissible occupational body burden for tritium is 2 millicuries.) Tritium concentration in urine was monitored for the following 15 days. These experiments were funded by the Atomic Energy Commission and were carried out at the Los Alamos Scientific Laboratory, New Mexico.

The objective of this experiment was to investigate the rate of appearance of tritium in urine. This knowledge would help in the establishment of occupational exposure limits. No follow up on these subjects was reported.

CATEGORY 12.003, NUMBER 174

Radioactive material administered to humans to calibrate equipment

Between 1965 and 1972, 8 individuals were involved in 13 different human experiments. All eight were employees of the Idaho Division of the Atomic Energy Commission. In four experiments, subjects inhaled Argon-41; in nine experiments, subjects swallowed capsules containing microcurie amounts of radioactivity. These experiments were funded and carried out by the Atomic Energy Commission.

The objective of this experiment was to calibrate instruments that measure radioactive substances inside the human body; such instruments are usually used to examine workers accidentally exposed or hospital patients receiving radioactive material for diagnostic purposes. A secondary objective of the experiments was to examine the metabolism of radionuclides ingested or inhaled by humans.

Some of these experiments were reported in scientific papers. In the first set of experiments, one subject was fed one microcurie of

Manganese-54; another subject was fed an unspecified amount of Iodine-131 (J.I. Anderson and D.G. Olson, Health Physics 13, 719–732, 1967). In a second set of experiments, individual subjects were fed 3.5 microcuries of Cesium-132, 1.9 microcuries of Potassium-42, or 1.1 microcuries of Manganese-54. In addition, 4 subjects inhaled Argon-41 in amounts of 1.3 to 2.2 microcuries (D.G. Olson, Health Physics 14, 439–447, 1968). In a third experiment, one subject was fed 1.5 microcuries each of Cobalt-60 and Cesium-137 (J.I. Anderson and D.G. Olson, Health Physics 23, 325–332, 1972).

The Department of Energy reported there was no medical follow up of any of these experimental subjects.

APPENDIX

CURRENT FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS

Current regulations on the use of human subjects for experiments are described in Title 45, Code of Federal Regulations, Part 46 (45 CFR 46), revised as of October 1, 1985. These regulations call for special requirements when prisoners, children, or other specified categories of persons are used as subjects.

GENERAL PROVISIONS

Experiments on human subjects must satisfy the following criteria:

(1) Risks to subjects should be minimized.

(2) Risks to subjects should be reasonable in relation to anticipated benefits, and the importance of the knowledge that may reasonably be expected to result.

(3) Subjects should be selected in an equitable manner.

(4) Informed consent shall be sought from each prospective subject or the subject's legally authorized representative. Informed consent includes a clear description of the risks and benefits of the experimental procedure. (45 CFR 46.111)

PRISONERS

Biomedical or behavioral research may involve prisoners as subjects only if the purpose of the proposed research is to:

(1) study the possible causes, effects, and processes of incarceration or of criminal behavior;

(2) study prisons as institutional structures or prisoners as incarcerated persons;

(3) conduct research on conditions particularly affecting prisoners as a class (for example, vaccine trials or other research on hepatitis, which is more prevalent among prisoners than the general population);

(4) examine practices, both accepted and experimental, which have the intent and reasonable probability of improving the health or well-being of the subject. (45 FR 46.306)

CHILDREN

A child is an individual who has not attained the legal age for consent to treatments or procedures involved in the research, under the applicable laws of the location where the research is to be conducted (45 FR 46.402)

A child may be used as a subject only upon receipt of permission from parents and assent from the child, under conditions where the child is judged capable of providing assent (45 FR 46.408). If permission and assent are obtained, research can be conducted only if one of the following conditions is met:

(1) The research poses no greater than minimal risk (45 FR 46.404).

(2) The research presents more than minimal risk, but the procedure holds out the prospect of direct benefit for the individual subject or is likely to contribute to the subject's well-being (45 FR 46.405).

(3) The research presents more than minimal risk, does not hold out the prospect of direct benefit to the subject, but the procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for understanding the disorder or condition (45 FR 46.406).

(4) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children (45 FR 46.407).

OTHER SUBJECTS

Where some or all of the human subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards must be included in the study to protect the rights and welfare of these subjects. (45 FR 46.111)

It should be noted that under these regulations, the experiments previously described with prisoners, and which used minors as subjects, would have been strictly prohibited. In addition, many other experiments used patients with severe illnesses or who were disadvantaged, and there is no indication that safeguards were incorporated into the experiments to protect these subjects.