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FACTSHEET HUMAN EXPERIMENTATION

Project Name:
A. Neutron Therapy
B. Heavy Particle Therapy

	A	B
Date Started:	1940	1954
Date Terminated:	1942	Present

Identification:

Principal Investigators:

James L. Born, Richard A. Carlson, Joseph R. Castro, Claude Chong, Jacob I. Fabrikant, Alexander Gottschalk, Robert P. Kling, John H. Lawrence, John A. Linfoot, Bertram V.A. Low-Beer, Rollin K. McCombs, Edward Manougian, Franco Sangalli, William M. Saunders, Henry H. Stauffer, Robert S. Stone.

Responsible Government Official(s):

Objectives:

To treat certain medical disorders with high-energy particle beams that can be precisely localized to the desired target area and deliver therapeutic radiation doses with minimal radiation to surrounding areas.

Short description:

1. Neutrons to treat malignant disease (1940-1942)
2. Protons (for pituitary ablation) to treat metastatic CaBr (11/54-8/55)
3. Alpha Particles (for pituitary ablation) to treat metastatic CaBr (10/57-3/72); to treat diabetic retinopathy (3/58-12/69)
4. Alpha particles to treat pituitary disorders (acromegaly, Cushing's, disease, Nelson's syndrome; chrompophobe adenoma, Prolactin Tumors) (2/58-10/79)
5. Alpha particles (Bragg peak) to treat Parkinsons disease, Brain tumors (1/62-4/66)
6. Alpha particles (Bragg peak) to treat soft tissue tumors. (4/71-10/74)
7. Helium ions to treat AV malformations (1980-present)
8. Helium ions to treat cancer (1975-present)
9. Heavy charged ions (argon, carbon, neon, silicon) to treat cancer. (1978-present)

Follow-up visits include routine physical examinations and interval histories, and appropriate supporting clinical laboratory studies and diagnostic studies (special endocrine studies for pituitary tumor patients, etc.).

At time of death, complete information is sought to determine cause of death. When available, the postmortem findings are reviewed.

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Attachments: Copies of above cited references.

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U.S. HOUSE OF REPRESENTATIVES
SUBCOMMITTEE ON ENERGY CONSERVATION AND POWER
OF THE
COMMITTEE ON ENERGY AND COMMERCE
WASHINGTON, D.C. 20515

October 23, 1984

The Honorable Donald P. Hodel
Secretary
Department of Energy
Forrestal Building
1000 Independence Avenue, S.W.
Washington, D.C. 20585

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Dear Secretary Hodel:

I appreciate your September 20, 1984 response to my earlier request for an accounting of radiation experiments performed on human subjects. I am aware of the difficulty in retrieving such information and recognize, as you do, that such information is to some degree, incomplete. However, the response raises a number of questions on which I would appreciate further clarification.

1. a.) The transmittal memorandum from Assistant Secretary Trivelpiece to the Secretary states that: "Many of the original records are currently unavailable because they have been lost or destroyed."

   Please provide the Department's policy regarding the destruction of the medical records, legal records and other documents relating to radiological exposure of test subjects, employees, military veterans, "downwinders", and residents of islands which received fallout from atomospheric bomb tests in the Pacific. Please also identify efforts made to maintain these documents, the names and addresses of the individuals to enable long-term evaluation.

   b.) The memorandum also states that for both volunteer studies and medical treatment it was "general practice to inform participants ... with respect to the purpose of ... and the potential hazards involved."

   Please provide all documentation supporting this statement.

2. Please provide all supporting documentation supporting the summary fact sheets provided to the Subcommittee.

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3. Regarding fact sheet numbered SFS1.002:

   a.) What were the results of these tests?

   b.) What tracking and documentation was maintained on these subjects after the 21 day and 4 month period?

   c.) Please identify the health status, names and addresses of each participant of these studies who is, or is thought to be, still living.

4. Regarding SFS2.001 and SFS2.002

   a.) How were the volunteers selected, was any screening method employed?

   b.) Did any test subject fail to have a vasectomy?

   c.) Where any of the test subjects subsequently released from incarceration?

   d.) Did any of the test subjects subsequently father any children? With what result?

   e.) Were any subjects tested for subsequent genetic or somatic damage?

   f.) Please identify the health status, names and addresses of each participant of these studies who is, or is thought to be, still living.

5. Please identify all legal claims, together with its status or outcome, which have been filed against the U.S. government as a result of the individual's participation in the experiments or treatments described in the September 20, 1984 response.

6. Please identify the most recent experiment(s) in which healthy human volunteers were subjected to radiological exposure.

7. Was the AEC in any way involved in the study, "Metabolism of Radiation following Whole-Body Radiation," conducted by Dr. Eugene Saenger at the Cincinnati General Hospital?

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8. Regarding SFS-1 001: what tests and follow-up examinations were performed provide the basis for the statement that "none of the deaths were related to plutonium exposure and there is no evidence to suggest that plutonium injection influenced the course of the diseases."

Please provide responses to these questions by November 2, 1984.

Sincerely,

Richard Ottinger

Richard L. Ottinger
Chairman

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SUMMARY FACTSHEET HUMAN EXPERIMENTATION SFS1.001

Project Category: Metabolism and Biological Effects of Plutonium, Polonium, Radium, Thorium, Uranium and Lead-212

Funding Source(s): [illegible] (one patient) [illegible]

Institution(s): University of Rochester, University of California, University of Chicago, Clinton Laboratories (Oak Ridge)

Principal Investigator: Robert S. Stone

Objective(s) of Project: To determine the excretion rate of plutonium in man in order to provide the information necessary for setting safety criteria for the several thousand MED workers handling plutonium.

Short Description: During the period 4-10-45 to 7-18-47 a total of 18 patients with an estimated life expectancy (because of existing disease) of less than 10 years were injected with on the average 0.3 microcurie of plutonium-239 or -238 (range: 0.05 to 6 micrpcurie) at: MED Hospital, Oak Ridge, TN (1 patient); Strong Mem. Hosp., Rochester, NY (11); Billings Hosp., U. of Chicago, IL (3); Univ. Hosp. UCSF, San Francisco, CA (3).

The patients included 13 males and 5 females. By race there were 16 whites and 3 blacks. The ages of 13 were 45-65 years, 4 were 18-45 and one was 4 years old. Body excretions were collected and measured for plutonium content for several weeks after injection. These data have been analyzed many times in efforts to find the best mathematical parameters.

Follow-up Data: Six of the patients died in less than 1 year, three in 1 to 3 years, three in 8 to 14 years, and four after 20 years. One is still living (Oct. 1983) and the status of one is unknown. None of the deaths was related to plutonium exposure and there is no evidence to suggest that plutonium injection influenced the course of the diseases. The bodies of four of the deceased patients have been studied for residual plutonium content. With the excretion data these studies provide a basis for estimating plutonium body burdens from plutonium urinary excretion rates.

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SUMMARY FACTSHEET HUMAN EXPERIMENTATION - SFS1.002

Project Category: Metabolism and Biological Effects of Plutonium, Polonium, Radium, Thorium, Uranium and Lead-212

Funding Source(s): AEC

Institution(s): Massachusetts Institute of Technology

Principal Investigator(s): Robley Evans

Objective(s) of Project: To determine the relative uptake via the gut of radium and thorium. This information was considered to be necessary in the interpretation of the toxicity data of radium dial painters.

Short Description: During the period 1961-1965, tracer doses of the short-lived nuclides radium-224 and thorium-234 were given by mouth to 20 volunteers (ages 63 to 83 years), and the relative absorptions measured. Metabolic studies, conducted over a period of 21 days for Ra and 4 months for Th, included measurements of blood, urine, feces and breath samples, and on the whole body and the upper 20% of the body with the GI tract shielded.

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SUMMARY FACTSHEET HUMAN EXPERIMENTATION - SFS1.003

[redacted]

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

Funding Source(s): MED/AEC

Institution(s): Univ. of Rochester (Polonium, Lead 212)
Los Alamos Scientific Laboratory (Uranium)
Massachusetts General Hospital (Uranium)
Oak Ridge National Laboratory (Uranium)

Principal Investigator(s): M. E. Silberstein (Polonium)
J. B. Hursa (Lead-212)
W. H. Sweet (Uranium)

Objective(s) of Project: Data on the distribution and metabolism of these substances in the body was needed for evaluation of the health hazards of exposure to these and related substances.

Short Description: In 1947 at Rochester, four human subjects were injected intravenously with 0.17 to 0.3 microcurie of polonium per kg body weight, and a fifth subject was given polonium orally. Fecal and urinary excretion rates were measured.

In Boston, Hexavalent uranium was given to 12 terminal brain tumor patients. Blood, urine and feces samples were obtained. Tissue samples were obtained at biopsy and autopsy and were studied at Oak Ridge (Oct. 1953-Oct. 1959).

In 1965 at Los Alamos the mean transit times for microspheres labeled with uranium-235 through the gastrointestinal tract was studied in 57 normal adults. Particle sizes were about 100 to a few hundred micrometers diameter. The mean transit times were 54.5 ± 16.6 hours.

In 1967 at Rochester, lead-212 was administered by mouth to three human subjects. Gastrointestinal absorptions of 1.3, 8.1 and 16.0% were found. Excretion rates were compared with those for two subjects who received lead-212 intravenously. The uptake and retention of lead in red blood cells was studied.

Follow-up Data: All of the brain tumor patients died of their disease within less than one and one-half years after entering the study. No follow-up was obtained in the other studies.

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[illegible] .001

Project Category: Effects of Radiation on the Human Testes

Funding Source(s): AEC/ERDA

Institution(s): Pacific Northwest Research Foundation, Seattle, WA

Principal Investigator(s): Carl C. Heller (succeeded by Mavis Rowley Feb. 27, 1973)

Objective(s) of Project: To obtain data on the effects of ionizing radiation on testicular cytochemistry and function in man

Short Description: During the period August 22, 1963 to May 6, 1971, 67 volunteers at the Oregon State Prison were subjected to testicular irradiation by 140 kvp X-rays. Radiation doses ranged from 8 to 600 R in single acute exposures except that six were irradiated a second time, one a third time, and one was given weekly irradiations of 5 R per week for eleven weeks. Studies included serial testicular biopsies, sperm counts, and urinary or plasma steroid and hormone evaluations.

Follow-up Data: 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.

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SUMMARY FACTSHEET HUMAN EXPERIMENTATION - SFS2.002

Project Category: Effects of Radiation on the Human Testes

Funding Source(s): AEC/ERDA

Institution(s): University of Washington

Principal Investigator(s): C. Alvin Paulsen

Objective(s) of Project: 1) To relate radiation dosage to changes in gonadal function, 2) to utilize the radiation gonadal changes as means for studying pituitary-testis interrelationships, 3) to explore therapeutic and medical protective measures with respect to gonadal irradiation, 4) to explore our current concepts concerning radiation dosage expressed in physical terms and their relation to biologic effects.

Short Description: During the period June 1, 1963 to February 1, 1973, 64 volunteers at the Washington State Prison were irradiated by 250 kvp X-rays. After appropriate baseline studies were performed, subjects received from 7.5 R to 400 R x-ray irradiation or sham irradiation to the testis only. Testicular biopsies were performed prior to and up to 6 years post-irradiation to assess changes in the germinal epithelium. Seminal fluid specimens were obtained at two-week intervals throughout the study and were analyzed for morphologic changes and changes in total number of sperm. Urine specimens were obtained monthly for evaluation of hormonal changes. Later, when the techniques were available, serum LH was measured by radioimmunoassay. Studies of ultrastructure changes in testis tissue were performed using electron microscopy. Subjects were followed until hormonal values returned to normal levels and until sperm counts returned to normal ranges. Vasectomies were performed prior to discharge from the study to eliminate the possibility of defective offspring. Only individuals desiring vasectomy were accepted for the study; but in several instances the volunteers changed their mind and did not desire a vasectomy at the conclusion of the study. Subjects were informed in detail regarding the study and signed consent forms were obtained from subjects and from spouses if subjects were married. Subjects were prison inmates only, thus eliminating the possibility of conception during the study.

Follow-up Data: 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.

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SUMMARY FACT SHEET HUMAN EXPERIMENTATION - SFSB-001

Project Category: Whole Body Irradiation

Funding Source(s): AEC (92%) NASA (8%)

Institution(s): Oak Ridge Institute of Nuclear Studies (ORINS)
Oak Ridge Associated Universities (ORAU)

Principal Investigator(s): Gould A. Andrews
Clarence C. Lushbaugh
R. M. Kniseley

Objective(s) of Project: 1) To explore the possibilities for treatment of chronic leukemia, lymphoma and polycythemia with radiation; 2) To obtain radiobiological data.

Short Description: In 1957 ORAU began a program designed for treatment of cancer patients and for assessment of the health effects of total body radiation. In 1964, NASA began to provide additional funds to include measuring the biological effects of low radiation doses and low dose rate exposures. Nearly 800 patients were treated with 50 or 100 R in a Cs-137 whole body irradiation facility. A few patients with acute leukemia were given doses of 800 R or more. Detailed and systematic studies were made of blood cells, bone marrow, clinical effects and selected laboratory tests. In some of the patients with high doses, the effects of autogenous and homologous bone marrow grafts were studied.

Follow-up Data: Measurements were continued for at least 6 weeks for each patient. The studies were not designed to analyze the late effects.

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SUMMARY FACTSHEET HUMAN EXPERIMENTATION - SFS4.001

Project Category: Teletherapy with Particle Beams

Funding Source(s): [redacted]

Institution(s): (1), (2) Univ. of California, Berkeley
(3) Univ. of California, San Francisco

Principal Investigator(s): (1) J. H. Lawrence, C. A. Tobias
(2) John A. Linfoot
(3) J. R. Castro

Objective(s) of Project: To determine possible beneficial effects in various neoplastic and metabolic diseases

Short Description: (1) In the period 1953-1959 the pituitary glands of patients with advanced metastatic mammary carcinoma or other endocrine related diseases were irradiated with beams from the 184 inch cyclotron at first with the 340 meV proton beam, later with the 900 meV alpha particle beam. Doses of 24,000 to 30,000 rad to the pituitary were given.

(2) Heavy particle irradiation was used (1968) for the irradiation of the pituitary in acromegaly, Cushing's disease, and chromophobe adenomas of the pituitary and in metabolic disease such as diabetic retinopathy, metastatic breast and prostatic carcinoma where these are sensitive to hormonal control through the pituitary or the endocrine end organs of the pituitary. Heavy particle irradiation was used for direct tumor irradiation at other sites in the body where the tumor boundaries can be adequately delineated.

(3) Since 1975, 94 patients with localized unresectable carcinoma of the pancreas have been irradiated using helium and heavier particles.

Follow-up Data: (1) By April 1959, 103 patients had been treated. Clinical and laboratory studies were conducted every 4-8 weeks on survivors. Twenty-nine of the 82 with metastatic carcinoma were living in 1959, the longest being 4 years post irradiation.

(2) Four hundred and twenty six patients have had heavy particle therapy. In the series of 66 patients with acromegaly, 90% have had a complete amelioration of their disease process establishing heavy particle irradiation to the pituitary as being the optimal form of treatment at the present time. Highly successful results have also been achieved in patients with Cushing's disease and in 10 patients with chromophobe adenomas. The results in diabetic retinopathy are promising, but require longer follow-up for definitive evaluation.

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(3) Many patients proved to have occult liver metastases manifested within 9 months post treatment. In addition, local and regional control of the primary neoplasm (approx. 20%) has been difficult to obtain even with doses of 6000 rad in 7 1/2 weeks. Gastric and biliary obstruction have required surgical bypass procedures since irradiation has not been successful in relieving obstructive symptoms. Evidence of gastrointestinal injury has been present in postradiation therapy in approximately 10% of patients.

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SUMMARY FACTSHEET HUMAN EXPERIMENTATION - SFS4.002

Project Category: Teletherapy with Particle Beams

Funding Source(s): DOE

Institution(s): Lawrence Berkeley Laboratory

Principal Investigator(s): Jacob I. Fabrikant

Objective(s) of Project: To establish stereotactic heavy-ion Bragg peak radiosurgery for brain disorders, including intracranial arteriovenous malformations.

Short Description: Initial observations in 55 patients treated to date (1980-1984) indicate that the clinical objectives of a decrease in (1) frequency of hemorrhages, (2) in neurological deficiencies, (3) subjective complaints incuding headaches, or (4) in frequency of seizures are being achieved.

Follow-up Data: There have been no neurological complications of radiation damage to the normal brain tissue; thus far, no evidence of brain injury or progressive or fixed neurological deficiencies have occurred as a result of the stereotactic radiosurgical procedure.

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SUMMARY FACTSHEET HUMAN EXPERIMENTATION - SF84.003

Project Category: Teletherapy with Particle Beams

Funding Source(s): AEC/ERDA/DOE, NCI

Institution(s): Los Alamos National Laboratory

Principal Investigator(s): M. Kligerman
S. Bush
R. D. Moseley
J. Bradbury

Objective(s) of Project: To conduct the necessary physical, biological, and clinical studies to evaluate the efficacy, potential benefit, and role of pions in the management of some types and stages of solid tumors.

Short Description: This program was a joint effort between the University of New Mexico and the Los Alamos National Laboratory utilizing negative pions produced by the 800 MeV LAMPF accelerator. The program involved beam development, radiobiology studies, new dosimetry and patient positioning techniques, and the evaluation of different total dose/fractionation schemes. During the program 234 patients were treated with tumor sites including prostate, head and neck, rectum and colon, cervix, brain, pancreas, and bladder. The studies began October 1974 and were terminated in late 1981.

Follow-up Data: One hundred and ninety-six patients have been followed for a minimum of 18 months. Crude survival data range from 11% for unresectable pancreatic carcinoma to 82% for stages C and D1 adenocarcinoma of the prostate indicate that this modality did not demonstrate advantages over more traditional radiotherapy and was therefore discontinued.

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SUMMARY FACTSHEET HUMAN EXPERIMENTATION - SFS4.004

Project Category: Neutron Therapy Facility

Funding Source(s): Funded by NCI in a DOE-owned facility

Institution(s): Fermi National Accelerator Laboratory

Principal Investigator(s): L. Cohen
F. R. Hendrickson

Objective(s) of Project: The scientific objective is to determine the effectiveness of neutron beam irradiation as compared to standard photon irradiation for the management of certain malignant tumors.

Short Description: Patients are identified as being eligible for inclusion in the clinical trials based on the type, extent and location of their cancer. Suitable candidates have tumors that are thought to be resistant to standard therapies. Informed consent is obtained. These clinical trials are conducted under the auspices of the Institutional Review Board. National cooperative trials are carried out in coordination with the Radiation Therapy Oncology Group (funded by the National Cancer Institute). Some patients are treated with neutron beam irradiation only. Others receive a combination of neutron beam irradiation and one or more standard modalities such as photon irradiation, surgery and chemotherapy. The program began in July 1975 and is continuing.

Follow-up Data: Approximately 1400 patients have been referred to this facility. Prior to treatment, patients must agree to comply with long term follow-up requirements. Physical examinations, laboratory tests and radiographic investigations are conducted regularly. If a patient does not keep his scheduled appointments, every effort is made to contact him. Fewer than 1% of the patients treated at this facility are considered currently lost to follow-up.

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SUMMARY FACTSHEET HUMAN EXPERIMENTATION - SFS5.001

Project Category: Other Teletherapy

Funding Source(s): AEC

Institution(s): (1) University of California, San Francisco
(2) University of Arkansas
(3) [illegible] Cancer Research Hospital
(5) Univ. of Michigan
(6) Oak Ridge Inst. of Nuclear Studies
(7) CEER, Puerto Rico

Principal Investigator(s): (1) R. S. Stone
(2) H. J. Barnhard
(3) M. L. Griem
(4) James W. J. Carpenter
(5) I. Lampe
(6) F. V. Comas
(7) V. Marcial

Objective(s) of Project: Development and Evaluation of Teletherapy Methods

Short Description: (1) During the years 1956 to 1958, 67 patients were irradiated with 70 MeV x-rays from the synchrotron. Doses were 5250 R in 5 weeks or 6000 R in 6 weeks. Patients with bronchogenic carcinoma, tumors of the oral cavity and carcinomas of the cervix were treated.

Follow-up Data: In August 1958, of the 67 patients treated, 25 had died within 2 years of starting treatment. A subsequent report indicates that as of June 1962, 310 patients had been treated but survial data is not given.

(2) A cobalt-60 teletherapy unit was used to treat 227 patients with various types of neoplasms (Progress report dated July 1956).

(3) From 1972 to 1979, Hodgkin's disease and other lymphomas were treated by a combination of laparotomy to improve staging and diagnosis, and carefully planned radiation to indicated organs of involvement. A number of malignancies were treated with ultra high dose rate electrons to study the effects of this radiation. Chromium-51 radioactive permanent implants were also evaluated. Head and neck malignancies were subjected to combined treatment schedules, including drug pre-treatment and split-course radiation. The sensitizing qualities of hydroxyurea and cytosine arabinoside were tested on a hair follicle indicating system before being tested on animal tumors and patients.

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(4) From 1962 to 1965 joint study was being carried out in conjunction with the Ear, Nose, and Throat Clinic in an attempt to evaluate the effects of pre and post-operative radiation treatment of various malignancies using the Van de Graaff x-ray generator, the rotational cobalt-60 machine, and the linear accelerator electron beam. All patients were seen in the ENT Clinic and randomized for treatment schedules. It was believed that some lung malignanies were made operable by irradiation.

Follow-up Data: One patient having an inoperable gastric malignancy treated with a combination of colchicine and radiation was still alive and gave no evidence of the disease after 2 years.

(5) During the period 1952-1966, cobalt-60 and cesium-137 teletherapy units were used in a comparative clinical evaluation in the radiation treatment of malignant disease. Modification of a theratron-B to permit clinical employment of a cesium-137 source was achieved and the radiation from this isotope was applied clinically to evaluate the potential role of this radiation in clinical radiotherapy in comparison with cobalt-60 radiation and past and current experience with orthovoltage radiation.

(6) In 1966, to determine the affects of cobalt-60 teletherapy on certain kinds of cancer two patients were given 500 R to spleen and liver. One patient showed no hematologic changes when the liver was irradiated, but a profound fall in circulating white blood cells occurred after irradiation of the spleen. The other patient responded to liver irradiation in a way undistinguishable from the changes occurring after spleen irradiation: in both instances the peripheral white count went from about 100,000 to 20,000 with a fast return to pretreatment levels.

(7) During the period 1964-1967 in a study of the optimal tumor dose in radiation therapy of cancer of the esophagus, half of the cases treated received cobalt teletherapy doses of 5000 roentgens in four weeks and the other half received doses of 6000 roentgens in six weeks. Disappearance of dysphagia and twelve months survival were compared in each group.

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SUMMARY FACTSHEET HUMAN EXPERIMENTATION - SFS5.002

Project Category: Treatment of Cancer with Supervoltage Machines

Funding Source(s): AEC

Institution(s): Argonne Cancer Research Hospital

Principal Investigator(s): M. L. Griem
J. W. J. Carpenter
L. H. Lanzl
L. S. Skaggs

Objective(s) of Project: To use new high-energy research machines to apply x-rays and gamma-rays to cancer patients

Short Description: Starting in 1954, with the ACRH 2-MeV Van de Graaff x-ray generator, a treatment field of sufficient size was made available so that patients with certain lymphomas could be treated from the neck to below the waist at one time, including all affected lymph nodes. This resulted in shorter overall treatment times and lowering of total radiation doses.

The cobalt-60 rotational therapy machine, with its small, high-specific-activity source and uranium shield, was designed and built at ACRH. Patients with advanced carcinoma of the uterus and cervix and other malignancies who were treated with this cobalt machine, sometimes in combination with other modalities such as the Van de Graaf, radium implants, surgery, or drugs, had favorable survival and cure rates.

Studies were also carried out on use of a variety of radiation-sensitizing agents, in an effort to achieve cures with lower doses of radiation.

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SUMMARY FACTSHEET HUMAN EXPERIMENTATION

Project Catego[illegible] with High-Energy Electrons [illegible]

Funding Source(s): AEC

Institution(s): Argonne Cancer Research Hospital

Principal Investigator(s): M. L. Grism
J. W. J. Carpenter
L. S. Skaggs
L. H. Lanzl

Objective(s) of Project: To use high-energy electrons from a scanning-beam linear accelerator in tumor treatment, alone and with other treatment modalities

Short Description: Starting in 1959, ACRH scientists developed a unique instrument for electron-beam therapy combining a linear accelerator of the Standard type with a beam-scanning device. This unit was constructed for investigation of the clinical advantages of electron-beam therapy. The linear accelerator and pencil beam scanning system were used in the treatment of different forms of cancer beginning in 1959. The malignant growths treated included head and neck cancer, chest tumors, mycosis fungoides, skin cancer, carcinoma of the urinary bladder, and others. By 1969, more than 500 patients had been irradiated with the electron beam, and a remarkable feature was the lack of a skin reaction in the patients.

Follow-up Data: The linear accelerator was used successfully for treatment of patients with mycosis fungoides. The high doses of electrons to the skin which became possible with this unit led to eradication of these difficult lesions, and in 1970, Dr. Grism reported very few recurrences up to 5 years after treatment in combination with Van de Graaff x-rays.

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SUMMARY FACTSHEET HUMAN EXPERIMENTATION - SFS6.001

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Project Categ[redacted]

Funding Source(s): Univ. of California, AEC (after 1945)

Institution(s): Univ. of California Radiation Laboratory

Principal Investigator(s): J. H. Lawrence

Objective(s) of Project: Treatment of Polycythemia Vera

Short Description: In 1938 two patients with polycythemia vera were treated with P-32. Over the next 10 years, 119 patients were treated. The patients ranged in age from 19 to 75 years. Of these, 56.5% were male and 43.5% female. Typical doses were 2 to 6 mCi of P-32. The patients usually received multiple doses over a period of several years.

Follow-up Data: At the time of a summary report in 1949 there had been 24 deaths. The causes of death were arteriosclerosis (6), leukemia (5), neoplasm (3), coronary occlusion (3), cardiac failure (2), portal thrombosis (1), and unknown (2). The high incidence of leukemia as a complication of polycythemia is well known. The incidence in this series was not significantly different from untreated series.

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[illegible]ARY FACTSHEET HUMAN EXPERIMENTATION - [illegible]

Project Cat[illegible] Hematological Effects

Funding Source(s): MED
AEC

Institution(s): 1) Univ. of Cal. Radiation Lab (AEC)
2) Memorial Hospital, New York (MED)
3) Metallurgical Lab, Manhattan Project (MED)
4) ORAU (AEC)
5) University of Cincinnati (AEC)

Principal Investigator(s): 1) B. V. A. Low-Beer; P. M. Aggeler
2) L. F. Craver
3) J. J. Nickson
4) G. A. Andrews
5) E. L. Saenger

Objective(s) of Project: To determine changes in the blood-forming organs and the peripheral blood as an index of exposure to total-body irradiation.

Short Description and Follow-up: 1) From 1943 to 1950, a total of 32 patients were treated with X-rays generated by 100, 200, and 1000 kv. Individual exposures varied from 5 to 50 R measured on the body surface at each treatment. The total accumulated doses varied from 100 to 390 R total-body dose as measured on the skin. The calculated tissue dose in the central plane of the body varied from approximately 60 to 264 R. The total elapsed time from the first to the last treatment varied between 6 and 92 days. The 32 patients treated in this manner were followed hematologically for periods as long as possible after treatment. The longest period of observation for any member of the group is six and one-half years, the average for the group as a whole is approximately four years.

2) From 1942 to 1944, patients were exposed using 180-185 kv x-rays to a total dose of 300 R at dose rates of 10, 15 or 20 R/day. Patients selected with untreatable metastatic cancer but able to tolerate procedure. Six patients received the planned 300 R. Two started but didn't finish. Three patients followed longer than 6 months. No deterioration of blood count or general health was attributable to radiation.

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[illegible] eight persons with incurable neoplasms were given single exposure doses of 27, 60, and 120 R in the period 1943 to 1944. Three patients with chronic diseases were given fractionated whole-body irradiation of 100, 300 and 500 R. Three volunteers were given fractionated irradiation totaling 21 R. No blood alterations were noted in the 21 R volunteer group. In the others, the predominant effect was lymphocyte depression.

4) Three groups of patients were treated in the period 1965 to 1966

1) chronic hematologic disorders
2) neoplasm
3) acute leukemia in relapse

Eleven patients with acute or subacute leukemia were treated with 200 to 900 R of total body irradiation. Of these, 5 showed incomplete suppression of the leukemia process, 5 showed apparent complete or nearly complete suppression, and 2 had early deaths (one patient was treated twice).

5) In the period 1961 to 1962, patients with metastatic or incurable neoplasms who had not received previous radio- or chemotherapy were given whole-body gamma radiation in doses varying from 85-336 R. Clinical and hematologic parameters were followed for 6-8 weeks subsequently.

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FACTSHEET HUMAN EXPERIMENTATION - [illegible]

[illegible]ject Category: Neutron Capture Therapy

[illegible]unding Source(s): AEC

[illegible]nstitution(s): Brookhaven National Laboratory

[illegible]rincipal Investigator(s): L. E. Farr
J. S. Robertson
R. Sweet
G. Brownell

[illegible]bjective(s) of Project: Brain tumor therapy

Short Description: Neutron capture therapy uses the localization of boron in tumors and the reaction of boron with neutrons to achieve localized radiation of brain tumors. Over a period of two years beginning February 15, 1951, 10 patients with proved glioblastoma were treated by neutron capture therapy at the graphite research reactor. The longest survival was 186 days.

A second series of [illegible] patients were treated with higher [illegible] one patient survived [illegible] months.

In 1959, a series using the Medical Research Reactor was started. Fifteen patients were treated. Survival times were in the same range as for the previous series.

Follow-up Data: Whole brain sections were obtained in at least 16 of the patients and studied for tissue reactions to radiation. With the boron compounds then in use it was not possible to achieve adequate tumor control without unacceptable damage to normal tissues and the project was discontinued.

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[illegible]MARY FACTSHEET [illegible]

Project Category: Other Radiation Therapy

Funding Source(s): MED
[illegible]AEC
[illegible]

Institution(s): 1) Argonne Cancer Research Hospital and Univ. of Chicago (AEC)
2) Brookhaven National Laboratory (AEC)
~~3) Lawrence Berkeley Laboratory (MED/AEC)~~
4) Oak Ridge Associated Univ. (AEC)
5) Piedmont Hospital, Atlanta (AEC)

Principal Investigator(s): 1) R. D. Moseley, W. M. S. Ironside, P. V. Harper
2) J. S. Robertson
3) N. I. Berlin, J. L. Born, L. Dobson, J. G. Hamilton, L. Hollander, J. H. Lawrence, B. W. Aublow-Bear, M. Rollyson, B. G. Rosenthal, H. H. Stauffer, R. C. Steinkamp, S. Winchell
4) C. C. Lushbaugh
5) E. D. Grady

Objective(s) of Project: To develop treatments for certain medical disorders with radioisotopes that can be selectively localized in tissues to be irradiated.

Short Description: During the period 1939-1974, several research projects were undertaken to improve therapy of cancer and other diseases by methods using radioisotopes. Radioisotopes (such as iodine-131, gallium-72, gold-198 and others) were given to patients under rigidly controlled conditions to determine whether their treatment could be improved by absorption (or localization) of the radioactivity directly in the cancer. Palladium-109 was administered by direct infiltration to three patients to study tissue and tumor response. Small 1-millicurie yttrium-90 pellets were implanted for treatment of certain cancers, notably metastatic breast and prostate carcinoma. In addition, yttrium-90 oxide particulate radioisotopes was established as an agent suitable for localizing radiation in an area by injecting the artery supplying that area. Thirty-five of 51 patients with advanced and otherwise uncontrollable cancer benefited from intravascular administration.

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labeled with phosphorus-32 were used to treat a variety of logical and medical disorders. Strontium-90 was used in the treatment bone metastases.

Follow-up Data: Initial follow-up visits were as frequent as required (weekly, monthly, etc.). Subsequent follow-ups were usually on an annual basis. Follow-up visits include routine physical examinations and interval histories, and appropriate supporting clinical laboratory studies and diagnostic studies.

At time of death, complete information was sought to determine cause of death. When available, the postmortem findings were reviewed.

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SUMMARY FACTSHEET HUMAN EXPERIMENTATION - SFS9.002

Project Category: Other Radiation Therapy

Funding Source(s): AEC

Institution(s): Center for Energy and Environmental Research, Puerto Rico

Principal Investigator(s): V. Marcial

Objective(s) of Project: To determine optimum fractionation of irradiation for cancer; to evaluate a split-dose technique for radiotherapy of cancer, and to determine the effectiveness of radiation therapy for the regional lymph nodes areas as an adjuvant to surgery for carcinoma of the breast.

Short Description: In the period 1964 to 1970, various fractionation regimes were studied (1 vs 5 per week and 3 vs 5 per week) to observe tumor effect, survival, and normal tissue reactions. Studies were conducted to compare the results obtained by the usual uninterrupted radiation treatment with a similar dose given in two separate two-week periods with a rest interval of two to three weeks halfway in the treatment (split-dose). Finally, post-operative irradiation of lymph node areas was studied to improve prognosis in patients with breast cancer treated with radical mastectomy.

Follow-up Data: Results for fractionation of irradiation showed that the curability and complication rates were identical at 3 years in a group of 260 patients.

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SUMMARY FACTSHEET HUMAN EXPERIMENTATION - SFS10.001

Project Catogory: Biological Effects of Iodine-131

Funding Source(s): AEC/ERDA

Institution(s): 1) Case Western Reserve Univ. (AEC/ERDA)
2) Univ. of Puerto Rico (AEC)
3) Sloan-Kettering Institute for Cancer Research (AEC)

Principal Investigator(s): 1) B. M. Dobyns
2) V. Marcial
3) R. W. Rawson

Objective(s) of Project: To determine the physiological and morphological effects of iodine-131 radiation on the thyroid of humans

Short Description and Follow-up Data:

1) During a 25 year period, 7/1/51 to 9/30/76, over 500 patients with hyperthyroidism were studied in great detail. During the first few days after treatment the observations essentially reflected unaltered function of the thyroid, but with the passage of time, the observations reflected the effects of radiation. The changing patterns of iodinated compounds in the blood, alterations in rate of return of the radioactivity to the thyroid, and the subsequent testing of the functional capacity of the gland permit an analysis of the effects of radiation.

2) During the period 1952 to 1958, radioiodine was used for therapy of hyperthyroidism and metastatic thyroid cancer. Therapeutic doses gave 2,000 to 100,000 rad to the thyroid. Whole body doses up to 20 rad. One patient with pulmonary metastases given 18 mCi I-131 received 40 to 80 rad whole body. This patient was doing well six years later.

3) In the 1948-1956 period, 22 patients were treated with therapeutic doses of I-131 to destroy thyroid tissue. Doses ranged from 95 to 329 mCi. In 1960, of 55 patients, 26 were known to be dead. Others being followed.

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SUMMARY FACTSHEET HUMAN EXPERIMENTATION - SFS11.001

Project Category: Other Biological Effects

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Funding Source(s): MED

Institution(s): 1a) Clinton Laboratory
1b) New York University
1c) Oak Ridge National Laboratory
2) Harvard Medical School
3) Lawrence Radiation Laboratory
Oak Ridge Associated Universities
4) Oak Ridge National Laboratory
General Electric Company

Principal Investigator(s): 1a) J. E. Wirth and J. R. Raper
1b) Unknown
1c) M. Nikson
2) F. D. Moore
3) J. H. Lawrence
H. Vodapick
4) E. C. Anderson, E. Pinson, V. Lote & C. W. Delong
5) C. W. Delong

Objective(s) of Project:
1) To determine the biological effects of irradiation to the skin
2) To study transplantation of tissues and whole organs
3) To evaluate the effects of internal irradiation from P-32, Y-90, Sr-90, and I-131 when therapeutically used in certain diseases, and the evaluation of the hematological response obtained from their use
4) To determine the distribution of tritium in the human body resulting from surface contamination, inhalation and ingestion

Short Description and Follow-up Data:
1a) Shielded disks of 1-inch diameter containing P-32 were used. Exposures were made by letting the source directly on the skin. Two groups of ten healthy volunteers each were exposed to doses of 140 to 1180 rep. The dose required to produce a visible reaction in 80% of the people was found to be between 170 and 200 rep. For an erythema the dose was determined to be 635 to 813 rep. (Report dated 1946.)

1b) Experiments carried out on living human skin in situ demonstrated that the iontophoresis of weak solutions of thorium X will increase its biological effects as judged by erythema and pigmentation, and cause greater penetration as shown by autoradiography. (Report dated 1955.)

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1c) Fifteen subjects were exposed on their left fourth finger to 200-600 R of 130kv x-rays in a single exposure. Microscopic observations were made before and after treatment. (Report dated 1947.)

2) During the period [redacted] received 250 R total body x-ray irradiation to suppress the immune reaction to a kidney transplant. Seven other patients received doses of 350 or 450 R. The treatment apparently was not successful but survival time wasn't stated.

3) During the period 1938 to 1963, internal irradiations using P-32, Y-90 and I-131 were continued and their clinical therapeutic and irradiation effects studied in patients with polycythemia, chronic leukemias, multiple myeloma, lymphogranuloses and thyroid disorders, including thyroid carcinoma. The patients receiving internal irradiation over the past 26 years have been closely followed. A high percentage post-mortem examinations have been obtained on the deceased patients.

4a) In 1950, six subjects received a few millicuries of tritium by inhalation of isotopically labeled hydrogen gas. Tritium concentration in urine was monitored for 15 subsequent days.

4b) In 1952, subjects inspired HTO saturated oxygen for 4 to 5 minutes. The HTO retained in the body during the exposure was obtained by subtracting the HTO expired from the HTO inspired.

4c) Also in 1952, measured amounts of tritium as HTO were ingested by male subjects. Venous blood and urine were monitored for tritium activity for 2-1/2 to 5 hours subsequently.

4d) The lower arm of subjects was exposed for variable lengths of time to various activities of HTO as water vapor and the HTO in water. Tritium activity in urine was monitored. (1952.)

4e) Air saturated with tritium oxide was circulated for one hour over a 9.8 cm^2 area of a male subject's forearm. Absorption was estimated from the tritium activity in urine passed several hours following exposure. (1952.)

5) In 1951, fourteen human subjects were exposed over a small area (~10 cm^2) on the forearm or abdomen to a water-vapor atmosphere labeled with tritium oxide (HTO). A single human subject was similarly exposed over his total skin area while breathing uncontaminated air. Absorption of tritium oxide was estimated by measurement of tritium oxide subsequently excreted in the subject's urine. The data from these experiments indicated a 4-fold greater absorption rate than that measured earlier in rats. These studies established the importance of the skin as a route of entry for tritium oxide and led to reductions in the allowable concentration of tritium oxide in air.

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SUMMARY FACTSHEET HUMAN EXPERIMENTATION - SFS12.001

Project Category: Metabolic and Physiological Studies

Funding Source(s): AEC/ERDA/DOE

Institution(s) and Principal Investigator:

Argonne Cancer Research Hospital
[redacted]
3. G. V. LeRoy
4. P. V. Harper

Argonne National Laboratory
5. R. E. Rowland

Los Alamos Scientific Laboratory
6. C. C. Lushbaugh

Pacific Northwest Laboratory
7. T. M. Beasley
8. H. E. Palmer

Sloan-Kettering Inst. for Cancer Research
9. J. S. Laughlin

Univ. California, Berkeley
10. M. Pollycove

Univ. California, Los Angeles
11. J. F. Ross
12. G. V. Taplin

Univ. Minnesota
13. M. B. Becaner

Univ. Pisa (Italy)
14. G. Monasterio

Univ. Washington
15. W. B. Welp

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Objective(s) of Project: Tracer studies using various radionuclides

Short Description: During the period 1950-1980 many tracer studies were conducted on human subjects for the purposes of studying the physiology and metabolism of labeled substances. Usually only a few subjects are involved in each study. No late effects are expected and in general, there has not been a systematic follow-up. Brief description of the studies are:

(1) Progesterone-4 labeled with carbon-14 was used to study progesterone metabolism in two patients. Doses were 5.27 and 37.81 uCi. A third patient who was 10 weeks pregnant was given 28.3 uCi. A therapeutic abortion 6 days later because of severe sickle cell anemia was performed. Activity in maternal and fetal tissues studied. Storage of the hormone in the fat compartments were found. (1958.)

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(2) 450 uCi of DL-glutamic acid-1-C14 were injected in a patient to investigate whether synthesis of Bence-Jones protein is related to that of myeloma globulin. Urinary and expiratory CO-2 were measured. (1958.)

(3) Metabolism of glucose studied with C-14, by CO-2 in expired air samples. (1958.)

(4) Sequential studies were made of the body potassium content of man in various cardiac disease states, in aldosteronism, and in hypertension with suspected hyperaldosteronism. A special study was made of the relationship between plasma potassium shifts and total-body content of potassium in man in various disease states. They are also measuring the effect of magnesium deficiency on levels of sodium, potassium, magnesium, and calcium in plasma, cerebrospinal fluid, brain and skeletal muscle. (1968.)

(5) Retention curve data with Ca-45, Sr-85, and radium were obtained. (1959.)

(6) An arm counter was used to measure activity in blood to determine the clearance of ^{131}I - Rose Bengal in the liver. The curve has two exponential components, interpreted as reflecting hepatic uptake and excretion rates. (1960.)

(7, 8 and 15) (1965.) A study was conducted to measure the long-term retention and localization of technetium in humans following both oral and intravenous administration and to derive mathematical models for excretion, which are very useful in determining the radiation dose to humans from technetium isotopes in the body. They are important from both medical and occupational standpoints.

^{95m}Tc and ^{96}Tc were administered to 8 subjects by physicians at the University of Washington Hospital in Seattle. The subjects were hospitalized at the University of Washington Clinical Research Center for the first week. Whole body counting and excreta measurements were made for 60 days. The University of Washington obtained and reimbursed the subjects for their services. The participation by PNL personnel was limited to providing the equipment, making the whole body counting and excreta measurements and analyzing the data. The PNL participation was funded by AEC but not the University of Washington participation.

(8) A study was conducted to determine the uptake, retention, distribution and excretion of promethium in humans following both oral and intravenous administration and to study the effectiveness of DTPA in removing promethium from the body. These concentrations were relevant to possible exposure of plant personnel. (1967.)

$^{143}PmCl_3$ was administered to 14 volunteers by physicians of the Hanford Environmental Health Foundation (HEHF). Whole body counting and excreta measurements were made by PNL for one year following administration of the ^{143}Pm. Six of the volunteers were also injected with DTPA at various intervals before and after the administration of the ^{143}Pm. Both the HEHF and PNL contributions to the study were funded by AEC.

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(9) (1977-1982.)

(9a) To extend the knowledge of tumor metabolism and to define the localization and improve the diagnosis of cancer in animal models and man, studies have been in progress over the seven year period (1977-1984).
The specific aims are as follows: (1) To synthesize from different radiolabeled precursors a large variety of: (a) N-13 and C-11 labeled amino acids using enzymatic procedures. (b) C-11 radiolabeled carboxylic acids. (c) 1-(C-[illegible] (c) 1-(C-11)-2-deoxy-D-glucose. (2) To employ the synthesized compounds for quantitative assessment of regional perfusion, transport, and metabolism to improve [illegible] treatment response.

(9b) To investigate the alteration in metabolic patterns related to cancer, methionine, technetium-99m and iodine-131 were used. These were used in various compounds for the study of their metabolism in bone, parathyroid tissue, liver, lung, pancreas and brain. Research was directed towards basic metabolic patterns and their alteration by malignant processes and by therapy, and also towards the development of useful diagnostic tests for early malignancy.

(10) Various hematological studies included: (1959.)
a) in 35 patients iron kinetics with Fe-59 and cell volume with P-32
b) survival of red cells, white cells and platelets with P-32 diisopropylfluoro-phosphonate.
c) intermediary metabolism of glucose and uric acid with C-14 glucose and C-14 uric acid.
d) heart function with I-131 albumin.
e) Co-60 vitamin B-12 absorption.

(11) The metabolic turnover of zinc-65 was studied, using a total body counter. (1966.)

(12) a) I-131 Hippuran was compared with other renogram agents and found to have the higher renal excretion efficiency.
b) I-131 cholegrafin was used in 35 patients to measure plasma volume as a substitute for human serum albumin.
c) I-131 Rose Bengal was used to study hepatic blood flow compared with [illegible] Gold-198 disappearance rate.
d) Sr-85 was used as a tracer for calcium metabolism. This is safer than [illegible] and more available than Ca-47. (1959.)

(13) A radioisotope technique for measuring regional blood flow was utilized to measure the effect of ionizing radiation on the bowel in experimental animals. [illegible] the effect of ionizing radiation on the colon was studied in [illegible] for carcinoma of the cervix. They were studied before radiation, immediately after radiation and 6-12 weeks after radiation when healing had occurred. In addition, other diseases of the colon such as ulcerative colitis and diverticulitis were investigated to find out if there were detectable disturbances in regional circulation. (1963-1968.)

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(14) To evaluate the mechanisms controlling pulmonary circulation, studies were carried out in normal and pathologic subjects, in basal conditions and under various stimulations. The data confirmed the relationships previously found between pulmonary blood volume, stroke volume and total blood volume and provided new material for an integrated evaluation of mechanisms controlling the pulmonary circulation. (1960-1965.)

(15) See item (7).

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SUMMARY FACTSHEET HUMAN EXPERIMENTATION - BF512.002

Project Category: Metabolic and Physiological Studies

Funding Source(s): AEC

Institution(s): INEL

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Principal Investigator(s): C. A. Hawley

Objective(s) of Project: To obtain quantitative information on the kinetics of radioiodine transport from the point of release to the atmosphere through the entire air-vegetation-cow-milk sequence in the human food chain.

Short Description: The preliminary experiment was conducted during May and June of 1963. The experiment was conducted near the southern boundary of the INEL (formerly the NRTS). Approximately one curie of Iodine-131 was released atmospherically, and deposited on pasture area downwind from the release point. Six dairy cows were placed on the contaminated pasture and seven human volunteers consumed portions of the resulting contaminated milk over an 18-day period.

During September 1964 approximately the same quantity and chemical form of Iodine-131 was atmospherically released to an area designated the Experimental Dairy Farm located on the INEL (approximately seven miles northeast of the Idaho Chemical Processing Plant). Three human volunteers were on the test area during the time of cloud passage and were later subjected to inhalation thyroid dose measurements.

During November 1965, the 1964 experiment was repeated using similar quantities and forms of Iodine-131 in the same area. Seven volunteers were seated in the test area next to high volume air samplers to correlate inhalation uptake with the amounts of iodine present in the air.

Follow-up Data: Due to the relatively short half-life of Iodine-131 (eight days) and the low thyroid doses received by the human volunteers (ingestion dose, range 230 to 630 mrad; inhalation dose, range 6.1 to 15 mrad) no follow-up data acquisition was considered necessary.

SUMMARY FACTSHEET HUMAN EXPERIMENTATION - SFS12.003

Project Category: Metabolic and Physiological Studies

Funding Source(s): AEC

Institution(s): INEL

Principal Investigator(s): C. W. Still

Objective(s) of Project: The determination of the metabolic fate of radionuclides ingested or inhaled by humans in good health, and calibration of both static and rotational scanning instruments for the direct in-vivo measurement of internally deposited radionuclides.

Short Description: Eight human volunteers were involved with the human studies endeavor, which consisted of thirteen individual experiments conducted during the period May 1965 to January 1972. All of the eight persons involved were employed by the ID-AEC, and all were associated with the Analytical Chemistry Branch of the Health and Safety Division. Four of the experiments involved inhalation of Argon-41 (a noble gas with a half life of 1.8 hours) and nine experiments resulted in the volunteers swallowing insoluble polyethylene capsules containing microcurie amounts of radioactivity.

Follow-up Data: The short half life of Argon-41 and its small residence time in the body resulted in very small radiation doses to the volunteers. The insoluble capsules required about 24 hours to pass through the body and produced very small doses due to the quantities of radioisotopes involved. As a consequence, no follow-up data acquisition was considered necessary.

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