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STATE OF WASHINGTON
DEPARTMENT OF HEALTH

Airustrial Center, Bldg 5 • Mail Stop XXXX • Olympia, Washington 98504

January 24, 1994

Richard L. Bangart, Director
Office of State Programs
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

FAXED
1/24/94

Dick
Dear Mr. Bangart:

This is the closeout of our reply to SP-94-011 requesting review of files potentially containing information on experiments in which humans were deliberately exposed to radiation for purposes other than radiopharmaceutical development. Files were selected based on the criteria set forth in the attachment to SP-94-011.

For the record, files which met the selection criteria and which were reviewed included:

Battelle Pacific Northwest Labs	No indication of human exp.
Fred Hutchinson Cancer Research Institute	Medical treatment of patients
Hanford Environmental Health Foundation	Pm-147 distrib. in volunteers
Tumor Institute, Swedish Hospital	Thymidine in testes of convicts
University of Washington	Neutron irrad. of gonads of convicts
Washington State University	No indication of human exp.

Enclosed is further information on the Hanford Environmental Health Foudation (repeated from my January 18, 1994 letter), the Tumor Institute, and the University of Washington. Since I have not heard to the contrary, information pertaining to the Fred Hutchinson Institute (the bilateral whole body irradiation of patients being prepared for bone marrow transplantation) has been excluded because it is a medical treatment rather than experimentation.

Any questions pertaining to the enclosed summaries should be directed to me at (206) 753-3461.

Sincerely,
Terry
Terry C. Frazee, Supervisor
Radioactive Materials Section

Enclosure

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STATE OF WASHINGTON
Historical Files

LICENSEE: Hanford Environmental Health Foundation
Richland, Washington

WA license number WN-L015-1
(issued August 16, 1968 to Hanford Occupational Health Foundation;
continuation of AEC license 46-11927-1 issued October 14, 1966)

License renewed but excluding human use, August 15, 1973
License terminated September 6, 1978

DATES OF THE STUDY: Inspection report indicates no use before July 11, 1967. Inventory record shows I.V. injections to 12 volunteers from October 16, 1967 to November 27, 1967 and oral ingestion to 2 volunteers from October 25 to November 6, 1967. Inspection reports in 1969 and 1973 indicated that human use occurred only in 1967.

TYPES AND PURPOSE OF RESEARCH STUDY: To determine the uptake, distribution, translocation and excretion patterns of promethium and plutonium in humans. The original study plan could have involved up to 36 individuals: six each for ingestion, injection, and inhalation of each isotope used. Only promethium was actually used.

IDENTIFICATION OF INDIVIDUAL RESEARCH SUBJECTS: None (as of the Sept 9, 1968 inspection there were only "five men and one woman, ages 22 to 47," still being followed as part of the study).

RANGE OF ACTIVITIES OR DOSES: Pm-143 -- approx. 0.1 microcuries injected I.V. and 6-7 microcuries given orally.

SPONSOR OF RESEARCH: Not specifically stated (Battelle and AEC mentioned)

LICENSEE: University of Washington
Seattle, Washington

AEC license number 46-01662-05
(issued July 1, 1966 to UW School of Medicine; authorizing a maximum of 15 curies of Tritium as foils to be used in a neutron generator; expiration extended to September 30, 1968 by Washington Radiation Control Program)

DATES OF THE STUDY: Approximately 1966-68.

TYPES AND PURPOSE OF RESEARCH STUDY: To be used at Washington State Penitentiary, Walla Walla, to complete a study of the effects of x-rays, 4 MeV and 15 MeV neutron doses on human testicular physiology. This license pertains only to the production of nominal 14 MeV neutrons.

IDENTIFICATION OF INDIVIDUAL RESEARCH SUBJECTS: None identified in file. License Condition requires individuals to have "voluntarily consented in writing..." Copy of proposed waiver and consent form for subject and spouse included in file.

RANGE OF ACTIVITIES OR DOSES: Neutron exposures of 0.5 to 15 rads (originally the study called for doses up to 40 rad but the University's Radiation Safety and Radioisotope Committee imposed a 15 rad limitation).

SPONSOR OF RESEARCH: AEC Contract Research AT(45-1)1781

LICENSEE: Tumor Institute of the Swedish Hospital
Seattle, Washington

AEC license number 46-922-1
(issued July 27, 1956; converted to WN-M008-1 issued April 4, 1967)

DATES OF THE STUDY: Unknown; first reference 1960, study location removed from Washington license in 1967.

TYPES AND PURPOSE OF RESEARCH STUDY: To study spermatogenesis in humans using tritiated thymidine in volunteer convicts at the Oregon State Penitentiary. (In June 1965 a request was made to the AEC to include students at the Rainier School for Retarded Children at Buckley, Washington but no information is available on whether this was approved).

IDENTIFICATION OF INDIVIDUAL RESEARCH SUBJECTS: None identified in file. License Condition requires individuals to have "voluntarily consented in writing..." Copy of proposed waiver and consent form for subject and spouse included in file.

RANGE OF ACTIVITIES OR DOSES: Six microcuries per injection.

SPONSOR OF RESEARCH: Unknown (but cross reference to Pacific Northwest Research Foundation)