UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V

1450 MARIA LANE
WALNUT CREEK, CALIFORNIA 94596-5368

January 14, 1994

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

FROM: Ross A. Scarano, Director
Division of Radiation Safety
and Safeguards

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

A total of twenty-five license files currently available in the Region V office were reviewed to determine if they may have authorized medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975. Eighteen licensees have been authorized to perform human research, of the eighteen, our records indicate five licensees conducted human research prior to 1975. Enclosure 1 contains the results of our review of licenses that may have conducted human research. Enclosure 2 is a list of the files reviewed that did not appear to contain evidence that human research was either authorized or conducted.

In addition to discussions with long-time NRC/AEC staff members, six former NRC radiation specialists (North, Fish, Thomas, Block, Fong, and Kabori) were contacted by telephone and asked if they recalled any information involving human research. Only Mr. Fong recalled any first-hand examples of human research other than New Drug Applications. Mr. North recalled that he had participated in an AEC inspection assignment in Philadelphia during which testing on prisoners was discussed. He was not sure if the testing was ever actually conducted. This information was passed on to Dr. Bellamy of Region I. Mr. Fish believed that the University of California at Los Angeles and San Francisco, the University of Oregon at Portland, and the U.S. Naval Hospital at San Diego were authorized to conduct human research before the FDA oversight committees were in place. We do not currently have these files in Region V.

Mr. Fong recalled three instances that occurred at the Naval Radiological Defense Laboratory (NRDL) while he was employed by the AEC licensee. The first instance involved individuals that were exposed to contaminated soil to determine the effectiveness of military clothing against contamination. The second involved direct application of 140La to small areas of the forearms of volunteers to evaluate decontamination techniques. These activities took place at Camp Stoneman, CA. The last instance took place at Hunters Point, CA and involved the injection of volunteers with 3H, 82Br, and 42K to study water and other body fluid exchanges. Mr. Fong believes these volunteers signed consent forms.

Questions regarding this review should be directed to the individuals designated on the review sheets in Enclosure 1.

Ross A. Scarano, Director
Division of Radiation Safety and
Safeguards

Enclosures: As stated

cc: J. Glenn, NMSS/IMAB
D. B. Howe, NMSS/IMAB
G. Cook, RV

ENCLOSURE 1

REGION V

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

License Number: 04-00181-04

Docket Number: 30-01213

Institutional Name: V.A. Los Angeles

City, State: Los Angeles, California

Reviewer's Name: Kent Prendergast Telephone: 975-0255

A. Is the licensee currently authorized for human research? (Note: check the authorized use license condition and/or inspection reports.)

Yes

B. Was the licensee authorized for human research between 1975 and 1994?

Yes

C. Did the licensee conduct medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975?

Based on a Nuclear Medicine Service Report submitted for FY-73, It appears that medical research to improve nuclear medicine techniques and radiopharmaceuticals was conducted on humans. The report describes new research activities, these activities included: treatment of thyrotoxis in Graves disease; a comparison of radioiron and indium 111 chloride; urecholine and glucagon to aid pancreatic scans, P-32 for synovial effusions, detection of increased iron absorbtion using 57 cobalt; and Tc-99 and I-131 labeled metronidazole for liver imaging. However, the report does not indicate whether the research was performed on animals or humans.

D. Was there evidence of radiation studies involving humans?

Yes, see above.

E. If there was evidence of radiation studies involving humans prior to 1975, answer the following questions:

1. Dates of the studies?

Research was indicated to be conducted to further nuclear medicine in 1973, 1974 and 1976. No specifics dates are given.

2. Types and purpose of research studies?

   Research to improve nuclear medicine.

3. Is there information available regarding the identity of individual research subjects?

   No.

4. What is the range of activities or doses reported?

   None given.

5. Who sponsored the research (ie. DOD, AEC, etc.)?

   No specifics are available.

F. If no records are currently available to answer question "E", are records available in archives?

   I doubt it. Records regarding the research specifics would be maintained by the hospital Radioisotope Committee and the researchers. They would not be submitted to the NRC or AEC.

G. Comments:

License Number: 04-001916-04

Docket Number: 30-101217

Institutional Name: V.A. Sepulveda

City, State:Sepulveda, California

Reviewer's Name: K. Prendergast Telephone:975-0255

A. Is the licensee currently authorized for human research? (Note: check the authorized use license condition and/or inspection reports.)

Yes

B. Was the licensee authorized for human research between 1975 and 1994?

Yes

C. Did the licensee conduct medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975?

Based on wording in the license applications it appears they did. There were a number of references indicating that all research on humans must be well planned and approved by the radioisotope committee. Also, based on the number of publications listed for some of the practicing M.D's, medical research on humans was performed.

D. Was there evidence of radiation studies involving humans?

Yes.

Example: Memorandum 71-21, 1971, contains the words under research " the research administration of radioactive materials to humans."

E. If there was evidence of radiation studies involving humans prior to 1975, answer the following questions:

There was no specific evidence of human research. The license authorizes medical research. However, there are no specific records in the license files relating to any specific research project.

1. Dates of the studies?

2. Types and purpose of research studies?

3. Is there information available regarding the identity of individual research subjects?

4. What is the range of activities or doses reported?

5. Who sponsored the research (ie. DOD, AEC, etc.)?

F. If no records are currently available to answer question "E", are records available in archives?

Unable to locate. Research records would be maintained in the licensee's radioisotope committee notes/minutes or in FDA records.

G. Comments:

It appears that the V.A. Sepulveda conducted medical research on humans to improve techniques and radiopharmaceuticals used in nuclear medicine. This speculation was based on the number of publications, regarding research in nuclear medicine in the CV's of the V.A. practicing M.D.s.

License Number: 46-1662-01 (Retired)

Docket Number: 030-08125

Institutional Name: University of Washington

City, State: Seattle, WA

Reviewer's Name: Dean Chaney Telephone: (510) 975-0229

A. Is the licensee currently authorized for human research? (Note: check the authorized use license condition and/or inspection reports.)

Unknown, would be under State of Washington License

B. Was the licensee authorized for human research between 1975 and 1994?

Unknown (license terminated in 1973)

C. Did the licensee conduct medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975?

Possible, the May 25, 1956 and subsequent 1959 license allowed use on humans and referenced the use of radioisotopes by the University at 4 Seattle hospitals, a blood bank, lake and oceanographic studies:

King County Hospital
325 9th Avenue

Children's Orthopedic Hospital
4800 Sand Point Way

US Government Public Health Services Hospital
14 South and Judkins

Veterans Administration Hospital

King County Central Blood Bank
Terry & Madison

D. Was there evidence of radiation studies involving humans?

No

E. If there was evidence of radiation studies involving humans prior to 1975, answer the following questions:

1. Dates of the studies?

2. Types and purpose of research studies?

3. Is there information available regarding the identity of individual research subjects?

4. What is the range of activities or doses reported?

5. Who sponsored the research (i.e., DOD, AEC, etc.)?

F. If no records are currently available to answer question "E", are records

available in archives?

Unable to locate.

G. Comments: Retired license file is available in Region

License Number: 46-1662-03 (Retired)

Docket Number: NA

Institutional Name: University of Washington
University Hospital
Radiation Therapy Department

City, State: Seattle, WA

Reviewer's Name: Dean Chaney Telephone: (510) 975-0229

A. Is the licensee currently authorized for human research? (Note: check the authorized use license condition and/or inspection reports.)

Unknown, the license was transferred to State of Washington control in 1967.

B. Was the licensee authorized for human research between 1975 and 1994?

Not known.

C. Did the licensee conduct medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975?

Unknown, but the license file contains a letter, dated 9/1/64, from the licensee discussing clinical investigations of hybaroxic radiation therapy that was to start in October 1964 using Co-60 teletherapy machine.

D. Was there evidence of radiation studies involving humans?

No

E. If there was evidence of radiation studies involving humans prior to 1975, answer the following questions:

1. Dates of the studies?

2. Types and purpose of research studies?

3. Is there information available regarding the identity of individual research subjects?

4. What is the range of activities or doses reported?

5. Who sponsored the research (i.e., DOD, AEC, etc.)?

F. If no records are currently available to answer question "E", are records available in archives?

Unable to locate.

G. Comments:

License Number: 04-487-02 (Retired)

Issued: August 21, 1956 Terminated: January 30, 1957

Docket Number: NA

Institutional Name:
Department of the Navy
Naval Radiological Defense Laboratory (NRDL)

City, State: San Francisco, CA

Authorized Use At: Hunter Point Naval Shipyard - SF, CA

Reviewer's Name: Dean Chaney, Telephone: (510) 975-0229

A. Is the licensee currently authorized for human research?
(Note: Check the authorized use license condition and/or inspection reports.)

NA

B. Was the licensee authorized for human research between 1975 and 1994?

NA

C. Did the licensee conduct medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975?

Authorized: "Measurements of Contamination on the Skin of Human Subjects" using Lanthanum-140.

D. Was there evidence of radiaiton studies involving humans?

No

E. If there was evidence of radiation studies involving humans prior to 1975, answer the following questions:

1. Dates of the studies?

Unknown

2. Types and purpose of research studies?

Skin decontamination technique development.

3. Is there information available regarding the identity of individual research subjects?

No

4. What is the range of activities or doses reported?

Unknown

5. Who sponsored the research (i.e., DOD, AEC, etc.)?

   DOD - US Army (Chemical Corps)

F. If no records are currently available to answer question "E", are records available in archives?
Unable to locate. Region V may have the only records left.

G. Comments: This license was superseded by 04-487-03.

License Number: 04-487-03 (Retired)

Issued: January 30, 1957 Terminated: October 28, 1969

Docket Number: NA

Institutional Name:
Department of the Navy
Naval Radiological Defense Laboratory (NRDL)

City, State: San Francisco, CA

Authorized Use At: Hunter Point Naval Shipyard - SF, CA
Camp Stoneman - Pittsburg, CA
Camp Parks - Pleasanton, CA
Any military facility

Reviewer's Name: Dean Chaney Telephone: (510) 975-0229

A. Is the licensee currently authorized for human research? (Note: check the authorized use license condition and/or inspection reports.)

NA

B. Was the licensee authorized for human research between 1975 and 1994?

NA

C. Did the licensee conduct medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975?

Appears to have been conducted under the auspices of this license; even though, human experiments were not allowed by the license using Lanthanum-140.

D. Was there evidence of radiation studies involving humans?

Yes, reference was made to "Beta Contact Study," in a May 1959, Technical Memorandum No. 111, titled: Radiological Safety Report - Operation Stoneman II, by NRDL (Page 13, Section E)

E. If there was evidence of radiation studies involving humans prior to 1975, answer the following questions:

1. Dates of the studies?

August and September 1958 at Camp Stoneman.

2. Types and purpose of research studies?

Skin decontamination technique development.

3. Is there information available regarding the identity of individual research subjects?

Possibly, Technical Memorandum No. 111 contains the names and doses

of 92 individuals, some of which may have been the volunteers involved.

4. What is the range of activities or doses reported?

   Clothing: 2 - 35 millirad/hr
   Skin: 2 - 24 millirad/hr
   Personnel doses ranged from 0.04 to 3.390 rem gamma and from 0.1 to 3.01 rad beta.

5. Who sponsored the research (i.e., DOD, AEC, etc.)?

   DOD - US Army (Chemical Corps)

F. If no records are currently available to answer question "E", are records available in archives?

   Unable to locate. Region V may have the only records left

G. Comments: This license was terminated upon disestablishment of the NRDL in 1969.

License Number: 04-187-04 (Retired)

Issued: May 7, 1958 Terminated: September 21, 1959

Docket Number: NA

Institutional Name:
Department of the Navy
Naval Radiological Defense Laboratory (NRDL)

City, State: San Francisco, CA

Authorized Use At: Hunter Point Naval Shipyard - SF, CA

Reviewer's Name: Dean Chaney Telephone: (510) 975-0229

A. Is the licensee currently authorized for human research? (Note: check the authorized use license condition and/or inspection reports.)

NA

B. Was the licensee authorized for human research between 1975 and 1994?

NA

C. Did the licensee conduct medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975?

Yes, Authorized to:

"Measurement of total exchangeable potassium, chloride and body water simultaneously in a total of 40 normal adults"

D. Was there evidence of radiation studies involving humans?

No records were found of the actual experiments. However a statement was made on page 10 of a 1959 "NRDL Annual Progress Report," (Progress Report USNRDL-P-24), that says, "The program of the Bio-Chemistry Branch involving the use of tritium, K-42 and Br-82, in humans was continued during the first quarter.

E. If there was evidence of radiation studies involving humans prior to 1975, answer the following questions:

1. Dates of the studies?

May have spanned from 5/58 through 8/61

2. Types and purpose of research studies?

Measure exchangeable potassium, chlorides and tritium in the body.

3. Is there information available regarding the identity of individual research subjects?

Statement in newspaper by California State employee (Filbert Fong)

that one A. Smith (NRDL Health Physics Laboratory Director) was a volunteer for the studies.

4. What is the range of activities or doses reported?

   Tritium 50 milliCuries
   Potassium 42, 3 milliCuries
   Bromine 82, 9 milliCuries

5. Who sponsored the research (i.e., DOD, AEC, etc.)?

   DOD, US Navy (BuMed)

F. If no records are currently available to answer question "E", are records available in archives?

   Unable to locate.

G. Comments: License

License Number: 04-487-07 (Retired)

Issued: September 21, 1959 Terminated: August 2, 1961

Docket Number: NA

Institutional Name:
Department of the Navy
Naval Radiological Defense Laboratory (NRDL)

City, State: San Francisco, CA

Authorized Use At: Hunter Point Naval Shipyard - SF, CA

Reviewer's Name: Dean Chaney Telephone: (510) 975-0229

A. Is the licensee currently authorized for human research? (Note: check the authorized use license condition and/or inspection reports.)

NA

B. Was the licensee authorized for human research between 1975 and 1994?

NA

C. Did the licensee conduct medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975?

Yes, Authorized to:

"Measurement of total exchangeable potassium, chloride and body water simultaneously in a total of 60 normal adults"

D. Was there evidence of radiation studies involving humans?

Yes, a statement was made on page 10 of a 1959 "NRDL Annual Progress Report," (Progress Report USNRDL-P-24), that says, "The program of the Bio-Chemistry Branch involving the use of tritium, K-42 and Br-82, in humans was continued during the first quarter.

E. If there was evidence of radiation studies involving humans prior to 1975, answer the following questions:

1. Dates of the studies?

May have spanned 5/58 - 8/61

2. Types and purpose of research studies?

Measure exchangeable potassium, chlorides and body water.

3. Is there information available regarding the identity of individual research subjects?

Statement in newspaper by California State employee (Filbert Fong)

that one A. Smith (NRDL Health Physics Laboratory Director) was a volunteer for the studies.

4. What is the range of activities or doses reported?

   Tritium 50 milliCuries
   Potassium 42, 3 milliCuries
   Bromine 82, 9 milliCuries

5. Who sponsored the research (i.e., DOD, AEC, etc.)?
   DOD, US Navy (BuMed)

F. If no records are currently available to answer question "E", are records available in archives?

   Unable to locate.

G. Comments: Material transferred to NRDL License -03.

License Number: 02-13990-01

Docket Number: 030-01211

Institutional Name: Department of Health & Human Services - National Institute of Diabetes and Digestive and Kidney Diseases

City, State: Phoenix, Arizona

Reviewer's Name: Frieda Y. Taylor Telephone: (510) 975-0236

A. Is the licensee currently authorized for human research? Yes
(Note: check the authorized use license condition and/or inspection reports.)

B. Was the licensee authorized for human research between 1975 and 1994?
Yes

C. Did the licensee conduct medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975?

Yes

D. Was there evidence of radiation studies involving humans?

Although there was no evidence, the isotopes authorized for human research are as follows: carbon-14, tritium, iodine-125, iodine-131,rubidium-86, nickel-63 and chromium-51.

Administration of isotopes for human research as follows: labelled proteins and hormones; measure rates of lipid synthesis in human obesity; experimental studies of C-14 and H-3 steroid compounds in clinical and laboratory investigations to over 40 people; C-14 metabolism of cholesterol, bile acids and phospholipids in humans; C-14 tagged bile acids and C-14 or H-3 tagged cholesterol to both ill and healthy volunteers; authorization number 1283 for the administration of 25 uCi I-125 or I-131 in the form of lipoprotein to patients; authorization number 1282 for the administration of 300 uCi of H-3 in the form of glycerol to patients with studies lasting approximately 10 days and a total body dose per individual of 23 mRad; authorization number 1350 for the administration of 280 uCi of H-3 in the form of d-glucose to patients.

E. If there was evidence of radiation studies involving humans prior to 1975, answer the following questions:

1. Dates of the studies?

2. Types and purpose of research studies?

3. Is there information available regarding the identity of individual research subjects?

4. What is the range of activities or doses reported?

5. Who sponsored the research (ie. DOD, AEC, etc.)?

F. If no records are currently available to answer question "E", are records available in archives?

Unable to locate.

G. Comments:
It appears the medical research was conducted at the Indian Health Service Hospital.

License Number: 04-00421-05

Docket Number: 030-01214

Institutional Name: Department of Veterans Affairs Medical Center

City, State: San Francisco, California

Reviewer's Name: Frieda Y. Taylor Telephone: (510) 975-0236

A. Is the licensee currently authorized for human research? Yes
(Note: check the authorized use license condition and/or inspection reports.)

B. Was the licensee authorized for human research between 1975 and 1994?

Yes

C. Did the licensee conduct medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975?

Yes

D. Was there evidence of radiation studies involving humans?

Although there was no evidence, the research was authorized:

a. "Carbohydrate Metabolism in Ischemic Heart Disease" - research was conducted by the cardiology laboratory and volunteer patients were utilized.

b. Thallium-201 for myocardial imaging.

c. Technetium-99 pyrophosphate for localizing myocardial infraction.

d. Routine clinical use of Tc-99m labeled human serum albumin for diagnostic imaging of the central blood pool, and for dynamic cardiac function test.

e. The effects of iodine on Thyroid function (two uptakes involving 10 mCi of I-123).

f. The effects of aspirin on blood flow in the ischemic myocardium. Involved injection of 8 mCi of Rb-81 per patient.

g. Determination of the rate of gastric emptying in man using Tc-99m labeled liver.

E. If there was evidence of radiation studies involving humans prior to 1975, answer the following questions:

1. Dates of the studies?

2. Types and purpose of research studies?

3. Is there information available regarding the identity of individual research subjects?

4. What is the range of activities or doses reported?

5. Who sponsored the research (ie. DOD, AEC, etc.)?

The licensee was licensed with the AEC and the NRC.

F. If no records are currently available to answer question "E", are records available in archives?

Unable to locate.

G. Comments:

License Number: 02-06186-01

Docket Number: 030-01208

Institutional Name: Veterans Administration Medical Center

City, State: Tucson, AZ 85723

Reviewer's Name: Frieda Y. Taylor Telephone: (510) 975-0236

A. Is the licensee currently authorized for human research?

No

(Note: check the authorized use license condition and/or inspection reports.)

B. Was the licensee authorized for human research between 1975 and 1994?

Yes

C. Did the licensee conduct medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975?

Yes

D. Was there evidence of radiation studies involving humans? Although there was no evidence, the licensee was authorized for the following:

a. Kidney imaging, kidney function studies imaging under New England Nuclear Food and Drug Administration IND 9730.

b. Cisternography studies in 25 patients with "reasonably" normal renal function.

c. Technetium-99m in the form of labeled (stannous colloid) macroaggregated human serum albumin for lung imaging for clinical trials under Medi-Physics Food and Drug Administration IND 8978.

d. Technetium-99m in the form of labeled hydrolyzed stannous chloride colloid for liver, spleen, and bone marrow imaging for clinical trials.

e. Technetium-99m in the form of labeled polyphosphatesfor bone imaging.

f. Technetium-99m in the form of labeled hydrolyzed stannous chloride colloid for liver and spleen imaging in 25 patients.

g. Strontium-85 for bone scans in fifteen patients with known fractures of the femur.

h. Investigational use of I-131.

E. If there was evidence of radiation studies involving humans prior to 1975, answer the following questions:

1. Dates of the studies?

2. Types and purpose of research studies?

3. Is there information available regarding the identity of individual research subjects?

4. What is the range of activities or doses reported?

5. Who sponsored the research (ie. DOD, AEC, etc.)?

F. If no records are currently available to answer question "E", are records available in archives?

Unable to locate.

G. Comments:

The licensee was licensed with the NRC.

License Number: 02-13990-01

Docket Number: 030-01211

Institutional Name: Department of Health & Human Services - National Institute of Diabetes and Digestive and Kidney Diseases

City, State: Phoenix, Arizona

Reviewer's Name: Frieda Y. Taylor Telephone: (510) 975-0236

A. Is the licensee currently authorized for human research? Yes
(Note: check the authorized use license condition and/or inspection reports.)

B. Was the licensee authorized for human research between 1975 and 1994?
Yes

C. Did the licensee conduct medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975?

Yes

D. Was there evidence of radiation studies involving humans?

Although there was no evidence, the isotopes authorized for human research are as follows: carbon-14, tritium, iodine-125, iodine-131,rubidium-86, nickel-63 and chromium-51.

Administration of isotopes for human research as follows: labelled proteins and hormones; measure rates of lipid synthesis in human obesity; experimental studies of C-14 and H-3 steroid compounds in clinical and laboratory investigations to over 40 people; C-14 metabolism of cholesterol, bile acids and phospholipids in humans; C-14 tagged bile acids and C-14 or H-3 tagged cholesterol to both ill and healthy volunteers; authorization number 1283 for the administration of 25 uCi I-125 or I-131 in the form of lipoprotein to patients; authorization number 1282 for the administration of 300 uCi of H-3 in the form of glycerol to patients with studies lasting approximately 10 days and a total body dose per individual of 23 mRad; authorization number 1350 for the administration of 280 uCi of H-3 in the form of d-glucose to patients.

E. If there was evidence of radiation studies involving humans prior to 1975, answer the following questions:

1. Dates of the studies?

2. Types and purpose of research studies?

3. Is there information available regarding the identity of individual research subjects?

4. What is the range of activities or doses reported?

5. Who sponsored the research (ie. DOD, AEC, etc.)?

F. If no records are currently available to answer question "E", are records available in archives?

Unable to locate.

G. Comments:

It appears the medical research was conducted at the Indian Health Service Hospital.

License Number: 53-00458-04

Docket Number: 30-03537

Institutional Name: Tripler ARMY Medical Center

City, State: Honolulu, HI

Reviewer's Name: K. Prendergast Telephone:975-0255

A. Is the licensee currently authorized for human research? yes
(Note: check the authorized use license condition and/or inspection reports.)

Yes

B. Was the licensee authorized for human research between 1975 and 1994?
Answer:

Yes

C. Did the licensee conduct medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975?

There was no indication research was performed on humans prior to 1975.

D. Was there evidence of radiation studies involving humans?

No. Based on a review of the license amendments and inspection reports, there is no indication of human research.

E. If there was evidence of radiation studies involving humans prior to 1975, answer the following questions:

1. Dates of the studies?

2. Types and purpose of research studies?

3. Is there information available regarding the identity of individual research subjects?

4. What is the range of activities or doses reported?

5. Who sponsored the research (ie. DOD, AEC, etc.)?

F. If no records are currently available to answer question "E", are records available in archives?

Unable to locate.

G. Comments:

License Number: 46-00990-01

Docket Number: 30-03367

Institutional Name: V.A. Seattle

City, State: Seattle, Washington

Reviewer's Name: Kent Prendergast Telephone: 975-0255

A. Is the licensee currently authorized for human research? (Note: check the authorized use license condition and/or inspection reports.)

Yes

B. Was the licensee authorized for human research between 1975 and 1994?

Yes. A March 22, 1990 letter documented the use of H-3 Norepinephrine in human research. This research was stated to have been approved by the RDRC, IRC, and RSC in 1983. A January 8, 1986 NRC Inspection Report also mentions medical research on humans being performed.

C. Did the licensee conduct medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975?

Based on a July 11, 1976 NRC inspection, invito human research was not conducted. This was based on the fact there was no mention of any human research being conducted in the "materials uses" portion of the report which described the licensee's program.

D. Was there evidence of radiation studies involving humans? Answer:

No

E. If there was evidence of radiation studies involving humans prior to 1975, answer the following questions:

1. Dates of the studies?

2. Types and purpose of research studies?

3. Is there information available regarding the identity of individual research subjects?

4. What is the range of activities or doses reported?

5. Who sponsored the research (ie. DOD, AEC, etc.)?

F. If no records are currently available to answer question "E", are records available in archives?

Answer: Unable to locate. Records were examined to 1964 and there were no specific references to human research being conducted.

License Number: 46-02645
Docket Number: 30-03368

Institutional Name: Madigan ARMY Medical Center

City, State: Ft. Lewis, Washington

Reviewer's Name: Kent Prendergast Telephone:975-0255

A. Is the licensee currently authorized for human research? (Note: check the authorized use license condition and/or inspection reports.)

Yes

B. Was the licensee authorized for human research between 1975 and 1994?

Yes

C. Did the licensee conduct medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975?

There was no indication research on humans was performed prior to 1975.

D. Was there evidence of radiation studies involving humans?

No

E. If there was evidence of radiation studies involving humans prior to 1975, answer the following questions:

1. Dates of the studies?

2. Types and purpose of research studies?

3. Is there information available regarding the identity of individual research subjects?

4. What is the range of activities or doses reported?

5. Who sponsored the research (ie. DOD, AEC, etc.)?

F. If no records are currently available to answer question "E", are records available in archives?

Unable to locate.

G. Comments:

License Number: 04-23242-01

Docket Number: 030-20404

Institutional Name: Department of Veterans Affairs Medical Center

City, State: Palo Alto, CA 94304

Reviewer's Name: Frieda Y. Taylor Telephone: (510) 975-0236

A. Is the licensee currently authorized for human research? Yes
(Note: check the authorized use license condition and/or inspection reports.)

B. Was the licensee authorized for human research between 1975 and 1994?
Yes

C. Did the licensee conduct medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975? No

D. Was there evidence of radiation studies involving humans?
No

E. If there was evidence of radiation studies involving humans prior to 1975, answer the following questions:

1. Dates of the studies?

2. Types and purpose of research studies?

3. Is there information available regarding the identity of individual research subjects?

4. What is the range of activities or doses reported?

5. Who sponsored the research (ie. DOD, AEC, etc.)?

F. If no records are currently available to answer question "E", are records available in archives?

Unable to locate.

G. Comments:

It appears that the license was issued August 11, 1986. The licensee was licensed with the NRC.

License Number: 04-09450-02

Docket Number: 030-01227

Institutional Name: V.A. Medical Center

City, State: Livermore, CA 94550

Reviewer's Name: Frieda Y. Taylor Telephone: (510) 975-0236

A. Is the licensee currently authorized for human research?

No

(Note: check the authorized use license condition and/or inspection reports.)

B. Was the licensee authorized for human research between 1975 and 1994?
Yes

C. Did the licensee conduct medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975? Yes

D. Was there evidence of radiation studies involving humans?

Although there was no evidence, the license authorized the following:

* Xenon-133 for blood flow and pulmonary studies.
* Iodine-131 for: fat absorption studies in the form of labeled fats and/or fatty acids; and kidney function studies, renograms in the form of labeled renal function compounds.
* Iron-59 for iron metabolism studies in the form of citrate and/or chloride.
* Iodine-125 or 131 and Iodine-125 or 129, in the form of thyroxine and/or triiodothyronine and iodide respectively, for the determination of secretion rates of iodinated thyroid compounds in ten adult patients (age 21-60), with solitary hyper-functioning nodules and in ten normal adult males (age 30 - 65).
* Calcium-45 or 47 in the form of chloride for studies of absorption of calcium by the gastrointestinal tract in 20 subjects with and without disease states affecting calcium and phosphorus metabolism in accordance with procedures stated in research protocol submitted with application dated November 15, 1966.
* Tritiated tetracycline which was to be used as follows: Protocol I - Restricted to candidates for major orthopedic surgery or non-metastasized malignant growth removal surgery, of age 60 or greater with all doses totalling less than 0.010 Curies of tritium; and Protocol II - Restricted to inoperable severe or terminal cancer cases, with extremely limited ($\leq$ 1 year) life expectancy with all doses totalling less than 1.0 Curie of tritium.

E. If there was evidence of radiation studies involving humans prior to 1975, answer the following questions:

1. Dates of the studies?

2. Types and purpose of research studies?

3. Is there information available regarding the identity of individual research subjects?

4. What is the range of activities or doses reported?

5. Who sponsored the research (ie. DOD, AEC, etc.)?

F. If no records are currently available to answer question "E", are records available in archives?

Unable to locate.

G. Comments:

Research was authorized under AEC and NRC.

License Number: 36-01395-01

Docket Number: 030-02935

Institutional Name: Veterans Affairs Medical Center

City, State: Portland, OR 97207

Reviewer's Name: Frieda Y. Taylor Telephone: (510) 975-0236

A. Is the licensee currently authorized for human research? Yes
(Note: check the authorized use license condition and/or inspection reports.)

B. Was the licensee authorized for human research between 1975 and 1994?
Yes

C. Did the licensee conduct medical or scientific radiation effects research on humans prior to the dissolution of the Atomic Energy Commission (AEC) in 1975? Yes

D. Was there evidence of radiation studies involving humans?
Although there was no evidence, the license authorized the following:

* Iodine-131 in the form of iodinated human serum albumin for cardiac output and circulation studies. Cisternography and ventriculography studies in 100 patients in accordance with protocol received August 10, 1970.
* Hydrogen-3 in the form of labeled ouabain for metabolic studies. in accordance with protocol submitted by application dated May 10, 1973.
* Technetium-99m in the form of labeled polyphosphates for bone imaging on 30 patients excluding pregnant and lactating females.
* Technetium-99m in the form of labelled macroaggregated albumin for lung imaging on 50 patients.
* Technetium-99m in the form of labelled (stannous colloid) macroaggregated human serum albumin for lung imaging in 25 patients.

E. If there was evidence of radiation studies involving humans prior to 1975, answer the following questions:

1. Dates of the studies?

2. Types and purpose of research studies?

3. Is there information available regarding the identity of individual research subjects?

4. What is the range of activities or doses reported?

5. Who sponsored the research (ie. DOD, AEC, etc.)?

F. If no records are currently available to answer question "E", are records available in archives?

Unable to locate.

G. Comments:
The licensee was licensed under the AEC and the NRC.

ENCLOSURE 2

There was no evidence currently in the Region V files that the following licensees ever conducted medical or scientific radiation effects involving humans prior to or after the dissolution of the AEC in 1975:

1. Aerojet, License No. 04-00647-03
2. McDonald Douglas (WA), License No. SNM-01016
3. Stanford Research Institute, License No. 04-01043-10
4. U.S. Air Force McClellan AFB, License No. 04-07177-01 & -02
5. U.S. Nuclear SOCAL, License No. SNM-01002
6. National Aeronautics & Space Administration, License No. 04-07845-04
7. University of California (Los Angeles), License No. 04-23285-01