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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199

JAN 14 1994

MEMORANDUM FOR: Robert M. Bernero, Director
Office of Nuclear Material Safety
and Safeguards

FROM: Stewart D. Ebnetter
Regional Administrator

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

This responds to H. Thompson's memorandum of January 7, 1994, requesting review of available license files to identify information on human subject experiments, other than for radiopharmaceutical development. Based on discussions with long-term members of our staff and review of a list of medical licenses prior to 1976, we selected several folders for more detailed review.

These licenses are listed in the Enclosure, and include academic and medical broad scope usage, as well as Veterans Medical Centers. Our available records on Military R & D Centers and Hospitals did not reveal licensed usage beyond radiopharmaceutical development and clinical use; however, they may have conducted human subject research under AEC/DOD programs not subject to license. Similarly, many of our larger Region II medical/academic institutions have come under Agreement States, and those files are no longer in our possession.

It was difficult to determine from the limited descriptions of authorized uses/studies in our files whether the uses were for radiopharmaceutical development or human subject experimental studies. As a result, we have included studies that in fact may have been for radiopharmaceutical development.

In conclusion, we found no direct evidence of human subject experiments and provide you the information we found in our files.

Stewart D. Ebnetter
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Enclosure:
Data Tables, 6 pages

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ENCLOSURE

Institution Name License No. Docket No.	Human Research	Study Dates	Type/purpose of Study	Subjects Id'd	Doses Reported	Sponsor		
Medical College of Hampton Roads - Va 45-15077-01 030-09947	None							
VA Durham - NC 32-011134-01 030-02630	None		See attached note					
VA Miami - FL 09-00239-06 030-01343	Suspect	1963&64	Xe-133, I-131 see attached notes	No	None	Unk		
WV University 47-23035-01 030-03296	None		Supersedes 47-01163-20					
Univ Virginia Charlottesville 45-00034-26 030-03296	None		All info prior to Apr 13, 1982 has been archived.					
VA Nashville - TN 41-00104-04 030-03250	Yes	1959-74	C-14, Fe-59, H-3, I-131 see attached notes	No	None	Unk		
Va Commonwealth Univ - Med Coll VA 45-00048-17 030-00511	None		No records prior to 1982 here. Previously archived.					
Old Dominion Univ 45-09599-03 030-10045	None		No records previous to 1979 here. Previously archived.					

Notes for VA Durham NC

1. The license file contains Amendments 45 (Jan 3, 1974) through 54. Previous amendments and background information have been archived.

Notes for VA Miami FL

1. Amendment dated Jul 30, 1964 - Xe-133 for evaluation of occlusive vascular disease in 20 patients.
2. Amendment dated Feb 18, 1963 - I-131 (Angiotensin II) for renal function studies and hypertension studies.

Notes for VA Nashville TN

1. Amendment dated Nov 9, 1973 - C-14 tracer to determine phenobarbital clearances in normal volunteers and patients.
2. Amendment dated Dec 29, 1959 - Iron-59 to study iron absorption in GI tract.
3. Amendment dated Dec 29, 1959 - C-14 to establish method for specific activity of total cholesterol in human serum by isotope dilution
4. Amendment dated Aug 8, 1962 - H-3 for quantitation by isotope dilution of aldosterone secretions in humans and elucidation of alteratrone induced by disease.
5. Amendment dated May 8, 1963 - I-131 fat metabolism studies

Studies conducted from about December 1959 - August 1974. Reference physician W.L. Alsobrook, MD. No background information about these studies are currently available to us. They have been placed in storage, therefore we are not able to be certain that the studies are the type being sought.

Institution Name License No. Docket No.	Human Research	Study Dates	Type/purpose of Study	Subjects Id'd	Doses Reported	Sponsor		
Va Polytech Inst 45-09475 030-11313	None							
VA Lexington - KY 16-08896-04 030-10027	None		Original issue Aug 23, 1974. Initial applic. has been archived					
VA Birmingham - AL 01-00643-02 030-01204	Suspect	1960-71	I-131, I-132 see attached notes					
VA Decatur - GA 10-01169-01 030-01350	Suspect	1961-73	I-131, Yb-169 see attached notes	No	None	unk		
Univ Puerto Rico 52-01946-07 030-13584	None		earliest record is 1978					
United Hosp. Ctr. 47-01458-01 030-03375	None							
VA - Huntington WV 47-03630-02 030-03379	None							
VA -Martinsburg WV 47-00714-02 030-03371	Suspect	1958-63	C-14, S-35, H-3, Hg-197, see attached notes	No	None	no		
VA - Memphis TN 41-00119-08 030-03253	Suspect	before 1960	I-131, Fe-55, Yb-169 see attached notes	No	None	unk		

Notes for VA - Birmingham AL

1. Amendment dated Jan 3, 1960 - I-132 for thyroid function and metabolism study
2. Amendment dated Nov 8, 1960 - I-131 for thyrotropic and insulin disappearance studies in 11 normal & 22 diabetic patients
3. Amendment dated Jan 8, 1963 - C-14 for metabolism studies
4. Amendment dated Apr 9, 1971 - I-125 for medical research

Notes for VA - Decatur GA

1. Amendment dated Oct 4, 1973 - Ytterbium-169 cisternography studies in.
2. Amendment dated Jun 29, 1966 - I-131 detection of metastatic bone lesions and muscle blood flow studies.
3. Amendment dated Mar 9, 1961 - I-131 determination of protein loss in patients with hypoalbuminosis.

Notes for VA - Martinsburg WV

1. Before 1958 - C-14 studies of wound healing.
2. 1960 - C-14 diabetic diagnoses
3. 1962 - H-3 & C-14 - tags for metabolic studies.
4. Amendment 11, 1963 - C-14 - metabolic studies
5. Amendment 22, 1964 - C-14 - testosterone comparisons young and old patients, Hg-197 experimental visualize spleen.

Notes for VA - Memphis TN

1. I-131 - tracer studies for insulin metabolism
2. I-131 - investigate GI disorders
3. Fe-55 - iron metabolism in 10 patients
4. Yb-169 - renal function in 25 normal patients

Institution Name License No. Docket No.	Human Research	Study Dates	Type/purpose of Study	Subjects Id'd	Doses Reported	Sponsor		
VA - Louisville KY 16-03121-02 030-01747	None		Only info later than Nov 2, 1982 (Amend 41- 48) here					
US Health & Human Services Envir Lab (USPHS) at Research Triangle Park NC 32-12358-01 030-05596	None		Broad scope program initially issued Jul 17, 1967, has never been auth use of lic mat'l on human being for any purpose.					
VA - Salisbury NC 32-15483-01 030-09184	None		Initial issue Mar 21, 1973. No indication found					
VA -FayettevilleNC 32-136541-01 030-02634	Suspect	Dec 10, 1974	Yb-169 Cisternography of 25 reasonably normal renal function pts					
VA - Asheville NC 32-05830-01 030-02632	Suspect	1966-68	Xe-133 see attached notes					

Notes for VA -Asheville NC

1. Amend dated Dec 7, 1966 - Xe-133 muscle blood flow measurments in 30 patients
2. Amend dated May 20, 1968 - additional 30 patients authorized.

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