

STATE OF NEW YORK DEPARTMENT OF HEALTH

Center for Environmental Health

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Albany, New York 12203-3399

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January 26, 1994

OFFICE OF PUBLIC HEALTH Lieve F Novick M.D. M.P.H. Director Diana Jones Ritter Executive Deputy Different William N. Stasiuk, P.E. Ph.D. Carrier Director

US Nuclear Regulatory Commission Office of State Programs Mail Stop 3-D-23 Washington, D.C. Attention: Rosetta Virgilio

Dear Ms. Virgilio:

Enclosed is a short list of research projects conducted by some New York State Department of Health radioactive materials licensees, involving the use of radioactive materials in humans for purposes other than radiopharmaceutical development. Seven licenses were reviewed for documentation of research activities.

Please note that given such short notice, the list is not a comprehensive summary of human-use research. Most broad medical licensees are conducting human-use research that is not necessarily reflected in the files, as those licenses authorize such research to be approved by the Institutional Review Board, Human Use Committees and Radiation Safety Committee within the facility. Also the available files only go back into the mid-1980's. Older files are in storage and would require more time and effort to review.

Please also note that none of the enclosed research projects involves efforts to determine radiotoxicity or other effects of radiation, but rather they utilize radioactive materials in the study of a certain process unrelated to the radiation. All of the research activies involved patient or volunteer consent.

If I may be of assistance please contact this office at 518-458-6485 or:

New York State Department of Health Bureau of Environmental Radiation Protection 2 University Place, Room 375 Albany, New York 12203

Christopher D. Parker

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Associate Radiological Health Specialist

Enclosure

Facility Name

Helen Hayes Hospital

NYSDOH License #

1886 (specific)

Research Activities

Intestinal absorption studies using Ca-45.

Note: Project authorized on the license 4/1/93.

Efficacy and safety of calculonin in prevention of steroid induced

osteopenia.

Note: Project, initiated in 1988, involved use of CT and bone

densitometry.

Facility Name

University of Rochester

NYSDOH License #

436 (broad academic and medical)

Research Activities

Assessment of hepatic glucose production during insulin infusions.

Note: H-3 labeled glucose; healthy a funteers; 1986.

Tc-99m DTPA used to assess breathing function effect of water ingestion and lung size.

Note: Late 1980's.

Pharmodynamic study of the direct isotropic properties of

intravenous amrinone.

Note: Use of Tc-99 to assess left ventricular function; MUGA

scans.

Skin and lung absorption of mercury vapor.

Note: Use of Hg-203

Mercury burden in liver using isotopic dilution tests.

Effects of DEHP on characteristics and survival of blood stored

in CPDA-1 and CPD/Adsol.

Note: Use of Cr-51 in volunteers.

Facility Name

North Shore University Medical Center

NYSDOH License #

1016 (broad medical)

Research Activities

All activities found were recent (1992) and involved only research and development of diagnostic and therapeutic uses of

radiopharmaceuticals.

Facility Name SUNY @ Stony Brook

NYSDOH License # 455 (broad academic and medical)

Research Activities No documentation in available files of human use experiments.

Facility Name Albany Medical Center

NYSDOH License # (broad medical)

Research Activities Inspection indicated use of fluoroscopy in two research projects

in 1991 and 1992, unrelated to the main purpose of the

research.

Facility Name SUNY @ Buffalo

NYSDOH License # 1049 (broad academic and medical)

Research Activities — All research activities found in available files are related to

radiopharmaceutical development.

Facility Name SUNY Health Science

NYSDOH License # 47 (broad medical)

Research Activities Discussion of human-use research indicated in recenst (1991)

Radiation Safety Committee minutes, however no details to type

of research.