

COPY

718163

GENERAL AUTHORIZATION FOR CLINICAL USE OF RADIOISOTOPES, REQUEST FOR

In accordance with the instructions received by letter November 19, 1951, from the radioisotopes branch of the isotopes division and those published in the Isotopes Catalog No. 4, pages 44-50, we are submitting AEC forms 313 and 313a requesting general authorization for the clinical use of radioisotopes. The following supplementary information is offered in support of this request.

The Brookhaven National Laboratory Hospital is singular in several respects. Except for an occasional employee or dependent hospitalized for an acute illness or injury, all of the patients are on the research service. In general, these patients are obtained through cooperation with metropolitan hospitals, and complete case work-ups, including consultations with the surgical, radiological, and other indicated services precede their admission to the Brookhaven Hospital. For this reason, it has not been necessary for us to include some of the usual specialties (such as general surgery) in the hospital's organization.

The research staff of the hospital is organized into four divisions: Pathology, Bacteriology, Biochemistry and Physiology, Biophysics being a subdivision of Physiology. The physician members of the research staff serve in caring for the patients, there being no separate hospital staff. A board certified radiologist is employed on a permanent but part-time basis and is a member of the local isotopes committee.

The local isotopes committee was organized December 12, 1949, and has subsequently been enlarged to provide a greater experience basis amongst committee members. All requests for the use of radioactive isotopes have been carefully reviewed and approved by this committee before being submitted to the isotopes division. The approval of the local committee will continue to be required for isotope procurement and use if this request for a general authorization is granted. The members and qualifications of the committee are as follows:

Lee E. Farr, M.D., Committee Chairman, Chairman, Medical Department and Head, Physiology Division, Brookhaven National Laboratory, 1949- . M.D., Yale, 1933. Certified American Board of Pediatrics, 1935. Assistant in Pediatrics, Yale University School of Medicine, 1933-34.. Assistant in Medicine,

400021

REPOSITORY BNL
COLLECTION Human Subjects Research Policies
BOX No. 1
FOLDER _____

1934-37, Associate in Medicine, 1937-40, Hospital of The Rockefeller Institute for Medical Research, New York City. Director of Research and Physician-in-Chief, Alfred I. duPont Institute of the Nemours Foundation, Wilmington, Delaware, 1940-49. Active duty, USNR, 1942-46 as staff member, Naval Medical Research Institute, Bethesda, Maryland, 1944-46. Field of major experience; nitrogen metabolism and renal physiology; at Brookhaven: use of radioactive isotopes as tracers in human physiology; therapy of thyroid carcinoma with radioactive iodine; effects of neutron radiation in humans; use of short lived radioactive isotopes in cancer therapy; effects of isotopic radiation on nitrogen metabolism.

James S. Robertson, M.D., Ph.D, Head, biophysics subdivision of Medical Department, Brookhaven National Laboratory, February 1950-
M.D., Minnesota 1945. Ph.D (Physiology) University of California at Berkeley, 1949. Assistant Physiologist, Donner Laboratory of Medical Physics, 1947-49. Trained in theory and methods involving radioactive tracers and in radioisotope therapy in humans at the Donner Laboratory.

John T. Godwin, M.D., Head, Division of Pathology, Brookhaven National Laboratory, Sept. 1, 1951-
M.D., Emory University, Atlanta, 1941. Certified Pathologist (Pathological Anatomy) 1949. Resident in Pathology, Touro Infirmary, New Orleans, 1947-48. American Cancer Society Fellow in Pathology, Memorial Hospital, New York City, 1948-50. Tissue radioautographic studies of effects of radiation, Sloan-Kettering Institute (Memorial Center) 1949-50. Pathologist, Ochsner Foundation Hospital (Tulane), New Orleans, 1950-51.

David L. Jellinger, M.D., Consultant, Radiology, Brookhaven National Laboratory, 1948-
M.D., Columbia, 1933. Resident in Radiotherapy, Montefiore Hospital, New York City, 1934-35. Resident in Roentgenology, Beth Israel Hospital, Brooklyn, 1935-36. Certified American Board of Radiology (Radiologist) 1938. Member American College of Radiology. Lt. Col., A.U.S., Chief of Radiology Services: England General Hospital, Atlantic City, N.J.; 60th General Hospital, overseas; Tilton General Hospital, Fort Dix, N.J., and Fort Jay Hospital, Governor's Island, N.Y., 1942-46. Private practice of radiology, 1936-42 and 1946-

William M. Hale, M.D., Head, Division of Bacteriology and Virology, Brookhaven National Laboratory, 1949-
M.D., Yale, 1929. Instructor of Immunology, Yale

University School of Medicine, 1929-32. Assistant Professor of Immunology, Yale, 1932-38. Professor and Head of Department of Bacteriology, State University of Iowa College of Medicine, 1938-49. Effects of radiation on immune processes and transplantable tumors, studies of radiation defense mechanisms.

Robert A. Love, M.D., Head, Division of Industrial Medicine, Brookhaven National Laboratory, 1949- . M.D., Cornell 1942. Resident in Medicine, King's County Hospital, New York City, 1946-47. Staff member, industrial medicine division, Brookhaven National Laboratory, 1947. Member BNL radiation safety committee, 1947- . Evaluation of radiation exposures in personnel.

Donald D. Van Slyke, Ph.D., Consultant, Brookhaven National Laboratory, 1949. Member Rockefeller Institute for Medical Research, 1909-49. Assistant Director, Life Sciences, Brookhaven National Laboratory, 1949-51. Advisory Director, Division of Biochemistry, Medical Department, Brookhaven National Laboratory, 1951- . Studies on metabolism of radioactive compounds, 1949- . Author, Vol. II, Quantitative Clinical Chemistry, Peters and Van Slyke, Williams and Wilkins, Baltimore 1933 and numerous scientific articles dealing with clinical chemistry and metabolism.

In addition to this local committee, Dr. R. Rawson of Memorial Hospital and Dr. G. Failla of Presbyterian Hospital in New York City are active collaborators in various activities of the department and on their periodic visits are fully consulted on particular problems in their fields of experience.

The duties of the committee conform to and include those recommended on page 61 of the Isotopes Catalog No. 4, viz.:

1. Review and grant permission for, or disapprove the use of radioisotopes within the medical department, from the standpoint of radiological safety both to personnel and to patients.
2. Prescribe special conditions as may be necessary.
3. Receive reports from the radiological safety officer and review his records.
4. Recommend disciplinary action when an investigator fails to comply with safety regulations.
5. Keep a record of actions taken in approving the use of isotopes and of other transactions, communications and reports.

4003023

Radiological Safety

Dr. J.B.H. Kuper is the chairman of the laboratory's Instrumentation and Health Physics Department. Dr. F.P. Cowan is the radiological safety officer in the sense used in the suggestions on page 62 of the Isotopes Catalog No. 4. The Health Physics division:

1. Provides film badge and pencil electrometer services to all laboratory personnel.
2. Supplies additional monitoring equipment when an experiment presents an above-average radiological hazard and when a new procedure is being tried.
3. Supervises storage and disposal of radioactive sources.
4. Supervises decontamination procedures.
5. Monitors storing and using areas; posts warning signs in contaminated and hazardous areas.
6. Reports hazardous conditions and overexposures to responsible personnel and to the chairman of the isotopes committee.

As indicated on form 313a, a separate group, the instrumentation and calibration division, supplies, calibrates and repairs survey instruments. This division is also under Dr. Kuper.

There is also a laboratory-wide Radiation Safety Committee headed by Dr. Kuper and consisting of the heads of all departments or their designated representatives. This committee was organized November 4, 1947. Since the committee's inception, Dr. R.A. Love, head of the Division of Industrial Medicine, has represented the medical department. The functions of the committee are to advise the Health Physics Officer in matters of policy and to consider proposed radiation safety measures. They investigate all radiation accidents and review known problems which may involve risks above established tolerances.

Dr. Robertson maintains liaison with the health physics and instrumentation groups for the medical department, maintains complete records of receipt, storage, use, transfer and disposal of all radioisotopes received by the hospital, and supervises storage and assay of all radioisotopes used in the medical department.

It perhaps should be mentioned that all isotopes coming into the laboratory are received by the laboratory's Isotope Production and Distribution Group. Dr. Marvin Fox is the leader of this group which takes care of recording receipt of shipments, monitoring

4003024

containers, opening the shipping containers and delivering the isotopes to the hospital. Only the small bottles containing the isotopes are handled within the medical department.

Projected Program

Attention is invited to the fact that the medical department has previously received the following specific authorizations for radioisotope procurement for use in humans:

<u>AEC Serial No.</u>	<u>BNL No.</u>	<u>Isotope</u>
R 1164	SCM 1	I 131
R 1213	SCM 2	Na 24
R 1346	SCM 3	P 32
7257 R	SCM 4	P 32
7432 R	SCM 5	K 42
7899 R	SCM 6	I 131
7900 R	SCM 7	Na 24
8312	SCM 8	K 42
8311	SCM 9	Na 24
8941 R	SCM 10	Na 24
8940 R	SCM 11	I 131
8939 R	SCM 12	I 131
8949 R	SCM 13	H 3
8938 R	SCM 14	K 42
8937 R	SCM 15	A 41
8927 R	SCM 16	P 32
9097 R	SCM 17	P 32
9177 R	SCM 18	I 132
9176 R	SCM 19	I 132
9742 R	SCM 20	Cr 51
11388	SCM 23	Cl 38

Future work will continue most of the projects initiated under the proposals which accompanied the requests for these authorizations. Further studies have been planned which will emphasize the use of short-lived isotopes, which are available to us from the Brookhaven reactor. In particular, studies are contemplated which will compare the effects of the radiation from these short-lived isotopes with certain of the longer-lived isotopes such as Au 195.

The Brookhaven National Laboratory Committee on Isotopes for Human Use has given careful and earnest consideration to this application. They are fully cognizant of the responsibilities which will devolve on them if this application be granted, and are prepared to meet fully those responsibilities along the lines which have previously been established by the AEC Advisory Subcommittee on Human Applications.

Lee E. Farr, M. D.

James S. Robertson, M. D.

John T. Godwin, M. D.

David L. Jellinger, M. D.

William M. Hale, M. D.

Robert A. Love, M. D.

Donald D. Van Slyke, Ph. D.