

Office Memorandum • UNITED STATES GOVERNMENT

TO : A. H. Holland, Jr., Director of Research
and Medicine

FROM : Paul C. Aebersold, Chief, Isotopes Division

SUBJECT: USE OF RADIOISOTOPES IN HUMAN SUBJECTS

DATE: October 5, 1949

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IR:SAL

Reference is made to communication of August 11, 1949, sent to you by Dr. Shields Warren, Director, Division of Biology and Medicine, regarding allocation of radioisotopes to be used in human subjects. It is noted that Dr. Warren instructed that such allocations would be made by the Isotopes Division only after review and approval by the Subcommittee on Human Applications of the Committee on Isotope Distribution. It should be emphasized that the instruction applies even though the radiomaterial is produced in the laboratory where it is to be used.

Since this procedure has not been uniformly followed in the past, we are writing to acquaint you with the appropriate details. Enclosed is a copy of our latest catalog. On pages 30 and 31 are presented the criteria governing the distribution of radioisotopes when these substances are to be used in humans. Enclosed also are six copies of Isotopes Division Circular D-4, which contains the same statement, and which may prove convenient to you in the process of acquainting members of your staff with this procedure.

Obviously applicants for radioisotopes to be used in human subjects will need to submit more information than has been offered on previous applications submitted on Form AEC-558. For the convenience of this office and of the Subcommittee on Human Applications, applications should be submitted on Form AEC-313. Special attention should be given to the information asked for on pages 30 and 31 of the Catalog and Price List No 3, July 1949. We shall assume, as in the past, that instrumentation, both for measurement and for health physics purposes, is adequate at Commission laboratories. It will not be necessary to use Part 2 of Form AEC-313. The Subcommittee has insisted that a physician be connected with all projects in which human subjects are used, so as to insure that the clinical care of the patients will be provided for. It should be emphasized that each application should be accompanied by a formal, written endorsement, signed by the Chairman of the local "Isotopes Committee," the recommended membership of which is outlined on pages 30 and 31 of the catalog. Your special attention is called to the Subcommittee's insistence that a complete dosage schedule be submitted with the application.

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More time will be required to review and approve your applications for the use of radioisotopes in human beings than was the case previously. The four members of the Subcommittee on Human Applications reside at widely separated places throughout the United States, and time is required for communication by mail. The delay incident upon review by the Subcommittee is significant, however, only on the first application connected with a given research program. Requests for additional amounts of a radioisotope to be used in the same project, supervised by the same investigators, can be handled in this office, usually in from one to two working days. This office can look upon requests for such additional amounts as supplementary to the first application and in most instances it is not necessary to submit the supplementary applications to the Subcommittee for their review.

Applications should be sent to Isotopes Division, Oak Ridge Operations, P. O. Box E, Oak Ridge, Tennessee, Attention: Dr. S. Allan Lough, Chief, Radioisotopes Branch.

It is hoped that the enclosures and the remarks in this letter will clarify the situation. If there are further questions, please present them to us.

Paul C. Aebersold
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Attachments:

1. Cir. D-4 (6)
2. Form 313, w/Inst. (6)
3. Catalog (6)

CC: Dr. Marshall Brucer, w/encls., ORINS
Dr. William G. Pollard, w/encls., ORINS
Dr. H. D. Bruner, w/encls., ORINS

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