

Boards, committess, etc.

# OFFICIAL AEC FILE

NO PAPERS WILL BE REMOVED HEREFROM:

BEST COPY AVAILABLE

REPOSITORY NARA - Atlanta  
 COLLECTION MED Mail + Records  
 BOX No. #141 67A803  
 FOLDER AEC 334 (R-Advisory  
 Committee on Human  
 Applications)

*R*

In Reply Refer to:  
IT:NMH

Woodruff/fli

Oak Ridge, Tennessee  
March 9, 1948

ATOMIC ENERGY COMMISSION

File No. AEC 334 (R-Comm on  
Human Application of  
Isotopes)

Dr. Hymer Friedell  
Dr. G. Failla  
Dr. Joseph G. Hamilton  
Dr. A. H. Holland, Jr.

Subject: MEETING OF SUBCOMMITTEE ON HUMAN APPLICATIONS IN WASHINGTON,  
MARCH 22 AND 23

Gentlemen:

Inasmuch as I will be in Texas on March 22 and 23 and will not be able to attend subject meeting, I have asked Dr. Woodruff, my alternate for Committee activities, to attend and he will be pleased to do so.

We would like to discuss briefly some of the problems which will be considered.

In considering allocation of radioisotopes for therapeutic use in human subjects, this office feels that insofar as possible objective criteria of facilities and personnel qualifications should be the basis on which allocations are made. By facilities and personnel qualifications we mean (1) physical equipment with which to handle and measure radioisotopes, and to protect working personnel from radiations, (2) personnel with proper training in the handling and use of radioisotopes, and (3) personnel with accredited medical training.

By placing allocations on this basis, the Subcommittee and Isotopes Division will not be placing itself in a position of passing upon a physician's treatment of particular patients. This responsibility for the patient rightly belongs to the attending physician.

Therefore, we suggest that the Subcommittee discuss this problem with view of recommending (1) physical facilities (2) prerequisite experience or required training of those responsible for handling the material, (3) prerequisite experience or required training of physicians responsible for the clinical phases of the work.

Since the problem is complex, it may be necessary to establish different

BEST COPY AVAILABLE

OFFICE	Isotopes	Isotopes			
NAME	Woodruff <i>W</i>	Aeberson <i>EA</i>			
DATE	3/9/48	3/8/48			

1151369

criteria for different isotopes and uses. For example, an application requesting  $^{32}\text{P}$  for the treatment of polycythemia vera may not have to meet as strict requirements as an application for  $^{131}\text{I}$  for treatment of thyroid carcinoma, or for  $^{198}\text{Au}$  for the treatment of certain leukemias.

If the above criteria can be established, any duly accredited hospital, medical school, clinic (public or private) or physician meeting the requirements should be eligible for allocation of radiomaterials. The meaning of "accredited" should be defined clearly.

Another problem which should be discussed at the meeting is use of radioisotopes of long half-life in moribund patients. Several approaches to the Isotopes Division have been made on this matter. For example, Dr. Dobyns, Massachusetts General Hospital, has requested in writing permission to use  $^{45}\text{Ca}$  to be transferred from an allocation made to Dr. R. D. Evans, Massachusetts Institute of Technology. A verbal request has also been received from a staff member at Presbyterian Hospital, Chicago, for the use of C 14-labeled testosterone in moribund patients.

This office feels that such requests should be allowed if a satisfactory mechanism for determining the "moribundness" of the patients in question is established. We believe that this question should be decided by a group of doctors and written evidence signed by the group filed with the Isotopes Division prior to the use of the material. This office has written Dr. Dobyns for the manner in which he or Massachusetts General Hospital will make such determinations. Dr. Woodruff will present this information if it is available at the time of the meeting.

In many clinical uses of allocated material, the treatment is so experimental that it may be advisable to require hospitalization of the patient for the purpose of obtaining satisfactory clinical data. Some clinical uses have become rather routine and may not require such extensive clinical observations as to require hospitalization. Some recommendations should be made concerning requirement of hospitalization in connection with specific types of treatment.

Some institutions, such as Mayo Clinic, which receive radioisotopes routinely and which have a great deal of clinical material at hand, have opportunities to use radioisotopes clinically in types of cases which may not have been noted on their applications. Strictly speaking, the applicant, if he does use the material in a manner not noted in the application, is at fault and could be censured for his actions. However, the Isotopes Division feels that some leeway on such matters is desirable. If a general philosophy could be developed on the degree of reliance on the judgement of the investigator, it would be helpful to this office.

SEARCHED					
INDEXED					
FILED					
DATE	11	5	13	70	

In developing specific mechanisms for handling applications, it is hoped that the Subcommittee will have in mind the keeping of paper work and necessary correspondence down to the minimum compatible with doing a good job. Radioisotope users will of course appreciate our keeping "red tape" to a minimum. Dr. Woodruff, who has been actively handling allocation work for the past eight or ten months in this office, is adequately qualified to appraise the mechanisms proposed. Dr. Woodruff may have some illustrative cases and a few specific details to present at the meeting.

We thank the Subcommittee for their assistance and for having this meeting at an early date.

Very truly yours,

Paul C. Ashersold, Chief  
Isotopes Division  
Oak Ridge Operations

NOT DISPATCHED BY MAIL AND RECORDS

OFFICE						
NAME						
DATE	11	5	13	71		