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cc: JM Nielsen - 2  
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DATE September 12, 1966

TO R. S. Paul

FROM J. J. Fuquay *JJ Fuquay*

SUBJECT THE METABOLISM, DISTRIBUTION, AND EXCRETION OF PROMETHIUM IN HUMANS

A planned research study on the metabolism of promethium in humans has reached the stage of use of human volunteers. This study is part of our Schedule 189 project titled Whole Body Counting approved for Fiscal Year 1967 and is a cooperative study with the Hanford Occupational Health Foundation (HOHF). The proposed study is detailed in the attachment to this letter.

Experiments involving the use of human volunteers on this project have been conducted for many years. Included among these studies was a study of technetium metabolism carried out in 1965 in cooperation with the University of Washington Medical School which is similar in many aspects to the study planned with promethium. In this study <sup>95</sup>Tc was administered to human volunteers by University of Washington medical doctors and its metabolic behavior and excretion rate were measured by Battelle-Northwest scientists using whole body counting and bioassay techniques. A contract was written by the AEC-RLOO to pay the volunteers by transferring Battelle-Northwest funds to the University of Washington. It was our understanding at that time that this was not necessarily the procedure to be used for subsequent work.

We, therefore, request a) your approval to perform this study, b) instructions as to the contractual procedures to follow for covering the costs incurred by HOHF in reimbursing the volunteers, and c) aid in evaluating the position of Battelle-Northwest and its personnel with respect to possible legal action resulting in economic loss and in obtaining insurance to cover such loss.

JJ Fuquay:JMN:flb

Attachment

REPOSITORY *PNL*  
COLLECTION *PROMETHIUM*  
BOX No. *2947*  
FOLDER *HSC 66-1*

Please indicate your approval to proceed by your signature on the approval line below.

APPROVED: \_\_\_\_\_  
Associate Director

\_\_\_\_\_ Date

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## THE METABOLISM, DISTRIBUTION, AND EXCRETION OF PROMETHIUM IN HUMANS

### Purpose of Study

This study is designed to define the general metabolic behavior of promethium in the human body. The beneficial results of the study are: 1) realistic exposure limits can be imposed for workers handling large quantities of  $^{147}\text{Pm}$  now being separated from Hanford wastes; 2) since rare earths such as promethium have a metabolic behavior similar to plutonium, this study will give an indication of the metabolic behavior of plutonium as well as useful experience for the planned experiments using the electron capture isotope  $^{237}\text{Pu}$ ; 3) any unique metabolic properties of rare earths which may have medical applications can be observed.

### General Procedure

In this experiment paid adult volunteers will ingest, will be injected with, and will inhale small quantities (0.1  $\mu\text{Ci}$ ) of  $^{143}\text{Pm}$ . This radionuclide will be radiochemically pure except for a few percent of  $^{144}\text{Pm}$ . Both  $^{144}\text{Pm}$  and  $^{143}\text{Pm}$  are electron capture isotopes which produce very low dose rates. As planned, six volunteers will be used for each mode of isotope administration. The isotopes were produced at the Oak Ridge Cyclotron and separated and purified at Battelle-Northwest laboratories. They will be sterilized and pyrogen tested by a Seattle pharmaceutical laboratory or by the University of Washington Medical School and in all three modes of administration described above, the isotope will be administered to the volunteers by medical doctors of Hanford Occupational Health Foundation without anesthesia. After administration the distribution, retention, and excretion will be measured by Battelle-Northwest laboratories by whole body counting, and gamma-ray counting of excreta. These studies will continue for about 1 year after initial administration.

### Radiation Dose

The radiochemical purity and the isotopic concentration of the material to be administered to the volunteers will be verified independently by Battelle-Northwest staff members of the Radiological Chemistry and the Radiological Analysis Units. Small amount of stable neodymium (target element) will be present but at concentrations a thousand times lower than an amount considered to be toxic to humans. Using data from animal experiments and the International Commission on Radiological Protection (ICRP) parameters, the total radiation dose that each volunteer would receive in the planned experiments has been calculated. The dose would be 0.006 rem

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Radiation Dose - cont'd.

for the whole body, 0.009 rem for bone, and 0.060 rem for the liver. The dose to the liver is about the same as the maximum permissible daily dose for an employee and is only 0.000003% of the ICRP maximum permissible working lifetime dose for the employees. HOHF will have the responsibility of calculating the dose, prescribing the amount to be given, and administering the radioisotope. Battelle-Northwest will confirm dose calculations and suggest the minimum amount of radioisotope needed to make the physical measurements.

Detailed Procedure

1. Hanford Occupational Health Foundation will advertise for adult volunteers through the graduate school and possibly the Hanford Project News.
2. Volunteers will be interviewed and selected, and will sign a voluntary consent agreement with Hanford Occupational Health Foundation.
3. Volunteers will be paid by Hanford Occupational Health Foundation with money transferred from Battelle-Northwest through the AEC to HOHF.
4.  $^{143}\text{Pm}$  will be administered to the volunteer by Hanford Occupational Health Foundation personnel by ingestion, injection, or inhalation.
5. Immediately after administration and for a period up to 1 year, measurements of the distribution, retention, and excretion of the isotope in the volunteer will be made by Battelle-Northwest personnel. These measurements will be made by whole body counting methods and analysis of blood and excretion samples. Scheduling of volunteers for studies, excretion collection, and blood sampling will all be arranged by Hanford Occupational Health Foundation but will be planned together by Hanford Occupational Health Foundation and Battelle-Northwest personnel. Hanford Occupational Health Foundation will approve all contact with the volunteers.
6. Data obtained from the studies will be analyzed by both Hanford Occupational Health Foundation and Battelle-Northwest and will be published as a co-authored paper from both institutions.

Note: Hanford Occupational Health Foundation has obtained liability insurance to cover the risk of any possible health damage claims. In our studies with the University of Washington, they are also insured against any possible claims.

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