



DEPARTMENT OF THE NAVY  
 NAVAL MEDICAL RESEARCH INSTITUTE  
 NAVAL MEDICAL COMMAND NATIONAL CAPITAL REGION  
 BETHESDA MD 20814

IN REPLY REFER TO

PROJECT TITLE: Scientifically Based Decompression Tables for Air Diving

SUBTITLE: Tracer Gas Kinetic Studies for Decompression Table Design

PRINCIPAL INVESTIGATOR: M.E. BRADLEY CAPT MC USN

REQUIREMENTS FOR REVIEW BY THE  
 COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

a. What are the risks that may or may not be encountered by the subjects?

The only risks inherent in the procedure are those arising from the special gas breathed. Chemical risks arise from the possibility of creating noxious gases in the radioactive nitrogen preparation. These could include ozone and nitrogen dioxide. The major risk is radiological, that is, the unavoidable exposure of subjects to ionizing radiation. The total dose of radiation from the studies is estimated to not exceed 0.5 rad to the lungs and trachea and 0.01 rad to the body (1). This dose can be compared to the 0.18 rad/year of natural background exposure of the total population; 0.026 rad for a single chest x-ray; 5.0 rad/year, the current federal statutory limit for occupational exposure; and 4,000 rad in clinical radiation therapy (2).

b. What are the safeguards against these risks:

The procedure to be used will attempt to minimize the chance of any chemical risks and to prevent any radiation exposure above the amount stated previously. The radioactive nitrogen and argon will be prepared using techniques developed by P. Meyer. Only very pure gases will be exposed to the gamma-ray source (LINAC electron beam with heavy metal target). After activation, samples of the gas will be taken and analyzed immediately for ozone and nitrogen dioxide. Only when these analyses are completed will the mixture be added to oxygen and breathed by the subject. Expired gases will be directly vented outside the lab building to prevent any other exposure. Subject doses will be calculated by standard methods (1) as the major exposure is too localized and transient to be measured directly.

Procedures will follow those established earlier in work unit M0099PN.01A.0001. In those experiments, the measured ozone and nitrogen dioxide were well below specification in every case. External dosimetry of test subjects showed no detectable radiation dose (less than 0.01 rad). Final internal dosimetry calculations showed lung doses in the subjects of 0.30 to 0.45 rad, compared to the chosen limits of 0.50 rad.

c. What benefit will science or the subject potentially realize?

No direct benefits will be realized by the subjects. Indirect benefits may be realized by U.S. Navy divers, a group that is expected to provide the majority of subjects. The project is designed to provide data on the rate of

1157399

nitrogen uptake and elimination in the human body. Decompression sickness among divers is thought to be caused by an inability to remove the excess nitrogen from a diver's body after breathing high-pressure air. Prevention of decompression sickness is approached by adherence to decompression tables that are calculated to match the rate of nitrogen removal with the rate of diver return to normal pressure. The proposed study will attempt to provide the data necessary for NMRI to provide the safer decompression tables required by the Navy.

d. Have the required elements of informed consent been satisfied? Discuss how the consent will be obtained and attach a copy of the consent form.

Consent forms for both NMRI and the Lawrence Livermore Laboratory are attached. Potential subjects will be briefed at both sites on the procedures, risks, and results to date. In previous experiments, the briefing questions and discussion have required 1-3 hr for each experimental subject.

e. Are the procedures established and accepted nationally and locally and are they for the patient's benefit?

The isotope preparation and detection, and the radiation dosimetry are established and accepted at the Livermore Laboratory. The procedures are specialized and use unusual facilities, so no national standard is possible. The breathing equipment is assembled with components common to pulmonary physiology laboratories. The subjects are healthy and the procedures are not for their individual benefit.

#### REFERENCES

1. Ozaki, C.B. (memorandum from the Lawrence Livermore Laboratory to Paul Meyer). Estimation of total absorbed doses from inhalation of <sup>13</sup>-N, <sup>15</sup>-O, <sup>37</sup>-Ar, and <sup>85</sup>-Kr. May 23, 1980.
2. The effects on population of exposure to low levels of ionizing radiation. National Academy of Science, National Research Council, Washington, D.C.

REPOSITORY LLNL  
 COLLECTION PAUL MEYER'S PAPERS  
HUMAN RESEARCH NAVY/DECOMP.  
 BOX No. SICKNESS EXPER. STUDY FILES  
 FOLDER N/A

1157400