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HUMAN SUBJECT EXPERIMENTS WITH AIR TAGGED WITH RADIOISOTOPES ^{13}N and ^{41}Ar

PREFACE

The Laboratory's basic safety policy is that operations must be planned and conducted in a manner that will prevent injury to personnel or damage to property. The minimum safety rules and practices necessary for achieving an accident-free work environment for the human subject experiments with air tagged with radioisotopes in Building 194 are stated in the Operational Safety Procedure.

Everyone in this building, i.e., visitor, maintenance and service employee, and regularly assigned employee, is required to abide by this procedure and the LLNL Health & Safety Manual to protect himself and other personnel from injury. Regular building personnel are responsible for assisting others in the building to understand the safety regulations relating to what they are doing and to abide by the safety requirements.

This procedure was prepared by building management assisted by Hazards Control. Confer with the Hazards Control safety team assigned to this building for interpretation of this procedure and for planning your operations to comply with safety requirements. Each individual in this building shall use this guidance effectively to avoid injury.

This Operational Safety Procedure has been reviewed by:

R. W. Bauer	E. Division
A. J. Toy	Hazards Control
D. C. Shepherd	Human Subject Committee

This Operational Safety Procedure is approved by:

John D. Anderson
Associate Director
for Physics

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HUMAN SUBJECT EXPERIMENTS WITH AIR TAGGED WITH RADIOISOTOPES ^{13}N and ^{41}Ar

A. INTRODUCTION:

1. General

The purpose of this study is to measure the rate of nitrogen and Argon uptake and elimination in the body of normal healthy humans. The experiments will involve breathing of ^{13}N and ^{41}Ar labelled air for no more than 120 minutes.

2. Changes

Any required change in operations that alters the scope or significantly decreases safety control will not be made until a revision or supplement to this procedure has been signed by the person authorized to approve this OSP. Any required change in operations that does not decrease the safety control may be made with the joint concurrence of the LINAC Operations Manager and the Hazards Control Safety Team Leader.

B. SCOPE

1. This procedure authorizes the exposure of human subjects to the following:

   a) Breathing of air tagged with ^{13}N and ^{41}Ar for up to 120 minutes.

C. HAZARDS ANALYSIS:

1. Radiation Hazard

Estimates of the radiation dose from ^{13}N and ^{41}Ar activities in the breathing mixture are based on calculations by Hazards Control's Health Physics Group (see letter from K. Shingleton of April 12, 1982). The dose per mCi per liter for ^{13}N is ~ 1000 mr and for ^{41}Ar: 6400 mr. To obtain extimates of the expected dose we take the gas mixes and decay activities into account as seen below:

^{13}N-activity at t=o (beam shut-off) = 1.8 mCi/liter
^{41}Ar activity at t=o (beam shut-off) = 0.001 mCi/liter

The breathing gas concentrations will be:

$*N_2$ (80%) + O_2 (20%) or $*N_2$ (75%) + *Ar (5%) + O_2 (20%)

Half lives ($T_{1/2}$) for the isotopes are ^{13}N: 10 min. and ^{41}AR: 109 min. Time elapsed from beam shut-off to administration will be ~ 20 minutes. With this in mind we obtain the estimates at t=20 min. for 120 minute exposure.

Total dose = (~~dose~~ dose/mCi/ℓ) (concentration)(activity) ($e^{-\lambda t}$)
$*N_2 + O_2$: (1000) (0.80) (1.8) (0.25) = 360 mr
$*Ar + *N_2 + O_2$: (6400) (0.05) (0.001) (0.881) + (1000) (0.75) (1.8) (0.25)
= 0.26 + 337.5 = 338 mr
revised 344

2. Gas Hazards (NO_2)

To generate the ^{13}N isotope, high-purity N_2 is irradiated with bremsstrahlung. Some trace of O_2 always is present and in this ionizing environment, NO_2 and N_2O forms. The concentration is controlled by minimizing the presence of O_2 in the nitrogen.

The Operational Controls in paragraph F will reduce the above hazards to an acceptable level.

D. RESPONSIBILITIES:

1. Supervisor

Paul Meyer is responsible for assuring that all work is performed in conformance with this OSP and the LLNL Health & Safety Manual. In his absence, the experiment will be terminated and a responsible person will be trained for the experiment.

2. Employee

All participating employees are responsible for performing their work according to the regulations of this OSP. They are expected to take all reasonable precautions to protect themselves and their fellow employees and to perform only those tasks that they believe can be accomplished safely. When participants have any doubt regarding the safety of any phase of their work, they are expected to check with the project supervisor before proceeding.

3. Hazards Control

The Hazards Control Safety Team assists management to institute and to maintain a low-risk work environment. In addition, Hazards Control may request that management or employees stop an operation when there appears to be an imminent danger to personnel or property (see Health & Safety Manual Section 1.06).

E. MATERIAL CONTROLS:

1. The target gases are:

a) AR: Zero grade

b) N_2: High purity nitrogen (silver colored bottles with pink top).

2. Waste gas disposal is achieved with large volumn blower which pumps gas from the site of the experiment to the outside of Bldg. 194 at the roof level.

F. OPERATIONAL CONTROLS:

1. All human subjects shall receive a whole body radiation scan by Hazards Control before and after inhalation of radioactive gases.

2. The radioactive gases shall be filtered with a HEPA filter before inhalation by the subjects. A visual inspection of the filter cartridge gaskets and canister will be made prior to filter installation. Only an approved and tested filter cartridge obtained from Hazards Control Respirator Service will be installed in the filter canister.

3. Radioactive gas preparation:

The evacuated target gas bottle, located in the 0^0 cave, is filled from a standard gas cylinder containing either high-purity nitrogen (N_2) or Zero grade Ar. Upon filling, the gas is being irradiated by LINAC bremsstrahlung.

In the case of N_2 as target gas, any undesired by-products come from small oxygen concentrations in the gas bottle. This can lead, in principle, to NO_2 and N_2O. Tests performed previously by Hazards Control personnel, found concentrations of less than 1 ppm of NO_2 and less than 22 ppm of N_2O in an irradiated sample. The breathing mixture will be tested for NO_2 and ozone before it is administered.

G. PROCEDURE

a) Evacuate target-gas bottle in 0^2 cave to $\leq$ 50 microns.

b) Fill target bottle with N_2 or N_2 + ^{40}Ar.

c) Bleed radioactive gas as described below, into plastic bag.

d) Check mixture for NO_2 (≤ 5 ppm).

e) Mix active N_2 with clean O_2 to 4 parts $*N_2$ and 1 part O_2 in plastic bag.

f) Navy personnel will continuously monitor and hold O_2 concentration to approximately 20%.

Exposure Procedure

$*N_2$ or $*N_2$ + *Ar

The prepared and tested gas mixture is taken from Trailer 930 to the subject in Bldg. 194 in a plastic bag which is then connected to the breathing valve. The subject then breathes for 120 minutes from the bag. The exhaled gas is passed through a soda lime trap to remove all Co_2 before returning to the bag. A concentration of ~20% O_2 is maintained in the bag and monitored with a bio-marine oxygen deficiency meter or equivalent during use by Navy personnel. At the end of the 120 minute period the bag is disconnected and the subject breathes room air with the washout being vented to the outside of Bldg. 194.

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