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Mr. A. L. Anderson
Hazards Control Dept. L-383
Lawrence Livermore National Laboratory
P.O. Box 808
Livermore, CA 94550

Dear Larry:

I am writing to express the support of the U.S. DOE Intercalibration Committee on Measurements of Low-energy Photon Emitters in Vivo for continuation of intercalibration experiments involving the administration of trace amounts of radioactivity to human volunteers. I have chaired the committee since 1980 and representatives of almost all DOE facilities with whole-body counters participate. As you are well aware, previous committee efforts have included design criteria for the Livermore phantom, intercalibration with the phantom, and validation of the phantom with in-vivo studies. Although Argonne is also participating in the current program, and in fact I plan to be one of the volunteers if time permits, I hope I can still present an unbiased evaluation of the program.

The point that a laboratory should not participate in the program unless it were willing to perform the entire protocol with its own employees is well taken. Consequently, we have to look at the risks and benefits involved in the program and determine if the latter justify the former. We must also keep in mind the current regulatory and public relations climate; indeed, the risk of adverse publicity to the laboratories far exceeds any conceivable radiation risk to the subjects involved. About three years ago, Representative Edward Markey (D, Mass.) successfully grabbed some headlines by "exposing" DOE's (and predecessor agencies') history of human experimentation involving radioactivity, comparing the program to Nazi "medical" experiments in the concentration camps. The severest criticism came from the use of "unknowing" subjects, specifically in Wright Langham's plutonium injection series in the late 1940's. To the question that if these experiments are so safe, why don't the scientists use themselves as subjects, the answer is, we do. There can be no question of informed consent in the current (and previous) Harwell 92mNb studies as all participants were and are scientific or technical staff members. Nevertheless, concerns still remain about the technical justification for this experiment.

The purpose of the experiment is to determine if the counting efficiency for inhaled plutonium is affected by its distribution in the lung, and if so, what corrections need to be made to the efficiencies predicted by the phantom, which takes only chest wall thickness and composition into account. We are testing the effect of distribution by administering 1.0-micron-diameter particles, and comparing the observed efficiency with that from the same volunteers who had previously inhaled 5.0-micron-diameter particles.

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Because there is not an a priori method of determining what the difference in distribution will be in humans, the experiment must be done by using volunteers. Animal experiments have indicated that the distribution will be different, but the results cannot be applied directly to humans because of differences in the morphometry of the respiratory tract.

The research is directed toward improving the calibration for measurement of inhaled plutonium in radiation workers. Thus, the results are directly applicable to human welfare, and are not science for science's sake.

By using eight volunteers covering a range of body sizes, the desired information will be obtained. Note that it is important to have two or three subjects in each range of body size: smaller than, similar to, or larger than the phantom, in order to preclude the possibility of the only data point in a given size range being an outlier due to individual variability.

The risk to the individual subject is that associated with a radiation dose of about 5 mrem committed effective dose equivalent to the lung. This dose is assumed to confer a risk of about 1×10^{-7} of developing lung cancer. Of course, there is no scientific evidence whatsoever that a dose of this magnitude is potentially carcinogenic at all. The predicted risk is based on the usual linear no-threshold extrapolation from doses about five orders of magnitude greater. This dose is 0.1% of the 5 rem limit for occupational workers, and 2.5% of the weighted lung dose received annually from average concentrations of indoor radon. To put the risk in further perspective, participation in the experiment involves air travel of about 15,000 miles . The risk of death from crashes involving regularly scheduled airlines is 7×10^{-10} per passenger mile. Therefore, the risk of being killed in an airplane crash is 1×10^{-5}, or 100 times greater than the risk of developing lung cancer, by participating in this experiment.

Space does not permit me to address the related experiments, such as [redacted] involvement in alkaline earth metabolism studies, but similar arguments obviously apply.

The point is simple: the work is oriented towards improved capability of protecting the health and safety of DOE radiation workers; the risk to the individual participant, if in fact there is any, is so low as to be negligible by any reasonable standard; although any human experimentation may be distasteful to some reviewers, the information to be obtained from this experiment is otherwise unavailable. Therefore, Livermore's participation in the experiment should be approved.

Sincerely,

Dick

R. E. Toohey, Ph.D
Health Physics Manager

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