



PROJECT NO. 2 vermc National Laboratory

717935

attach to
file

September 10, 1987

Mr. James Davis
U.S. Department of Energy
DOE SAN
1333 Broadway
Oakland, CA 94612

SUBJECT: Visit Request and Whole Body Counting of Employee from AERE
Harwell, U.K.

Dear Mr. Davis:

Enclosed for your information are documents submitted to the LLNL Human Subjects Committee regarding proposed Whole body counter measurements in mid-October 1987 for [REDACTED], a radiobiologist employed by AERE Harwell. The purpose of [REDACTED] visit is to measure the residual radioactivity present in his body from Ba-133 and Sr-85 which were administered in the United Kingdom. [REDACTED] came to the Laboratory for earlier measurements in March 1987 after receiving a planned administration of 76 kBq (2.05 uCi) of Ba-133 in an AERE experiment formally approved by their Tracer and Irradiation Studies Approval Committee. In June of 1987, [REDACTED] received an additional administration of 106 kBq (2.86 uCi) Sr-85 in another program, which was also approved by the UK ethics committee.

[REDACTED] was measured by several U.S. laboratories during his March visit to the United States and will be measured by at least three U.S. laboratories during his visit in October. These measurements are useful to LLNL and other DOE facilities as a means of calibrating radiation detectors used in various in vivo monitoring programs and have produced valuable data, enabling us to perform our work more accurately and with more confidence. If you have any questions regarding the above, please call Larry Anderson or Deborah Kruchten, of my staff on FTS 532-5158 or 532-5199 respectively.

Sincerely,

Thomas R. Crites, Acting Head
Hazards Control Department

TC/pc
Attachments

cc: Bart Gledhill
w/o attachments

REPOSITORY LLNL B361 Rm. B940A

COLLECTION Institutional Review Board

BOX No. IRB Protocol File

FOLDER P.I.A. Anderson IRB No. 87-113
Whole Body Counting of Visitor from
AERE Harwell UK to Measure Residual
Activity from Ba-133 & Ra-226

1122180

FROM: D. NEWTON, HARWELL LABORATORY

TO: LARRY ANDERSON, HAZARDS CONTROL,
LAWRENCE LIVERMORE LABORATORY.

SACNET

1987 SEP 10 AM 7:48

COMMUNICATIONS

MESSAGE

The following two pages demonstrate that in administering the ⁸⁵Sr we complied with current UK legislation governing the use of active tracers for medicinal and research purposes. This may assist in your impending submission.



CERTIFICATE
FOR THE
ADMINISTRATION OF RADIOACTIVE MEDICINAL PRODUCTS

No. EPC 313-2 (11)

The Health Ministers within the meaning of the Medicines Act 1968 hereby certify that for the purposes of section 60 of that Act and of regulation 2 of the Medicines (Administration of Radioactive Substances) Regulations 1978

Dr. J. C. E. Evans
ARE Harwell, Oxon

may administer for 2^{*} year(s) from the date of this certificate the radioactive medicinal products specified in the Schedule to this certificate for the purpose(s) there specified.

Signed by authority of the Health Ministers

[Signature]
.....

Date: 3rd December 86

Health Services Division
Department of Health and Social Security

1122182

* as the duration of the project,
wherever is as stated.



SCHEDULE TO CERTIFICATE No. R.P.C. 313-2(11)

Serial*	Radionuclide	Chemical Form	Purpose of administration
	^{85}Sr	SrCl_2	<u>RESEARCH</u> To investigate age-related change in the metabolism of strontium.

*From Appendix I (Reference 1979/1) to Notes for Guidance

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PROTECTION OF HUMAN SUBJECTS
ASSURANCE/CERTIFICATION/DECLARATION☐ ORIGINAL ☐ FOLLOWUP ☐ EXEMPTION
(previously undesignated)☐ GRANT ☐ CONTRACT ☐ FELLOW ☐ OTHER
☐ New ☐ Competing continuation ☐ Noncompeting continuation ☐ Supplemental

APPLICATION IDENTIFICATION NO. (if known)

POLICY: A research activity involving human subjects that is not exempt from HHS regulations may not be funded unless an Institutional Review Board (IRB) has reviewed and approved the activity in accordance with Section 474 of the Public Health Service Act as implemented by Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46—as revised). The applicant institution must submit certification of IRB approval to HHS unless the applicant institution has designated a specific exemption under Section 46.101(b) which applies to the proposed research activity. Institutions with an assurance of compliance on file with HHS which covers the proposed activity should submit certification of IRB review and approval with each application. (In exceptional cases, certification may be accepted up to 60 days after the receipt date for which the application is submitted.) In the case of institutions which do not have an assurance of compliance on file with HHS covering the proposed activity, certification of IRB review and approval must be submitted within 30 days of the receipt of a written request from HHS for certification.

1. TITLE OF APPLICATION OR ACTIVITY

Whole Body Counting of Visitor from AERE Harwell UK to Measure Residual Activity from Ba-133 & Ra-226

2. PRINCIPAL INVESTIGATOR, PROGRAM DIRECTOR, OR FELLOW

A. L. Anderson

3. FOOD AND DRUG ADMINISTRATION REQUIRED INFORMATION (see reverse side)

4. HHS ASSURANCE STATUS

☒ This institution has an approved assurance of compliance on file with HHS which covers this activity.

M-1415

Assurance identification number

01XB

IRB identification number

☐ No assurance of compliance which applies to this activity has been established with HHS, but the applicant institution will provide written assurance of compliance and certification of IRB review and approval in accordance with 45 CFR 46 upon request.

5. CERTIFICATION OF IRB REVIEW OR DECLARATION OF EXEMPTION

☒ This activity has been reviewed and approved by an IRB in accordance with the requirements of 45 CFR 46, including its relevant Subparts. This certification fulfills, when applicable, requirements for certifying FDA status for each investigational new drug or device. (See reverse side of this form.)

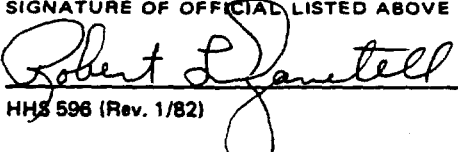
9/29/87

(month/day/year)

Date of IRB review and approval. (If approval is pending, write "pending." Followup certification is required.)

☒ Full Board Review☐ Expedited Review☐ This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by 45 CFR 46 will be reviewed and approved before they are initiated and that appropriate further certification (Form HHS 596) will be submitted.☐ Human subjects are involved, but this activity qualifies for exemption under 46.101(b) in accordance with paragraph _____ (insert paragraph number of exemption in 46.101(b), 1 through 5), but the institution did not designate that exemption on the application.

6. Each official signing below certifies that the information provided on this form is correct and that each institution assumes responsibility for assuring required future reviews, approvals, and submissions of certification.

APPLICANT INSTITUTION	COOPERATING INSTITUTION
NAME, ADDRESS, AND TELEPHONE NO. Lawrence Livermore National Laboratory P.O. Box 808 Livermore, CA 94550 (415) 422-9136	NAME, ADDRESS, AND TELEPHONE NO.
NAME AND TITLE OF OFFICIAL (print or type) Robert L. Zanetell, Finance Manager	NAME AND TITLE OF OFFICIAL (print or type)
SIGNATURE OF OFFICIAL LISTED ABOVE (and date)  10/13/87	SIGNATURE OF OFFICIAL LISTED ABOVE (and date)