

unw NIOBIA Study

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INSTITUTIONAL REVIEW BOARD

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STAFF IN CONFIDENCE

Page 1 of 2

PART I

Title of Study: INHALATION OF LABELLED POLYSTYRENE PARTICLES

Purpose of investigation:

To study the response of external X-ray counters to an inhaled radioactive aerosol.

Description of Study:

1. Inhalation by mouth of 1-um monodisperse polystyrene particles incorporating ^{92m}Nb .
2. Assessment of alveolar deposition by scintillation counting of gamma-ray emissions, and study of X-ray flux from the thorax.

TISAC paper (86) 8 Minute Reference (86)M2

ARSAC Cert RPC 313-2 (12) Held by Dr JC Evans

Radionuclide(s) ^{92m}Nb Likely No of administrations 1

Total activity deposited in pulmonary region 40 kBq maximum

Anticipated committed dose equivalent to organ(s): (uSv)

Lungs	440
Gut	180
Thymus	100

Committed effective dose equivalent 70

Name: D. NEWTON

Signed: D Newton

(Investigator)

Date: 13/12/88

REPOSITORY LLNL B361 Rm. B940A
COLLECTION Institutional Review Board

BOX # IRB Protocol File
Anderson IRB 88-101
FOLDER Counting of Human Subjects Containing
Nb-92m, Ba-133 & Sr-90 at the LLNL
Whole Body Counter (title change at 3/8/89 mtg)

1121995

STUDY TITLE: _____

PART II

I confirm that I have explained the nature, purpose and possible hazards of this study to this volunteer.

Name: _____

Signed: [Signature]
(Medical Examiner)

Date: 19/12/88

PART III

The nature of the study and its possible hazards have been explained to me by Dr JEFF MORGAN. I have informed the Doctor of any medication/drugs that I have recently taken, am taking or planning to take, whether prescribed or not.

I will not be referred to by name in any report describing the study, which is disclosed to a third party without my consent. I shall not claim to be entitled to restrict, in any way, the use to which the results of said study may be put.

I understand that the study may be of a confidential nature and I undertake not to divulge unnecessarily the existence of the study or its nature. I may, however, consult my GP on my participation.

It is understood that I may withdraw from this study at any time, without the need to justify my decision.

I hereby consent to take part, and to carry out the procedures outlined above.

Name: _____

Signed: _____

Date: 19/12/88

PART IV

In consideration of (Volunteer's name) ('The Volunteer') agreeing to participate in the study described above, the United Kingdom Atomic Energy Authority ('The UKAEA') will pay compensation to the Volunteer or his or her dependants without proof of negligence on the part of the UKAEA in the event of the volunteer suffering any injury or damage as a result of his participation in the said study provided that such compensation may be reduced to take account of any fault on the part of the volunteer which has contributed to the injury or damage.

Name: D. NEWTON

Signed: [Signature]

Date: 19/12/88

(Investigator)

STUDY TITLE: _____

PART II

I confirm that I have explained the nature, purpose and possible hazards of this study to this volunteer.

Name: J. R. MORGANSigned: [Signature]
(Medical Examiner)Date: 13/12/88PART III

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Name: _____ Signed: _____ Date 13/12/88PART IV

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Name: D. NEWTON Signed: [Signature] Date 14/12/88
(Investigator)

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Committed effective dose equivalent 70Name: D NEWTONSigned: *D Newton*
(Investigator)Date: 23 / 5 / 88

STUDY TITLE: INHALATION OF LABELLED POLYSTYRENE PARTICLESPART II

I confirm that I have explained the nature, purpose and possible hazards of this study to this volunteer.

Name: Jeffery MorganSigned: [Signature]

(Medical Examiner)

Date: 23/5/88PART III

The nature of the study and its possible hazards have been explained to me by Dr J. R. MORGAN. I have informed the Doctor of any medication/drugs that I have recently taken, am taking or planning to take, whether prescribed or not.

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Name: _____

Signed: _____

Date: 23/5/88PART IV

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Name: D. NEWTONSigned: [Signature]Date: 23/5/88

(Investigator)

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Committed effective dose equivalent 70

Name: D. NEWTON

Signed: *D. Newton*

(Investigator)

Date: 28 / 1 / 88

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Name: D. NEWTON

Signed: *D. Newton*
(Investigator)

Date: 28/ 1 / 88

STUDY TITLE: _____

PART II

I confirm that I have explained the nature, purpose and possible hazards of this study to this volunteer.

Name: JEFFERY MORGAN

Signed: [Signature]
(Medical Examiner)

Date: 5/2/88

PART III

The nature of the study and its possible hazards have been explained to me by Dr J.R. MORGAN. I have informed the Doctor of any medication/drugs that I have recently taken, am taking or planning to take, whether prescribed or not.

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I hereby consent to take part, and to carry out the procedures outlined above.

Name: _____ Signed: _____ Date 5/2/88

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Name: D NEWTON

Signed: [Signature]
(Investigator)

Date 5/2/88