

03033396

VOID SHEET

TO: License Fee Management Branch
FROM: RI
SUBJECT: VOIDED APPLICATION

Control Number: 119069
Applicant: Randolph Jr/Sr High School
Date Voided: April 7, 1994
Reason for Void: After review, it was determined that
the source would not use byproduct material
but accelerator-produced and thus not
subject to licensing by the NRC.
030-33396

Rebecca J. Brown 4/7/94
Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

Refund Authorized and processed

☒ No Refund Due

Fee Exempt or Fee Not Required

Comments: After Review

Log completed

Processed by: _____

110133

9610110218 960407
PDR ADOCK 03033396
C PDR

OFFICIAL RECORD COPY ML 10

APR 7 1994

The attached
is a Xerox
Copy of the ORC.

Docket No. 030-33396
Control No. 119069

The ORC was
given to David
Chawaga for
forwarding to
Commonwealth of
Massachusetts.

Dear Dr. Hu:

As requested in your letter dated April 6, 1994, we have voided your request for a radioactive materials license. The cadmium 109 source which you intend to utilize is not byproduct material as defined in 10 CFR 30.4 and is therefore not subject to licensing by the Nuclear Regulatory Commission. Therefore, you may procure and use it without an NRC license. However, you should contact the Commonwealth of Massachusetts regulatory authorities to determine the State licensing or registration requirements for use of this radionuclide.

Your cooperation with us is appreciated.

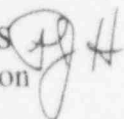
Sincerely,

Original Signed By:

Pamela J. Henderson
Nuclear Material Safety Branch
Division of Radiation Safety
and Safeguards

Enclosure:
10 CFR Part 30

cc:
N. K. Stablein, EDO
J. Glenn, NMSS
Commonwealth of Massachusetts

RI:DRSS 
Henderson

4/7/94

OFFICIAL RECORD COPY - C:\WP51\HU - 04/07/94

ML 10



HARVARD SCHOOL OF PUBLIC HEALTH

Department of Environmental Health
Occupational Health Program

030-33396

K7

April 6, 1994

Pam Henderson
Nuclear Regulatory Commission
FAX: (610) 337-5324

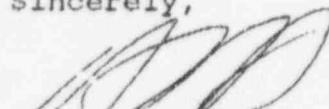
Re: Our application for an individual license for project at
Randolph High School (Mail Control Number 119069)

Dear Ms. Henderson,

I am writing to request that the application referenced above be terminated. As discussed with you, this is because the ¹⁰⁰Cadmium source we have is accelerator-produced (Amersham, Inc.), and thus is not under N.R.C. jurisdiction.

Thank you for your assistance in this matter.

Sincerely,



Howard Hu, M.D., M.P.H., Sc.D.
Associate Professor

030-33396

K7



HARVARD SCHOOL OF PUBLIC HEALTH

Department of Environmental Health
Occupational Health Program

April 6, 1994

Pam Henderson
Nuclear Regulatory Commission
FAX: (610) 337-5324

Re: Our application for an individual license for project at
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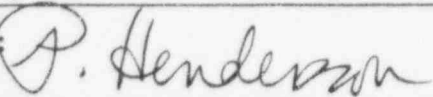
Sincerely,

Howard Hu, M.D., M.P.H., Sc.D.
Associate Professor

119069

APR - 6 1994

TOTAL P.02

TELEPHONE CONVERSATION RECORD		Date: 4/5/94	Time: AM
Mail Control No.: 119069		License No.: NA	Docket No.: 030-33396
Person Calling: Gus Savistano		Organization: Commonwealth of Massachusetts	Telephone Number: (617) 727-6214
Person Called: Pamela J. Henderson			
Subject: Howard Hu, M.D.			
Summary: <p>Mr. Savistano called to inquire about Dr. Hu's application for use of cadmium 109 sealed source in a device to measure bone lead density.</p> <p>We discussed the fact that this is a human use research protocol involving minors. I explained to Mr. Savistano that the NRC's major concern centered on institutional oversight of the use. I explained that the Brigham had some concerns about off site use of radioactive materials and was reluctant to add this location of use to their license.</p> <p>Mr. Savistano asked if the device was registered. I explained that I was not sure that it was a registered device. However, one of Dr. Hu's staff had mentioned to me that the device was a modified (they modified it) ABIOMED device and I recommended that he check into this.</p>			
Action Required/Taken: File telephone conversation record.			
Signature: 		Date: 4/5/94	



HARVARD SCHOOL OF PUBLIC HEALTH

Department of Environmental Health
Environmental Science and Engineering Program

030-33396

K7

March 22, 1994

Pamela Henderson
Nuclear Regulatory Commission Region I
Nuclear Materials Safety Section
475 Allendale St.
King of Prussia, PA 19406

Re: Mail Control Number 119069

Dear Ms. Henderson:

Included below is information you requested regarding the source model number and the equipment description for our bone lead scanning machine. I apologize for its delay.

The bone lead scanning machine (XRF3) operates using a 1.11 GBq ^{109}Cd source (model number CUCK5216) in a stainless steel capsule (model number X1017/1), both manufactured by Amersham (Chicago, IL). The product descriptions from Amersham are enclosed.

The equipment in which the source is used has been developed by Dr. Antonio Aro of our laboratory. The equipment is similar to a commercially available apparatus manufactured by ABIOMED, Inc. (Danvers, MA). We have improved upon this technology in order to measure lower bone lead concentrations.

The apparatus is configured as illustrated in Figure 1. The ^{109}Cd source (3-mm diameter) of activity 1.11 GBq in a X1017/1 capsule (Amersham, Chicago, IL) is housed in a tungsten alloy (Mi-Tech Metals, Indianapolis, IN) source holder with a 2-mm wall thickness; the diameter of the collimator is 2 mm. The ^{109}Cd source is positioned coaxial with and at the center of an intrinsic Ge detector with crystal dimensions 5 cm diameter and 2 cm thick (Canberra GL 2020R, Canberra Nuclear, Itasca, IL) with the use of an acrylic holder in a back-scattering geometry. The pre-amplifier (Canberra 2001) signal is passed to an amplifier (Canberra 2024), which was operated in Gaussian (unipolar) mode with a shaping time constant of 1 second. The amplifier output (analogue signal) is converted into a digital signal with a fast analog-to-digital converter (Canberra 8706). The digital signal is then passed to a PC-based multichannel analyzer (MCA) board (Canberra 4610I).

665 Huntington Avenue, Boston, Massachusetts 02115 Program Office (617) 432-1170 Fax (617) 432-3349

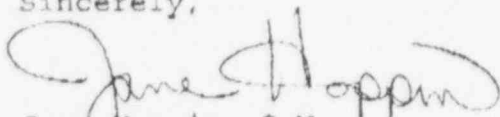
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119069
MAR 23 1994

There are several differences between XRF3 and the commercial systems; the most important differences are the dimensions and method of production of the ^{109}Cd sources. The commercial system (ABIOMED, Danvers, MA) uses an 11-mm-diameter, reactor-produced source (DuPont, Billerica, MA), whereas XRF3 uses a 3-mm-diameter, cyclotron-produced source (Amersham, Chicago, IL). The ^{109}Cd source strengths are approximately 1.1 GBq and 4.8 GBq for the XRF3 and the Abiomed system, respectively. Other differences include: the mean scattering angle ($\theta_{\text{XRF3}} = 157.4$ vs. $\theta_{\text{Abio}} = 150.5$, where θ is the mean scattering angle measured from the Compton peak), the peak extraction method, and specific hardware components.

Please let me know if you need any further information. We greatly appreciate your help so far with our license application.

Sincerely,



Jane Hopkin, S.M.
Coordinator, Community Lead Study

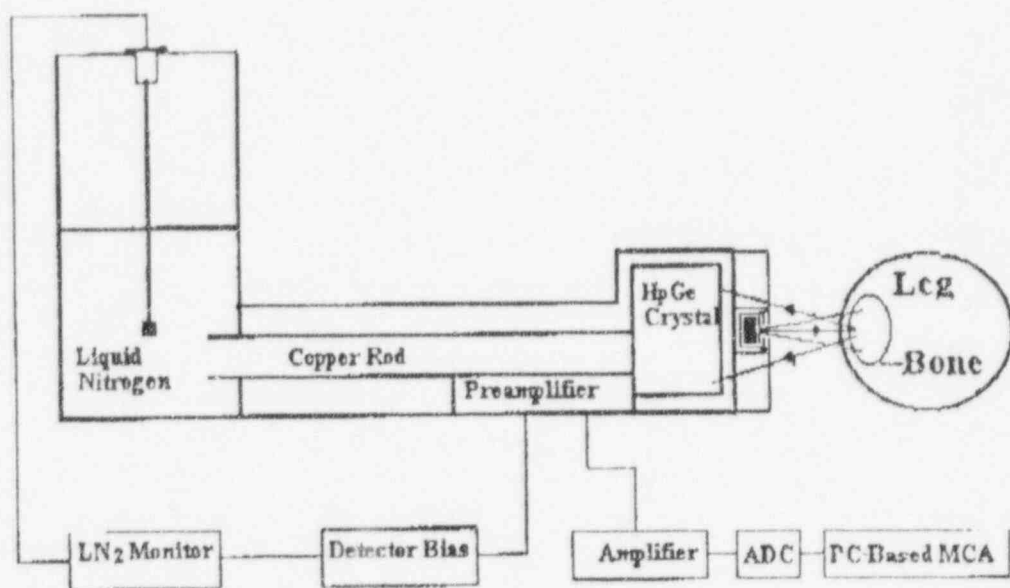


Figure 1

Amersham Corporation
O&S Products and Services
2635 South Clearbrook Drive
Arlington Heights, Illinois 60005
(708) 593-6300
(800) 323-6695

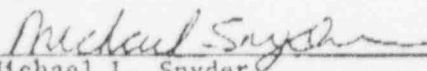
Quotation number: E-539-93
Quotation date: 05/27/93
Expiration date: 08/27/93

Dr. Antonio Aro
Harvard Medical School
Department of Medicine
180 Longwood Avenue
Boston MA 02115

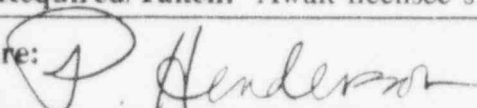
Phone: 617-432-2070 FAX: 617-731-1541

Senior Account Manager: Dan Mueller

Product	Description	Quantity	Unit Price
ISO 9001	THE SOURCES DESCRIBED BELOW WILL BE MANUFACTURED UNDER A QUALITY ASSURANCE SYSTEM (ISO 9001) WHICH IS EQUIVALENT TO ANSI/ASQC91. AMERSHAM'S QA SYSTEM IS INDEPENDENTLY AUDITED FOR COMPLIANCE BY LLOYD'S REGISTER OF QUALITY ASSURANCE.		
CUCK5216	Cadmium-109 Low Energy Gamma Source Cd-109 electroplated on a silver substrate in a welded stainless steel X.1017/1 capsule. Nominal activity 30mCi, +20%, -10% Emission determined by activity	01 2-4	\$6,670.00 6,200.00
Delivery: 10-12 weeks from receipt of order			
SHIPMENT SIZE		QUANTITY	
1		1	
2		2	


Michael L. Snyder
Associate Product Manager

Any purchase order placed against this quotation is subject to the Terms and Conditions on the next page.

TELEPHONE CONVERSATION RECORD		Date: 3/29/94	Time: 10:00 AM
Mail Control No.: 119069	License No.: new license	Docket No.: 030-33396	
Person Called: Brian Baker Regulatory Affairs	Organization: Amersham	Telephone Number: (708) 593-6300 X379	
Person Calling: Pamela J. Henderson			
Subject: Cadmium-109 Sealed Source			
Summary: Asked Amersham to clarify whether the applicant's sealed source (CUCK5126 X.1017/1 capsule) 30 mCi Cd-109 is accelerator produced or byproduct material. Mr. Baker stated that all current inventory of Cd-109 is accelerator produced material.			
Action Required/Taken: Await licensee's request to terminate license application.			
Signature: 		Date: 3/29/94	



HARVARD SCHOOL OF PUBLIC HEALTH

030-33396

K7

Department of Environmental Health
Environmental Science and Engineering Program

Parental Consent for Environmental Bone Lead Study

Purpose

We would like permission to enroll your child as a participant in a research study. The purpose of this study is to measure lead content in your child's leg bones to study the relationship between bone lead content and environmental lead exposure.

Procedure

We are asking you and your child to fill out a questionnaire (requiring 30 minutes; you may skip questions you do not wish to answer) regarding school, employment, housing history, and health; come to the study office at Randolph Junior Senior High School for a 1 hour visit during which time: 1) a questionnaire on your child's diet and other personal habits will be administered and 2) a special bone lead scanning examination will be performed on your child's legs.

Bone lead scanning uses a low energy gamma ray to measure any lead atoms which are present in bones. When a beam of rays hits the lead in a leg bone, the lead absorbs some of the rays, changes them slightly in a way that is characteristic of lead, and sends them back. The amount sent back tells us how much lead there is in the bone.

You or your child may contact Dr. Hu at (617) 432-2736, Dr. P. Barry Ryan at (617) 432-1167, or Ms. Jane Hoppin at (617) 432-1849 for answers to questions about the study. We will have a technician on the school campus available to answer any questions.

Risks and Discomforts

This research study involves exposure to radiation from the bone-scanner. However, the amount of radiation exposure your child will receive from this procedure is equivalent to 0.001% (or 7 minutes) of the amount of natural background radiation exposure the average person receives in the United States annually. The risk from radiation exposure of this magnitude is too small to be measured directly and is considered to be negligible when compared with everyday risks.

Benefits

There may be no direct benefits to you or your child as a result of these tests, although the analysis of these data will provide valuable information for public health and medical science. You will receive a copy of your individual diet and lead results with interpretation.

Standard Paragraphs

The following paragraphs contain standard information which, in the opinion of the Committee on the Use of Human Subjects in Research Committee of the Harvard School of Public Health generally applies to persons involved in a research study and are required on all consent forms.

Page 1 of 2

665 Huntington Avenue, Boston, Massachusetts 02115 Program Office (617) 432-1170 Fax (617) 432-3349

119069

(Parental Consent for Environmental Bone Lead Study, continued)

In the event that your child should be injured as a result of this study, he or she will be provided with the necessary care. This care does not imply negligence on the part of the Hospital or any of the physicians involved. Where applicable, the School of Public Health reserves the right to bill third-party payers for the services rendered. The Harvard School of Public Health does not provide you with any additional compensation as a result of such injuries.

In the event that any time during the course of this project you or your child feel you have not been adequately informed as to the risks, benefits, alternative procedures, or your rights as a research subject/parent of research subject, or feel under duress to continue against your wishes, the Committee Administrator of the Human Research Committee, or representative, is available to speak with you during normal working hours (8 a.m. - 4:30 p.m.) at 617-432-4513.

Confidential information contained in your child's medical record may not be furnished to anyone unaffiliated with the Harvard School of Public Health without your written consent, except as required by law or regulation.

A signed copy of this consent form will be made available to you.

You are free to withdraw your consent and to discontinue participation in this study at any time, and such discontinuance will not affect your child's regular treatments or medical care in any way.

I have fully explained the procedures, identifying those which are investigational, and have explained their purpose. I have asked whether or not any questions have arisen regarding the procedures and have answered these questions to the best of my ability.

Date

Responsible Investigator

I have been fully informed as to the procedures to be followed, including those which are investigational, and have been given a description of the attendant discomforts, risks and benefits to be expected and the appropriate alternate procedures. In signing this consent form, I agree to allow my child to participate in this project and I understand that I or my child are free to withdraw my consent and have this study discontinued at any time. I understand also that if I have any questions at any time, they will be answered.

Date

Parent of Research Subject

Date

Research Subject

RANDOLPH PUBLIC SCHOOLS

LYN A. HUTTUNEN, Ed.D
SUPERINTENDENT
(617) 961-6205

ARTHUR J. MELIA
ASSISTANT SUPERINTENDENT
(617) 961-6204
Fax. (617) 986-1812



030-33396 K7
RANDOLPH JR/SR HIGH SCHOOL

JAMES E. WATSON
HEADMASTER

ROBERT A. JOHNSON
HOUSEMASTER FOR BUSINESS & OPERATIONS

JOHN P. GIUGGIO
HOUSEMASTER
GRADES 7-9

GERARD J. LINEHAN
HOUSEMASTER
GRADES 10-12

February 25, 1994

Pamela Henderson
Nuclear Materials Safety Section
475 Allendale Street
King of Prussia PA 09406

Dear Ms. Henderson :

I am writing to express our continued interest in participating in the Community Lead Study being conducted by Dr. Howard Hu and Dr. P. Barry Ryan of the Harvard School of Public Health. We understand that the measurement of bone lead levels in our students will require the usage and storage of a K-x-ray fluorescence instrument with a 109 cadmium source in Randolph Junior/Senior High School.

As part of the study protocol, the bone lead scanner will be stored in a locked room on the school campus. Drs. Hu and Ryan and their staff, along with our management personnel, will have sole access to this room. In the event that after hours access to the school is necessary, study personnel will have access to school officials with the authority to deactivate the school's alarm system. Except in the case of emergency, no one will enter the room with the bone lead scanner without study personnel present.

We are eager for this study to go ahead and will be happy to address any further concerns of the Nuclear Regulatory Commission.

Sincerely,

Robert A. Johnson
Robert A. Johnson
Housemaster
Business & Operations

RAJ/jb

cc : Arthur J. Melia, Assistant Superintendent

HEADMASTER - (617) 961-6220

70 MEMORIAL PARKWAY; RANDOLPH, MA 02368

MAR - 7 1994

HOUSEMASTERS - (617) 961-6214

OFFICIAL RECORD COPY ML 10

FAX REC'D FEB 28 1994

Supplemental
Info to MS-15

119069

REPORT OF ACTION



BRIGHAM
AND
WOMEN'S
HOSPITAL

Human Research Committee

333 Longwood Avenue
Suite 650
Boston, Massachusetts 02115-5711
(617) 732-7200
FAX (617) 232-9216

Ruth E. Tuomala, M.D., Chairperson
Keith A. Marcotte, Executive Secretary
Mary B. d'Entremont, Coordinator

MS-16

K7

PRINCIPAL INVESTIGATOR: Howard Hu, M.D.

PROTOCOL NUMBER: 91-2316-06

PROTOCOL TITLE: Lead, Blood Pressure, Neurologic and Renal Function in Two Study Populations

This is to certify that the application identified above has been reviewed by the Committee appointed to review proposals involving clinical research and other investigations involving human beings, and has considered specifically:

- (1) the rights and welfare of the individual or individuals involved,
- (2) the appropriateness of the methods used to secure informed consent, and
- (3) the risks and potential medical benefits of the investigation.

The Human Research Committee has reviewed this research protocol and recommends approval. Please use only the enclosed authorized copies of the consent form(s), questionnaire(s), letters(s), advertisement(s), etc. in your research.

ANY MODIFICATIONS MADE TO THIS STUDY MUST BE REVIEWED AND APPROVED BY THE HUMAN RESEARCH COMMITTEE IN ADVANCE OF USE. REASONS FOR ASKING FOR THE USE OF MODIFIED PROCEDURES MUST BE INDIVIDUALLY AND SPECIFICALLY DOCUMENTED.

NOTE: Approvals are granted for the period of one year only and must be renewed annually. In addition, adverse reactions of any kind must be reported immediately in writing to the Committee, as they occur.

FOR THE HUMAN RESEARCH COMMITTEE

Ruth E. Tuomala, M.D.
CHAIRMAN

MAY 4, 1993
DATE OF COMMITTEE ACTION

Keith A. Marcotte
EXECUTIVE SECRETARY

MAY 16, 1994
EXPIRATION DATE

Im 5/6/93
ADMINISTRATOR DATE

ADMINISTRATIVE APPROVAL
REVIEW GROUP

AMENDED TO: ADD LETTER TO WATERTOWN HS STUDENT
PARENT

C R C



A Teaching Affiliate of Harvard Medical School

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FEB 23 1994

119069

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

Community Lead Study/Superfund #1

2. PRINCIPAL INVESTIGATOR, PROGRAM DIRECTOR, OR FELLOW

P. Barry Ryan, Howard Hu

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.

M1208 Assurance identification number 01 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 Subjects. This certification fulfills, when applicable, requirements for certifying FDA status for each investigational new drug or device. (See reverse side of this form.)

May 27, 1993

(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(h), 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
NAME, ADDRESS, AND TELEPHONE NO.Harvard School of Public Health
677 Huntington Avenue
Boston, MA 02115
(617) 432-4313

NAME AND TITLE OF OFFICIAL (print or type)

Troyen A. Brennan, MD, Chairperson
Human Subjects Committee

SIGNATURE OF OFFICIAL LISTED ABOVE (and date)

 6/1/93

COOPERATING INSTITUTION

NAME, ADDRESS, AND TELEPHONE NO.

NAME AND TITLE OF OFFICIAL (print or type)

SIGNATURE OF OFFICIAL LISTED ABOVE (and date)

INTER-INSTITUTIONAL APPLICATION FORM SHEET

Beth Israel Hospital
Brigham-Women's Hospital
Children's Hospital Medical Center
Dana Farber Cancer Institute

Harvard Medical School
Harvard School of Public Health
Massachusetts Eye & Ear Infirmary
Massachusetts General Hospital
New England Deaconess Hospital

In order to conform to DHHS and FDA regulations, and to provide data to the review board concerning the use of human subjects, applicants are requested to complete all of the following items. Please type or print.

I. GENERAL INFORMATION:

1. Project Title: Community Lead Study / Superfund #1
2. Principal Investigator(s) P. Barry Ryan, Howard Hu
3. PI's Institution Harvard School of Public Health
4. PI's Department/Service Environmental Health
5. Name of person(s) who will conduct study if different from the principal investigator. Indicate individual's status (fellow, student, house officer, etc.). If this varies between institutions, list the responsible individual at each study site:

<u>Name:</u>	<u>Study Site:</u>	<u>Status:</u>
<u>Jane Hoppin</u>	<u>HSPH</u>	<u>Doctoral Student</u>
<u>Marisa Barr</u>	<u>HSPH/BWH</u>	<u>Research Associate</u>
6. Approximate date study will begin: June 1, 1993
7. Estimate duration of entire study or project: 2 Years

II. ENDORSEMENT:

The undersigned accepts responsibility for assuming adherence to Harvard University and DHHS policies relative to the protection of the rights and welfare of patients/subjects used in this study.

[Signature]
Principal Investigator

13 May 93
Date

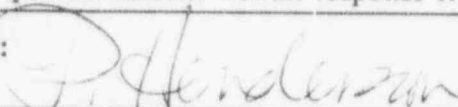
[Signature]
Department Head

13 May 93
Date

Conditions or Recommendations:

[Signature]
Chairman of Committee

6/1/93
Date

TELEPHONE CONVERSATION RECORD		Date: 2/22/94	Time:
Mail Control No.: 119069		License No.: New	Docket No.: 030-33396
Person Called: Jane Hoppin		Organization: Harvard School of Public Health	Telephone Number: (617) 432-1849
Person Calling: Pamela J. Henderson			
Subject: Institutional Oversight			
<p>Summary:</p> <p>Spoke with Frank Costello and by telephone with John Glenn regarding this license application. The license application requests that the licensee be a single individual (Dr. Hu) and involves human use research on minors. Dr. Glenn, Frank and I concur that institutional oversight of such a project is warranted.</p> <p>This study has been reviewed and approved by two separate IRBs - the Brigham and Women's and Harvard School of Public Health. The cover letter for the license application is on Brigham and Women's/Harvard Medical School letterhead where Dr. Hu is an Associate Physician and Assistant Professor of Medicine and Occupational Medicine.</p> <p>Attempted to reach Dr. Hu who will be out of town until March 7, 1994. Reached Jane Hoppin who is the Coordinator of the Community Trial Study & with this study (co-investigator??). She stated that they had approached Brigham and Women's about adding this study to their license. However, she stated that the Brigham did not want to take responsibility for an off-site project having had a negative experience in the past. I suggested that she speak with Frank Castronovo (Brigham's RSO) and discuss the NRC concerns regarding institutional oversight of this human use research project.</p>			
Action Required/Taken: Await response from applicant.			
Signature: 		Date: 3/1/94	



HARVARD SCHOOL OF PUBLIC HEALTH

030-33396

K7

Department of Environmental Health
Occupational Health Program

February 16, 1994

Pamela Henderson
U.S. Nuclear Regulatory Commission
FAX: (610) 337-5324

Re: Our application for an individual license for project at
Randolph High School (Mail Control Number 119069)

Dear Ms. Henderson,

I greatly appreciate your call to me yesterday.

As I had expressed to you, we are interested primarily in securing the license under our name (rather than Randolph High School), because we will probably change the locale of this study to another location over the next year (while preserving the exact same protocol).

We appreciate your concern that we secure total control of access to our facility (you mentioned previous situations in which a landlord would change the locks on a facility, disabling an RSO from servicing the facility). We have already obtained this commitment verbally from the school, and my colleague Professor Barry Ryan will fax to you as soon as possible a signed letter from the school administration detailing this commitment to giving us total access to the k-x-ray fluorescence facility.

Dr. Ryan will also fax to you our approval from the Harvard School of Public Health Human Subjects Committee, as well as our informed consent forms.

As I mentioned to you, there is a precedent for this type of project, and I am attaching to this fax a copy of the materials license obtained by the University of California to perform the same type of project in a town in Pennsylvania. They used a sealed source 109-cadmium k-x-ray fluorescence instrument like our own; in fact, ours has an even weaker source with less radiation exposure. I'm sorry for the poor quality of the fax (it is a fax of a fax); their license number, in case you can't read it, is 04-28672-01.

I hope you will appreciate the urgency we feel in obtaining this license. We have a whole research team ready to go, with full

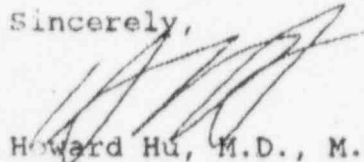
665 Huntington Avenue, Boston MA 02115 Tel: 617 432-1260 Fax: 617 432-0219

119069

support from the National Institutes of Health, pending your approval. Unfortunately, we sent in our application more than 2 months ago!

Once again, thanks for assisting us with this process. Please call myself or Professor Barry Ryan (617-432-1167) if there is ANYTHING we can do to clarify things or speed up the process. I will be out of the country Feb. 22-March 7.

Sincerely,



Howard Hu, M.D., M.P.H., Sc.D.

Assistant Professor of Occupational Medicine (HSPH)

Assistant Professor of Medicine (HMS)

Associate Physician (Brigham and Women's Hospital)

(617) 432-2736

FAX: (617) 432-0362

INTERNET: rehhu@gauss.med.harvard.edu

cc: Jane Hoppin
Marisa Barr

NRC FORM 274
(10-88)

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 3 PAGES

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee 1. University of California - San Francisco 50 Medical Center Way 2. Box No. 0942 San Francisco, California 94143-0942		3. License number 04-28672-01 4. Expiration date July 31, 1996 5. Docket or Reference No 030-32426
6. Byproduct, source, and/or special nuclear material A. Cadmium 109	7. Chemical and/or physical form A. Sealed Sources (duPont Model No. NER-4655)	8. Maximum amount that licensee may possess at any one time under this license A. 200 millicuries per source and 400 millicuries total
9. Authorized use A. For use in an ABOMED Body Lead Analyzer for medical research in humans.		

CONDITIONS

10. Licensed material may be used only at the licensee's facilities at Pavuk Professional Building, 200 Main Street, Blakely, Pennsylvania.
11. A. Licensed material shall be used by, or under the supervision of, Michael J. Kosnett, M.D., Charles E. Becker, M.D., or John Osterloh, M.D.
 B. The Radiation Safety Officer for this license is Mark L. Kohn.
12. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed 3 years.
 B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
 C. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
 D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

NRC Form 274A
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number	04-28672-01
Division or Reference Number	030-32426

(12. Continued)

CONDITIONS

E. Sealed sources and detector cells need not be leak tested if:

- (i) they contain only hydrogen 3; or
- (ii) they contain only a gas; or
- (iii) the half-life of the isotope is 30 days or less; or
- (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
- (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Results of leak test results shall be kept in units of microcuries and shall be retained for inspection by the Commission. If the test results show a leakage of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission. The source shall be removed from service and decontaminated, repaired, or replaced in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken.

G. The licensee is authorized to call for leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

- 13. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee.
- 14. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory.
- 15. The licensee may transport licensed material in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."
- 16. Replacement-exchange of the source/source-holder combination may be performed by the licensee in accordance with the instructions contained in the manufacturer's letter dated July 24, 1991.

A H Z O M E N ' s

NRC Form 274a
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number	04-28672-01
Device or Machine number	030-32426

(Continued)

CONDITIONS

17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated July 12, 1991.
 B. Letter dated July 18, 1991 with enclosures.
 C. Facsimile dated July 23, 1991 with enclosures.

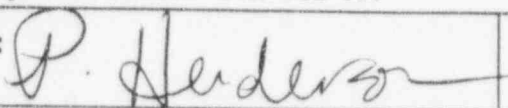


For the U.S. Nuclear Regulatory Commission

Date JUL 26 1991

By *[Signature]*
 Nuclear Regulatory Safety Branch
 Section 1

TOTAL P.05

TELEPHONE CONVERSATION RECORD		Date: 2/15/94	Time: 10:00AM
Mail Control No.: 119069		License No.: New	Docket No.: 030-33396
Person Called: Howard Hu, M.D.		Organization:	Telephone Number: (617) 432-2736
Person Calling: Pamela J. Henderson			
Subject: New License Application			
Summary: <p>Explained to licensee that the NRC wanted to issue the license in the name of the institution where the source would be used/stored. The reasoning being the institution had ultimate control over the security of the device and would be responsible for it.</p> <p>Dr. Hu stated that he would obtain a written statement from the facility which gave him complete and total access to the device at any time. In addition, he stated that he would be adding another location in the Fall.</p> <p>Also requested that he send a copy of the IRB approved consent form.</p>			
Action Required/Taken: File MS-15.			
Signature: 		Date: February 18, 1994	



BRIGHAM
AND
WOMEN'S
HOSPITAL



Harvard Medical School

Department of Medicine
Channing Laboratory

180 Longwood Avenue
Boston, Massachusetts 02115
Tel: (617) 432-2275
Fax: (617) 731-1541

December 3, 1993

John Kinnerman
Nuclear Regulatory Commission Region I
Nuclear Materials Safety Section
475 Allendale St.
King of Prussia, PA 19406

L&L 30109
030-33396
02201

Dear Mr. Kinnerman,

We are interested in applying for a license to use a sealed ^{109}Cd source in a K-X-ray Fluorescence (K-XRF) bone lead scanner to measure bone lead concentrations in teenagers at Randolph Junior/Senior High School in Randolph, MA. This project is scheduled to take place from February 1994 to September 1994.

In summary, a sealed ^{109}Cd source is an integral part of a K-X-ray fluorescence (K-XRF) instrument that is currently located in the Brigham and Women's Hospital. Use of this source is currently covered by the Brigham and Women's Hospital's site license (#20-17131-01). With this application we are applying for an individual license to operate the equipment at another location, and as part of this application, we will continue to utilize the Brigham and Women's Hospital's radiation safety program.

We would like to transport the instrument and source from the Brigham and Women's Hospital to Randolph, Massachusetts, where it will be used to measure bone lead concentrations in students at Randolph Junior/Senior High School in a study that has been funded by the National Institutes of Health. Students and their parents will be informed of the bone lead measurement procedure and potential radiation exposure. The Randolph School District is eager to participate in this investigation; a copy of their letter approving the use of the K-XRF instrument in the high school is attached.

Enclosed you will find two copies of the NRC license application, a detailed description of the steps we intend to take to ensure the safety of the project, and a check for \$1400 to cover the cost of license application.

If you have any questions about this application, do not hesitate to contact me at (617) 432-2736; FAX: (617) 432-0362.

Sincerely,

Howard Hu, M.D., M.P.H., Sc.D.
Associate Physician

Assistant Professor of Medicine and Occupational Medicine

Enclosures

License Fee Information

on Appl. dtd 12/3/93

119063

OFFICIAL RECORD COPY ML 10

DEC 06 1993

Rec'd
L&L
12/13/93



BRIGHAM
AND
WOMEN'S
HOSPITAL



Harvard Medical School

Frank P. Castronovo, Jr., Ph.D.
Director, Department of Health Physics
and Radiopharmacology
Radiation Safety Officer

Brigham and Women's Hospital

71 Francis Street
Boston, Massachusetts 02115
Tel: 617-355-1177
Fax: 617-355-9374



MEMORANDUM



TO: Howard Hu, M.D.
Channing Laboratory
Brigham and Women's Hospital

FROM: Frank P. Castronovo, Ph.D. *FPC*
Director, Department of Health Physics & Radiopharmacology
Brigham and Women's Hospital

DATE: December 3, 1993

SUBJECT: **NRC LICENSE APPLICATION**

This letter is in support of your effort to apply for your own Cd-109 human use license with the Nuclear Regulatory Commission. Our records indicate that you have been issued 4 human use permits by the Radiation Safety Committee for the human diagnosis of skeletal concentrations of lead when using the Cd-109 sealed source since 1989. The record also shows no areas of noncompliance relative to radiation safety. Your laboratory has an outstanding record in this regard and I'm confident that a similar situation will exist under your own license.

cc: Permit File
Radiation Safety Committee Docket

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST 3.25 HOURS. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNB 7714) U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120) OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT. SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA. SEND APPLICATIONS TO:

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2500
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN. SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING. SEND APPLICATIONS TO:

MATERIAL RADIATION PROTECTION SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC. SEND APPLICATIONS TO:

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

LAL 30109
030-38396
02201

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item):

- ☒ A. NEW LICENSE
☐ B. AMENDMENT TO LICENSE NUMBER _____
☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Includes Zip Code):

Howard Hu, MD, MPH, ScD
Assistant Professor of Medicine
Channing Laboratory/Brigham & Women's
180 Longwood Ave., Boston, MA 02115

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED:

Randolph Junior/Senior High School
70 Memorial Parkway Room 128
Randolph, MA 02368

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION:

Howard Hu, MD

TELEPHONE NUMBER:

617 432-2736

SUBMIT ITEMS 1 THROUGH 11 ON 8 1/2 x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL:

a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED:

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE:

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS:

9. FACILITIES AND EQUIPMENT:

10. RADIATION SAFETY PROGRAM:

11. WASTE MANAGEMENT:

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31):

FEE CATEGORY:

AMOUNT ENCLOSED \$1,400.

13. CERTIFICATION (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE - CERTIFYING OFFICER:

TYPED PRINTED NAME:

Howard Hu, MD

TITLE:

Assistant Professor
of Medicine

DATE:

12/3/93

FOR NRC USE ONLY

TYPE OF FEE:

APP

FEE LOG:

Dec 8

FEE CATEGORY:

K

COMMENTS:

\$ 8300.00 Refunded
Reaction, Harvard University
(sent to Brigham & Women's Univ.)

AMOUNT RECEIVED:

\$1400

CHECK NUMBER:

608549

APPROVED BY:

B

DATE:

12/20/93

NRC License Application Additional Information
Applicant: Dr. Howard Hu

5. Radioactive Material

The radioactive material is a ^{109}Cd sealed source (3 mm diameter) of activity 1.11 GBq in a X1017/1 stainless steel capsule (Amersham, USA) housed in a 2 mm thick wall of tungsten. A maximum of two sources will be possessed at any one time; this will allow for measurement of two bone sites simultaneously.

6. Purpose for which licensed material is to be used.

The bone lead analyzer will be used to measure tibial and patellar lead concentrations in adolescents and young adults at Randolph Junior/Senior High School. Bone lead measurement is estimated to take one hour at each bone site.

The effective dose to the subject during an in vivo KXRF measurement is very low and can be compared to natural background radiation. In the U.S., the average effective dose rate for such exposures is around 3 mSv per year. A recent paper reported by Todd et al. (1992), describes in detail the radiation dosimetry studies involving similar KXRF instruments. The calculations of the effective doses were performed using the new ICRP recommendations (ICRP 21) and are summarized in Table 1. According to these results, the effective dose from a single KXRF measurement of tibia is 0.2% and 0.1% of the average effective dose from a dental and chest X-ray, respectively. This is also equivalent to approximately 10 minutes of natural background radiation (Todd et al., 1992). It should be emphasized that the effective doses reported in Table 1 were obtained by using a 2.2 GBq ^{109}Cd annular source, which is about twice the strength of the point source used in our machine (1.11 GBq). Therefore, the combination of reduced activity and source area leads to a significant reduction in the effective dose from our instrument.

NRC License Application Additional Information
Applicant: Dr. Howard Hu

TABLE 1

Effective Dose for Tibia Lead Measurement
(based on a 2.2 GBq ^{109}Cd annular source)

Age	^{109}Cd KXRF (μSv)
1	1.10
5	0.42
10	0.19
Adult	0.04

Source: Todd AC, McNeill FE, Palethorpe JE, Peach DE, Chettle DR, Tobin MJ, Strosko SJ, and Rosen JC. In Vivo X-Ray Fluorescence of Lead in Bone Using K X-Ray Excitation with ^{109}Cd Sources: Radiation Dosimetry Studies. Environmental Research. 57: 117-132. 1992.

7. Individuals Responsible for Radiation Safety Program

Howard Hu, M.D. and Antonio Aro, Ph.D., will serve as radiation safety officers. Michael Oh, Arif Shahabuddin, Ronda Appelbaum, and Jane Hoppin will serve as equipment operators. Appendix A contains copies of the radiation safety officers' resumes.

All safety officers and operators have participated in the Brigham and Women's Hospital's (BWH) Basic Radiation Safety Training Course, are BWH radiation badge holders, and have been trained on equipment operation by the instrument developers.

Brigham and Women's Hospital is itself licensed to possess these ^{109}Cd sources. As a permit holder in the Brigham and Women's Hospital, Dr. Hu has been working with ^{109}Cd in vivo K-XRF instruments for the past 5 years.

NRC License Application Additional Information
Applicant: Dr. Howard Hu

8. Training for Individuals Working in or Frequenting Restricted Areas.

Dr. Hu is a physician who is board certified in internal medicine and occupational medicine. During his occupational medicine training, he had a full semester course in Radiation Biology as well as a full semester courses in Industrial Hygiene and Introduction to Occupational Medicine which covered radiation safety topics. He is a radiation permit holder registered in the Brigham and Women's Hospital.

Dr. Aro is a health physicist with a Ph.D. from the University of Birmingham, U.K. Trained in all aspects of radiation safety, Dr. Aro is the chief designer and supervisor of all of our technical work using ^{109}Cd in vivo K-XRF instruments.

All operators have received basic radiation safety training from the Brigham and Women's Hospital. There are no restricted areas.

9. Facilities and Equipment

During the course of the investigation, the equipment will be housed in Room 128 of the Randolph Junior/Senior High School on Memorial Highway in Randolph, Massachusetts. Room 128 is 12.5' by 30' and has two doors of heavy construction. The room will be equipped with a key pad lock on the front door and a key lock on the side door. The side door will be locked from the inside of the bone lead measurement room. The room is located across the hall from the administration office of the high school. The room will remain locked at all times with only XRF operators and school management officials having access to the room. Signs will be placed on both doors with the names and phone numbers of Drs. Hu and Aro for contacting in case of emergency. Figure 1 shows a map of the high school with all doors marked; Figure 2 is a sketch drawing of the bone lead measurement facility.

School management officials are aware of the project and have approved of our activities. Appendix B is a copy of the approval letter from the Randolph Public Schools.

Transport of any ^{109}Cd source to and from Randolph High School will be conducted through Federal Express, which is licensed to perform transfer of radioactive material of this nature. Both the release and acceptance of any ^{109}Cd source will take

NRC License Application Additional Information
Applicant: Dr. Howard Hu

place person-to-person only (between Federal Express and one of our radiation safety officers). Appendix C describes our chain of custody procedures for transport of radioactive sources.

The ^{109}Cd source will be used in the K-XRF bone lead analyzer diagrammed in Figure 3. The sealed source is positioned at the center of a HpGe detector (5 cm diameter, 2 cm thick crystal, Canberra model GL 2020R) with the use of an acrylic holder in a back scattering geometry. The analyzer is equipped with a mechanical shutter to prevent inadvertent radiation exposure.

The system is equipped with a liquid nitrogen (LN_2) monitor (Canberra, model 1786). It automatically shuts off the detector power supply (HV = - 1500 Volts, Canberra model 3106D) when the LN_2 level drops below the sensor (thermocouple). The pre-amplifier (Canberra model 2001) is located inside the detector case, to reduce noise problems. The pre-amplified signal is fed into a Fast Spectroscopy Amplifier (Canberra model 2024); it is operated in a Gaussian (unipolar) mode with a gain of 100×0.46 and 1 microsecond shaping time. The analog output is converted into digital signal through the use of a Fast ADC (Canberra model 8706) at a gain of 2k and 1k offset. This digital output is analyzed by a PC based MCA (Multi Channel Analyzer) board.

10. Radiation Safety Program

We will continue to participate in the Brigham and Women's Hospital (BWH) Radiation Safety Program for monitoring equipment calibration and personnel monitoring.

A survey for radiation leakage will be conducted weekly using both a sodium iodide crystal (Ludlum Instruments, Inc., Sweetwater, TX, Model 44-3, Serial Number 096318) with survey meter (Ludlum Model 3) and a Geiger Counter (Bicron Surveyor 200). These instruments are calibrated by the Brigham and Women's Radiation Safety Program on a regular basis. If levels greater than background are detected, the XRF room will be evacuated and locked, and the radiation safety officer will be notified. The radiation safety officer will conduct an investigation of the perimeter and interior of the room, and notify the NRC if significant contamination is suspected.

NRC License Application Additional Information
Applicant: Dr. Howard Hu

All operators will be provided with a TLD badge each month. Badges will be worn while working in the bone lead measurement room. All badges will be processed by the BWH Radiation Safety Program.

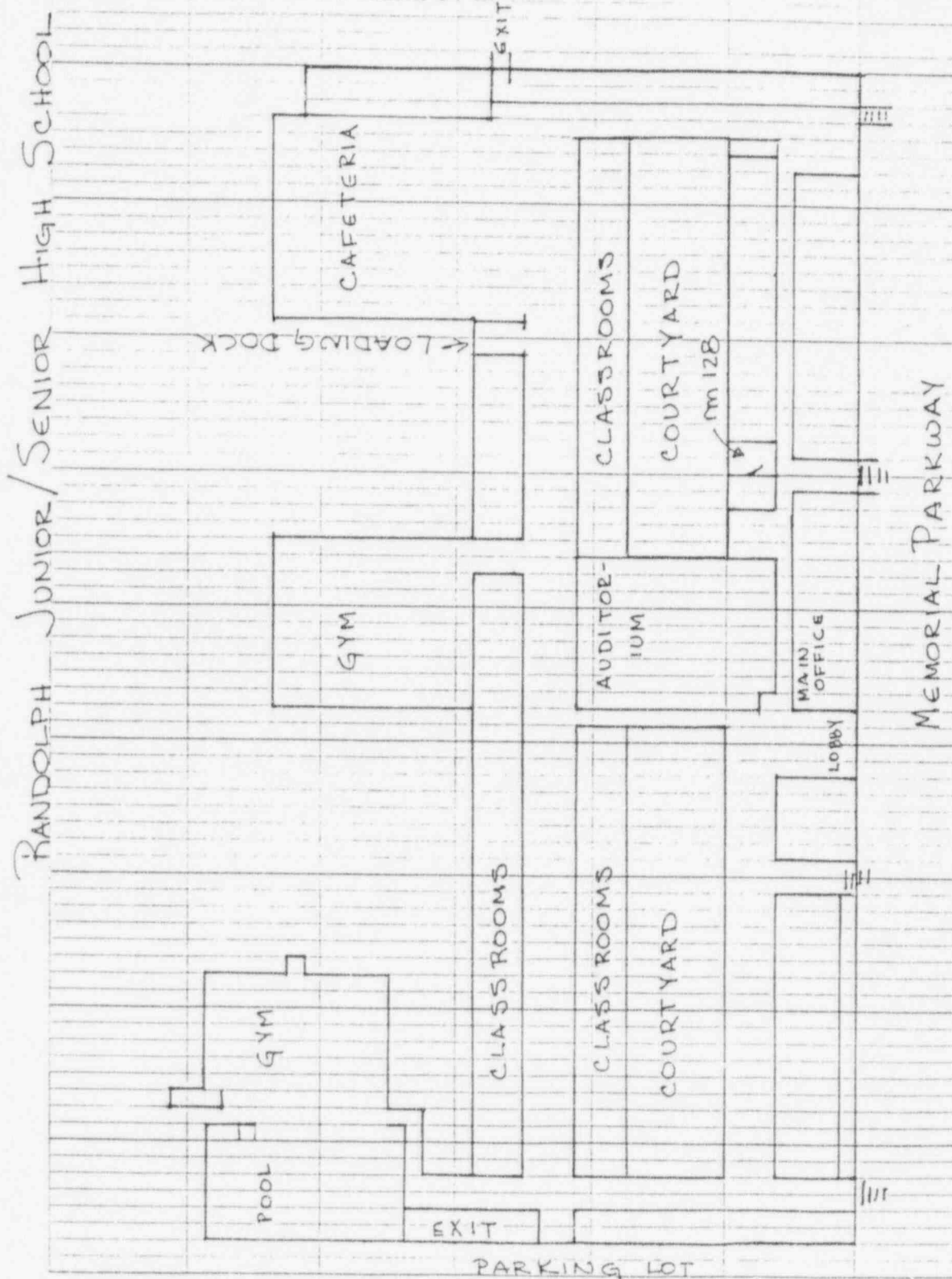
11. Waste Management

Since we are only working with sealed sources, there is no radiation waste per se. Once a sealed source has outlived its usefulness, the source will be delivered back to the source's manufacturer (Amersham, USA) for re-processing. Isotope delivery will be accomplished using established procedures for the transport of radioactive material (Federal Express).

NRC License Application Additional Information
Applicant: Dr. Howard Hu

FIGURES

FIGURE 1



NRC License Application Additional Information
Applicant: Dr. Howard Hu

LAYOUT FOR THE BONE LEAD
DETECTOR AT RANDOLPH HIGH SCHOOL

LEGEND

- 1 - K-XRF INSTRUMENT
- 2 - LEAD FREE CHAIR
- 3 - COMPUTER AND VIDEO MONITOR
- 4 - KEYBOARD
- 5 - PRINTER
- 6 - PORTABLE BIN (ELECTRONICS)
- 7 - CHAIR
- 8 - SINK
- 9 - WAITING ROOM
- 10 - DOOR WITH COMBINATION LOCK
- 11 - DOOR FOR EMERGENCY EXIT ONLY

SCALE: 1:36

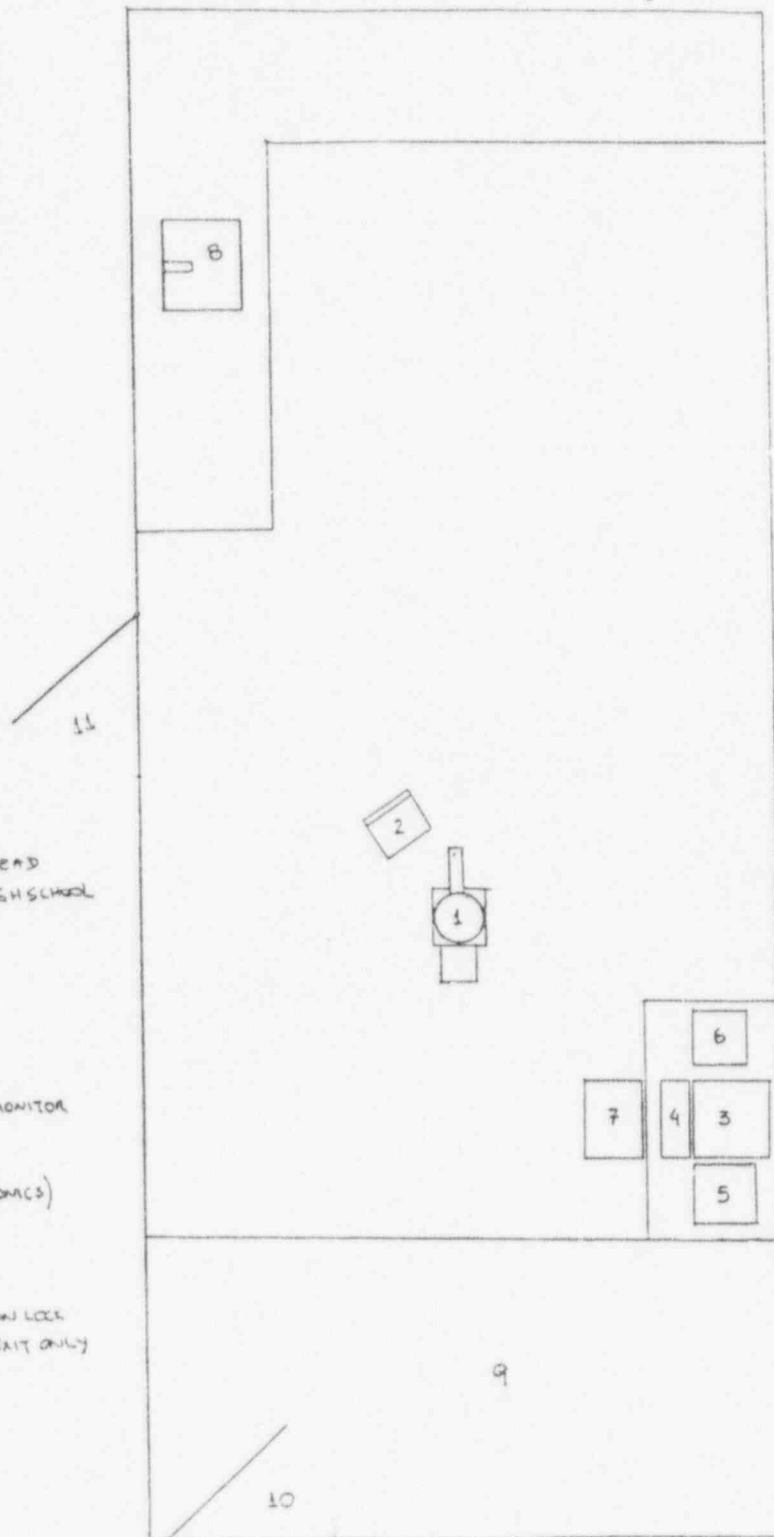
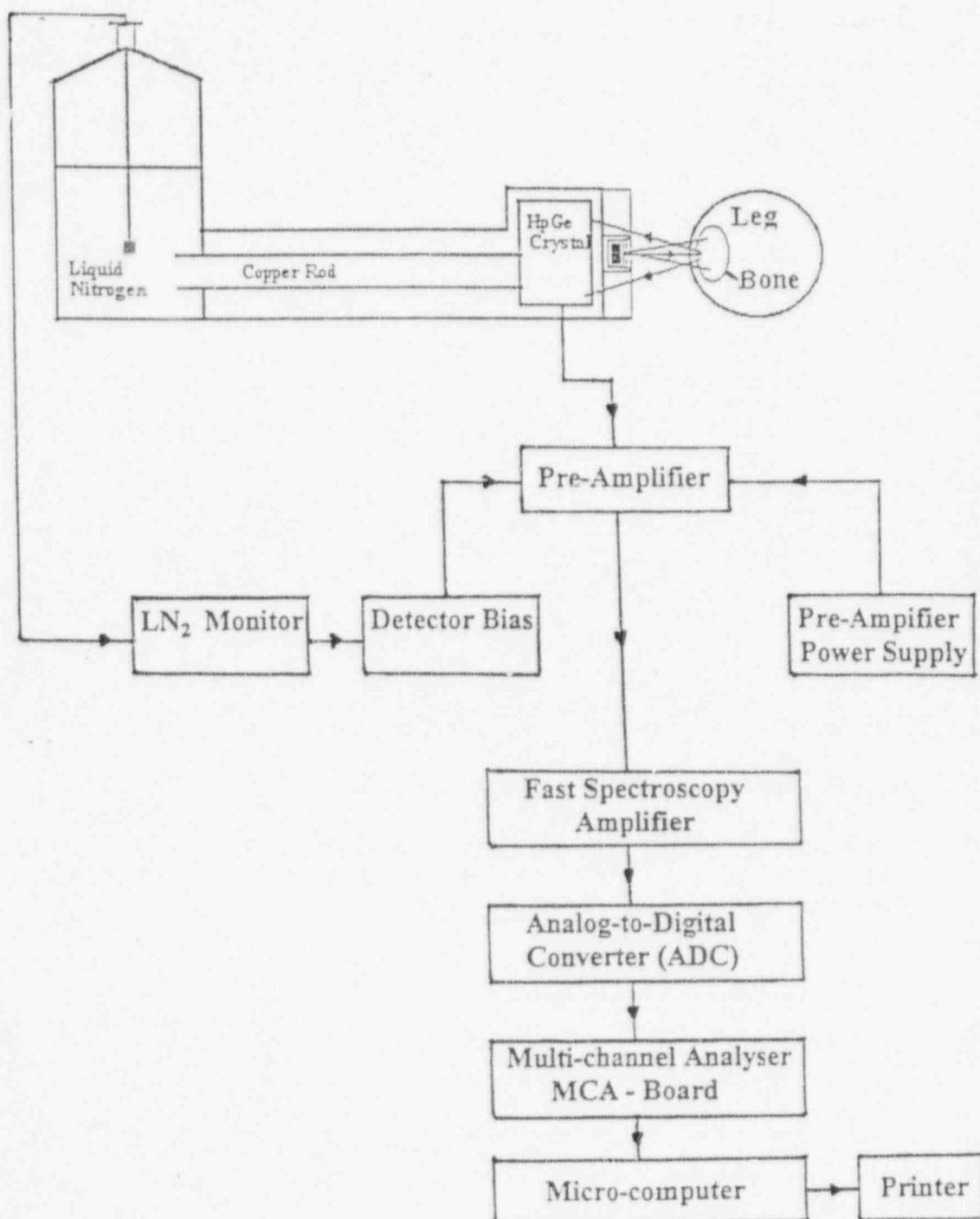


FIGURE 3



NRC License Application Additional Information
Applicant: Dr. Howard Hu

APPENDIX A

Participation Letter From the Randolph Public Schools

RANDOLPH PUBLIC SCHOOLS

LYN A. HUTTUNEN, Ed.D
SUPERINTENDENT
(617) 961-6205

ARTHUR J. MELIA
ADMINISTRATIVE ASSISTANT
TO THE SUPERINTENDENT
(617) 961-6204



TOWN OF RANDOLPH
INC 1793

OFFICE OF THE SUPERINTENDENT
ADMINISTRATIVE OFFICES
40 HIGHLAND AVENUE
RANDOLPH, MA 02368
(617) 961-6200
FAX (617) 986-1812

November 10, 1993

Mr. John Kinnerman
Nuclear Materials Safety Section
475 Allendale Street
King of Prussia, PA 19406

Dear Mr. Kinnerman:

I am writing to express the willingness of our school system to cooperate with Dr. Howard Hu of the Brigham and Women's Hospital and Harvard School of Public Health, Boston, in a project in which a K-x-ray fluorescence instrument with a 109 cadmium source will be used to measure bone lead levels of high school students on-site in our junior-senior high school beginning on February 8, 1994 (with set-up and testing of the instrument on February 1, 1994).

The instrument will be situated for the duration of the study in room 128 in the junior-senior high school. This room will be kept locked at all times, with the key held only by Dr. Hu, his staff, and our management staff.

I understand that Dr. Hu will serve as the Radiation Safety Officer for the project, and that all activity associated with the instrument will comply with Nuclear Regulatory Commission (NRC) guidelines and rules. I also understand from Dr. Hu that the radiation exposure to test subjects is minimal, and that there will be no radiation exposure from the instrument outside of the room.

Please let me know if you need further information regarding our facility.

Sincerely,

A handwritten signature in cursive script, appearing to read "Lyn A. Huttunen".

Lyn A. Huttunen
Superintendent of Schools

NRC License Application Additional Information
Applicant: Dr. Howard Hu

APPENDIX B

Resumes from Radiation Safety Officers

BIOGRAPHICAL SKETCH

Give the following information for the key personnel and consultants and collaborators. Begin with the principal investigator/program director. Photocopy this page for each person.

NAME	POSITION TITLE
Howard Hu (154-46-7827)	Assistant Professor of Occupational Medicine Assistant Professor of Medicine

EDUCATION (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training)

INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY
Brown University, Providence RI	Sc.B.	1976	Biology
Albert Einstein Coll. Medicine, Bronx NY	M.D.	1982	
Harvard School of Public Health, Boston MA	M.P.H.	1982	Occupational Health
Harvard School of Public Health, Boston MA	Sc.D.	1990	Epidemiology

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Key personnel include the principal investigator and any other individuals who participate in the scientific development or execution of the project. Key personnel typically will include all individuals with doctoral or other professional degrees, but in some projects will include individuals at the masters or baccalaureate level provided they contribute in a substantive way to the scientific development or execution of the project. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. DO NOT EXCEED TWO PAGES.

- 1979-1980 National Institute for Occupational Safety and Health Training Award
- 1982-1985 Intern, Junior Assistant Resident, Senior Assistant Resident in Medicine: Boston City Hospital, Boston, MA
- 1985 Diplomate, American Board of Internal Medicine
- 1985-1988 National Institute for Environmental Health Sciences National Research Service Award (PI: Dr. Richard Monson), Dept. Epidemiology, Harvard School of Public Health
- 1985-1987 Resident in Occupational Medicine, Harvard School of Public Health, Occupational Health Program
- 1987 Diplomate, American Board of Preventive Medicine (Occupational Medicine Specialty)
- 1988-1992 Instructor in Medicine, Harvard Medical School
- 1988- Associate Physician and Asst. Director, Occupational/Environmental Medicine Center, Brigham and Women's Hospital, Boston, MA
- 1990- Assistant Professor of Occupational Medicine, Harvard School of Public Health
- 1990-1992 Fellow, Agency for Toxic Substances and Disease Registry Clinical Environmental Medicine Program
- 1992- Assistant Professor of Medicine, Harvard Medical School

Selected Publications

- Hu H. Occupational health: on the job training for medical students. The New Physician, May 1979
- Frumkin H, Hu H. (editors) Occupational and Environmental Health: A Resource Guide for Health Science Students (National Institute of Occupational Safety and Health), Publication # 90-118 March 1980
- Hu H, Markowitz SB. A case-study of industrial bladder cancer. Einstein Quarterly Review of Biology and Medicine 1982;1:29-35.
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- Hu H, Milder F, Burger DE. The Use of K-X-Ray Fluorescence for measuring lead burden in epidemiological studies: high and low lead burdens, and measurement uncertainty. *Environ Health Persp* 1991;94:107-110.
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- Korman P, Hu H, Planatamura D. Lead Abatement Manual: A Union Training Course for Workers and Supervisors. Commonwealth of Massachusetts, Department of Industrial Accidents. 1991.
- Hu H, Christiani D. Reactive airways dysfunction syndrome following exposure to tear gas. *Lancet* 1992;339:1535.
- Hu H, Weiss ST, Sparrow D. Serum albumin is associated with systolic and diastolic blood pressure. *Am J Epi* 1992;136:1465-1473.
- White R, Diamond R, Proctor S, Morey C, Hu H. Residual cognitive deficits 50 years after childhood plumbism. *Br J Industr Med* 1993;50:613-622.
- Hu H, Beckett L, Kelsey K, Christiani D. The left-sided predominance of asbestos-related pleural disease. *Am Rev Resp Dis* 148:981-984.
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- Payton M, Hu H, Sparrow D, Young JB, Landsberg L, Weiss ST. The relationship between blood lead and urinary biogenic amines in community-exposed men. *Am J Epidem* (in press).
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- Guo H-R, Chen C-J, Chiang H-S, Hu H, Lipsitz SR, Monson RR. Arsenic in drinking water and urinary cancers: a preliminary report. *J Geochem and Health* (in press).

Howard Hu, M.D., M.P.H., Sc.D.

12/1/93

Specialized Training in Radiation Protection

1979-1980 Master in Public Health (specialization in Occupational Medicine)

1 semester course in Radiation Biology

Other: 1 semester courses with at least one 2-hour lecture related to Radiation Protection in each course

Principles of Environmental Health
Introduction to Occupational Medicine
Basic Problems in Occupational Health
Fundamentals of Industrial Hygiene

CURRICULUM VITAE

Date Prepared: 10/93

NAME: ANTONIO CARLOS ALVES DE ARO
ADDRESS: 6 Shepherd Avenue Apt. 1F, Boston, MA 02115
PLACE OF BIRTH: Bauru, Brazil

EDUCATION:

1981	BA	University of Rio de Janeiro Estate
1982	BS	Associacao Educ. Veiga Almeida
1984	MSc	Federal University of Rio do Janeiro (Nuclear Engineering)
1991	PhD	University of Birmingham (Medical Physics)

ACADEMIC APPOINTMENTS:

1992- Research Associate, Harvard Medical School, Boston, Massachusetts

OTHER PROFESSIONAL POSITIONS:

1984-1987 Nuclear Engineer, Nuclear Energy Institute, Brazil

MAJOR RESEARCH INTERESTS:

1. Microdosimetry
2. Radiation Protection
3. Neutron activation analysis "in vivo"
4. K-XRF Technique

SELF REPORT OF TEACHING:

1. Local Contributions

a. Catholic University of Petropolis

1985-1987 Fluid Mechanics for Electrical and Mechanical Engineering Course
Lecturer
50 Engineering Students
4 hours/week Lecture, 6 hours/week preparation

BIBLIOGRAPHY:

Original Reports

1. Green S, Aro ACA, Taylor GC and Scott MC. The development of microdosimetric detectors for investigating LET distributions in different body tissues. *Radiat Prot Dos*; 1990; 31 No 1/4: 137-141.
2. Aro ACA, Green S, Koohi-Fayegh R, Scott MC, Shahid T, Taylor GC. Measurement and prediction of real tissue microdosimetric responses for neutrons up to 62 MeV. *Radiat Prot Dos* 1992;4:77-83.
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4. Hu H, Aro ACA, Rotnitzky A. Bone Lead measured by x-ray fluorescence: Epidemiological methods. *Environ Health Perspect Suppl* (In press).
5. Aro ACA, Todd AC, Amarasiriwardena C, Hu H. Improvements in calibrating Cd-109 KXRF systems for measuring bone lead *in vivo* (In preparation).
6. Aro ACA, Amarasiriwardena C, Chettle DR, Gordon CL, Hu H, McNeill FE, Todd AC. Preliminary intercomparisons of K-XRF instruments used to measure bone lead *in vivo* (In preparation).

Abstracts

1. Aro ACA, Bonnet D, Cosgrove V, Green S, Kacperek A, Scott MC and Taylor GC. Microdosimetric measurements on the Clatterbridge proton therapy beam. *Proceedings of the 2nd European Particle Accelerator Conference 1990*, 1: 271-273.
2. Scott MC, Aro ACA, Green S, Taylor GC. Elemental synthesis of real tissue microdosimetric responses to high energy neutrons: principles and limitations. *Proceedings of the 2nd European Particle Accelerator Conference 1990*, 2: 1799-1801.
3. Aro ACA, Green S, Scott MC, Taylor GC. Design studies for a real tissue neutron microdosimetric counter. *Seventh Symposium on Neutron Dosimetry, Berlin 1991*.
4. Schrewe UJ, Aro ACA, Brede HJ, Dangendorf V, DeLuca PM, Gerdung S, Lim T, Newhauser W, Nolte R, Schmelzbach P, Schuhmacher H, Scott MC. Ionisation yield spectra in nitrogen and oxygen for neutron energies of 17 MeV, 45 MeV and 66 MeV. *Eleventh Symposium of Microdosimetry, USA 1992 (Sept.)*
5. Aro ACA. Aplicacao de tecnicas microdosimetricas relacionadas a terapia do cancer com protons de altas energias. *Proceedings of the I Forum Nacional de Ciencia e Tecnologia em Saude, Caxambu, Brazil 1992 (Nov.)*;1:626-629.

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7. Amarasiriwardena C, Hu H, Aro ACA, Barnes RM. Calibration standards used for in vivo k-x-ray fluorescence bone lead measurements: verification of lead concentration using isotope dilution inductively coupled plasma mass spectrometry. 39th Canadian Spectroscopy Conference, Quebec, Canada 1993 (August).

NRC License Application Additional Information
Applicant: Dr. Howard Hu

APPENDIX C

Superfund Project 1: Teenage Bone Lead Study
Chain of Custody and Security for ^{109}Cd Source

- (1) The ^{109}Cd source that will be used for this research was manufactured by Amersham, USA, and is currently located in our K-X-ray fluorescence (K-XRF) instrument in Room 133 of the Richardson-Fuller Building of Channing Laboratories, 221 Longwood Avenue, Boston, MA under broad license # 20-17131-01. Its current source strength is 30 mCi. The K-XRF instrument was manufactured by Dr. Antonio Aro, our chief physicist. Dr. Howard Hu is the Director of all research utilizing the K-XRF instruments. He is a Brigham and Women's Hospital radiation permit holder (#801). Room 133 is a locked instrument facility dedicated solely to utilization of the K-XRF instrument.

The ^{109}Cd source is approximately 3 mm x 3 mm in dimension. It is surrounded on 5 of its 6 sides by tungsten shielding. The collimator is made of tungsten, as is the shutter.

- (2) On the day of shipping, the ^{109}Cd source will be removed from the instrument by Drs. Hu and Aro and placed in a shielded container and then into a type A shipping container. All appropriate labelling and paperwork will have been prepared. Removal of the source will involve: a survey with the radiation meter; closing the shutter; inserting a tungsten slug into the collimator; unscrewing the back of the collimator and then removing the source.
- (3) A representative of Federal Express, Inc. will come to room 133, and the ^{109}Cd source will be given to her/him by Drs. Hu and Aro. Federal Express is licensed to perform transportation of radioactive materials.
- (4) The following day, Drs. Hu and Aro will receive the ^{109}Cd source from Federal Express in the reception area of Randolph Junior/Senior High School (See Figure 1). The source will be transported to room 128 and inserted in the K-XRF instrument.
- (5) The K-XRF instrument will be located in a secure room with a combination lock entry. Only Drs. Hu and Aro, members of the research team, and the high school vice principal and custodian will have access to the room.

NRC License Application Additional Information
Applicant: Dr. Howard Hu

- (6) The K-XRF instrument will be operated by Dr. Aro, Michael Oh, Arif Shahabuddin, Ronda Appelbaum, and Jane Hoppin. Mr. Oh, Mr. Shahabuddin, and Ms. Appelbaum are full-time research assistants of Dr. Hu, employed by the Brigham and Women's Hospital, and are certified badge-holders through the BWH Radiation Safety Office. Ms. Hoppin is a doctoral student at the Harvard School of Public Health and coordinator of the Randolph study; she is also a BWH badge-holder. Dr. Aro will be the radiation physicist for the duration of the project.
- (7) Setup and testing of the K-XRF instrument will take place on the afternoon of receipt of the ^{109}Cd source. A wipe test will be conducted on the ^{109}Cd source at that time. Measurements will be taken with a radiation meter beginning the following day. At the beginning and end of each day, measurements will be taken from a distance of 1 cm and 1 m from the collimator containing the ^{109}Cd source to ensure that there is no scatter radiation or leakage. When unused and unoccupied, the K-XRF facility will be locked.
- (8) At the close of the project, expected to occur by September 1994, the K-XRF instrument will be disassembled. The ^{109}Cd source will be packaged by Drs. Hu and Aro.
- (9) In the afternoon of closure, the packaged ^{109}Cd source will be given to a Federal Express representative for shipping back to the Richardson-Fuller Building.
- (10) Drs. Hu and Aro will receive the ^{109}Cd source from Federal Express in Room 133 of the Richardson-Fuller Building. The source will be directly inserted in the K-XRF instrument. A wipe test and measurements will be conducted. Operation using the instrument for other studies will then resume.

DIVISION OF ACCOUNTING AND FINANCE
REQUEST FOR REFUND TO EMPLOYEE/VENDOR

DEC 21 1993

THE EMPLOYEE/VENDOR IDENTIFIED BELOW HAS OVERPAID THE NUCLEAR
REGULATORY COMMISSION FOR GOODS OR SERVICES PROVIDED AND IS DUE A
REFUND.

EMPLOYEE/VENDOR/PAYEE CODE: * _____

NAME: Brigham and Women's Hospital

ADDRESS: ATTN: Chris Brown

ADDRESS: 180 Longwood Avenue

CITY: Boston STATE: MA ZIP: 02115

TRANS CODE: PX TRANS TYPE: _____ FUND: _____

JOB CODE: _____ (FOR FE TRANS TYPE) REFUND AMOUNT: \$300.00

COMMENTS: Randolph HS Lic App Overpymt CK608549

(limit comments to 40 characters, including spaces)

PREPARED BY: B - DATE: 12/20/93

AUTHORIZED BY: Landra Kimberley TITLE: Lic Fee Analyst

OFFICE: OC/DAF/RTKRB DATE: 12/20/93

ORIGINAL
INVOICE #: _____ DATE PAID: _____ AMOUNT: \$ _____

REFUND ENTERED INTO COLLECT BY: _____

REFUND DETERMINED BY: _____ DATE: _____

PLEASE ATTACH APPROPRIATE SUPPORTING DOCUMENTATION.

* AN ADDRESS MUST BE PROVIDED FOR VENDORS NOT FOUND ON THE VEND
TABLE.

Not: Has aid
to send refund
Ch to above
address.

Rec'd E
pd 9/14/93
11/9/93 (70)
App Rec 13 11/11/93
App: (11/12/93)

(FOR LFMS USE)
INFORMATION FROM LTS

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: PROGRAM CODE: 02201  
: STATUS CODE: 3  
: FEE CATEGORY: -----  
: EXP. DATE: 0  
: FEE COMMENTS: -----  
: DECOM FIN ASSUR REQD: --  
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A. REGION

APPLICANT/LICENSEE: RANDOLPH JUNIOR/SENIOR HIGH SCHOOL
RECEIVED DATE: 931206
DOCKET NO: 3033396
CONTROL NO.: 119069
LICENSE NO.:
ACTION TYPE: NEW LICENSEE

AMOUNT: 1400.00
CHECK NO.: 608549

SIGNED M.A. Perkins
DATE 12/06/93

1. FEE CATEGORY AND AMOUNT: 70 \$11.00

AMENDMENT _____
RENEWAL _____
LICENSE ☒ _____

SIGNED _____
DATE 12/20/93